



CONSENT TO TAKE PART IN RESEARCH

Simple Study Title: Lavender Sandalwood Aromatherapy Study

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

Protocol No.: HSC-MS-25-0731

Principal Investigator: Mi Park, MSN, RNC at Memorial Hermann Memorial City Hospital

Study Contact: Mi Park, MSN, Nurse, 713-242-3600

The purpose of this study is to assess the effect of lavender sandalwood aromatherapy on mood and pain among women who have undergoing a planned Cesarean-section. If you choose to participate in this study, you will be randomly placed into an intervention group that receives aromatherapy and a control group that does not. You will be asked to complete surveys on at least two different occasions. The total amount of time you will spend on this study is from the time that you consent to when you are discharged from the hospital.

There are potential risks involved with this study that are described in this document. Some known risks include eye irritation, skin irritation, and allergic reactions. You may not receive any benefit from participating in this study. The alternative to participating is to not participate.

Participation in this research study is voluntary. You may choose not to take part in this research study or may choose to leave the research study at any time. Your decision will not affect the clinical care you receive at the University of Texas Health Science Center at Houston (UTHealth Houston), Memorial Hermann Memorial City Medical Center.

If you are interested in participating, please continue to read below.

What is the purpose of this research study?

The purpose of this study is to see if lavender sandalwood aromatherapy effects mood and pain in women who have undergoing a scheduled cesarean section. As the result of improved pain and mood, this study also examines the increase in patient satisfaction.

Who is being asked to take part in this study?

You are being asked to take part in this research study because you have a scheduled cesarean section. This study is being conducted at Memorial Hermann Memorial City Hospital. About 182 people will take part in the study in Houston, Texas at UTHealth Houston, Memorial Hermann Memorial

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City Hospital.

What will happen if I take part in this study?

If you agree to take part in this study, you will be randomized (like flipping a coin) to a group. Depending on your group, you may receive a Elequil Lavender Sandalwood Aromatab in addition to the standard medical care, or you may receive only the standard care. If you choose to participate in this study, you will be randomly assigned to one of two groups. At this time, it is not known whether aromatherapy provides additional benefits.

For this reason, some study participants will not receive aromatherapy. This will allow a careful comparison to study the benefits. There is a 50% chance you will receive aromatherapy and a 50% chance that you will not.

If you choose to participate in this study, you will be asked to provide your consent. You will also be asked to complete a survey at both 24 hours and 48 hours after delivery or prior to discharge. A QR code will be provided to allow you to easily access and complete the survey.

If you are in the experimental group, 24 hours post surgery, in addition to the standard of care, you will have a lavender sandalwood aromatab applied on top of your gown and you will be encouraged to wear it for 24 hours. A member of the research team will remove the aromatherapy tab after 48 hours post surgery, when you will be asked to complete the survey again.

If you are in the control group, you will receive the standard of care that all patients receive. For the control group, a research team will invite you to complete the survey 24 hours and at 48 hours after delivery or prior to discharge. You may skip any questions that you do not wish to answer.

How long will you be in the study?

If you agree to take part, your participation will last from the pre-admit visit until you are discharged from the hospital or 48 hours after delivery.

What choices do you have other than this study?

You may choose not to participate in this study, which means that you will receive standard care during your hospitalization.

What are the risks of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

If you choose to participate in this study, you may experience certain risks, including potential eye irritation, skin irritation, allergic reactions, or sensitivity such as rash or swelling at the site of contact.

If you have an allergy to essential oils, we will exclude you from the study. If you do show signs of an

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allergic reaction, the aromatherapy tab will be removed and you will receive standard care. There may be some risks that the study team does not yet know about. There is a risk that information about you may become known to people outside this study.

What are the benefits to taking part in this study?

There is some evidence in postpartum patients after cesarean section delivery that aromatherapy can reduce pain and reduce anxiety. However, we do not now if this will happen to everyone with Cesarean section deliveries. This study may help the researchers learn things that may help other people in the future.

Can you stop taking part in this study?

You may decide to stop taking part in the study at any time. To withdraw from the study, please contact Mi Park at 713-242-3600 or mi.park@memorialhermann.org.

The Principal Investigator may stop your participation in the study if your condition changes, the study is stopped, aromatherapy is no longer available, you do not meet all the requirements of the study, or the study is not in your best interest.

If you stop participating in this study, the information already collected about you will still be used in the data analysis. However, no further information will be collected without your permission.

While taking part in this study, the study team will notify you of new information that may become available and could affect your willingness to stay in the study.

What happens if you are injured during the study?

In the event of injury resulting from this research, UTHealth Houston and/or Memorial Hermann Health System are not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities, emergency treatment, and professional services will be available to you, just as they are to the general community. You or your insurance company will be billed for any treatment.

You should report any such reaction to Mi Park 713-242-3600 and to the Committee for the Protection of Human Subjects at 713-500-7943. You will not give up any of your legal rights by signing this consent form.

What are the costs of taking part in this study?

If you decide to take part in this research study, you will not incur any additional costs. The study will not require special tests and examinations that are not otherwise part of your standard medical care.

If you receive a bill that you believe is related to your taking part in this research study, please contact Mi Park at 713-242-3600 with any questions.

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**Will you be paid for taking part in this study?**

You will not receive any compensation for taking part in this study.

The University of Texas Health Science Center at Houston owns any data collected and the use of the data, results, treatments, or inventions that can be made from the research. The University's ownership includes the right to license or transfer the use or ownership to other parties including, without limitation, commercial entities contracting with UTHealth Houston. There are no plans to compensate you for any patents or discoveries that may result from your participation in this research study. You will not be paid for any use of your data, samples, or results.

How will privacy and confidentiality be protected?

Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed.

If you sign this document, you give permission to UTHealth Houston and Memorial Hermann Healthcare System to use and disclose (release) your health information. The health information that we may use or disclose for this research includes demographics (e.g. your age range, race, ethnicity, gravity and parity), the general category of your admission, length of hospital stay, mood assessments, anesthesia, surgery procedure records, health history and pain scores. Please understand that health information used and disclosed may include information relating to HIV infection, drug abuse, alcohol abuse, behavioral health, and psychiatric care.

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the private information (data) collected in this study. After we remove all identifiers, the data may be used for future research or shared with other researchers without your additional informed consent.

If you are not comfortable with the use of your data in future research, you may not want to participate in this study.

Representatives of the organizations listed below will see your name and other personal identifiers when they review your research records and medical records for the purpose of verifying study data:

- Representatives of UTHealth Houston and/or Memorial Hermann Health System
- Representatives from the U.S. Food and Drug Administration (FDA)
- Companies engaged with UTHealth Houston for the commercialization of the results of the research study

Please note that you do not have to sign this Authorization, but if you do not, you may not participate in this research study. UTHealth Houston and/or Memorial Hermann Health System may not withhold treatment or refuse treating you if you do not sign this Authorization.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to privacy@uth.tmc.edu or Privacy Officer, PO Box 20036, Houston, TX

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This Authorization will expire 15 years after the end of the study.

Whom can you contact if you have questions about the study?

If you have questions at any time about this research study, please feel free to contact Mi Park at 713-242-3600, as she will be glad to answer your questions. You can contact the study team to discuss problems, report injuries, voice concerns, obtain information in addition to asking questions about the research.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this web site at any time.

The Committee for Protection of Human Subjects at the University of Texas Health Science Center has reviewed this research study. You may contact them for any questions about your rights as a research subject, and to discuss any concerns, comments, or complaints about taking part in a research study at (713) 500-7943.

SIGNATURES

Sign below only if you understand the information given to you about the research and you choose to take part in this research study. Make sure that all your questions have been answered. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

_____ Printed Name of Subject	_____ Signature of Subject	_____ Date	_____ Time
_____ Printed Name of Person Obtaining Informed Consent	_____ Signature of Person Obtaining Informed Consent	_____ Date	_____ Time

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