Using Aromatherapy for Comfort, Ease, and Stress for Adults Being Treated for Substance Use Disorder in North Central Appalachia: A Randomized Controlled Trial

NCT05660434

March 28, 2024

Key Information for:

Using aromatherapy for comfort, ease, and stress for adults being treated for substance use disorder in north central Appalachia: A randomized controlled trial

You are being asked to participate in the research described below. This page provides key information that may help you to make this decision; more detailed information can be found after this section.

Why is this research being done and what is involved?

- The purpose of this study is to see if using an essential oil called Bergamot will have any effect on your comfort, ease, and stress
- You will be asked to use an aroma inhaler, which is a small container about the size of a lipstick container, that contains a small amount of pure essential oil, three times a day for one week. Surveys are completed at the beginning and at the end of the week. A daily logbook with a short checklist is also used.
- The study lasts for one week (7 days)

Do I have to participate and what are the risks involved?

Participation in this research study is completely voluntary and you are free to withdraw from the research at any time. If you do not wish to participate, please discuss alternatives with the researcher or refer to the "Alternatives" section in the consent form. You may or may not directly benefit from participating in this research.

Risks from participation in this study include having an adverse reaction to the essential oil of Bergamot that is contained in the aroma inhaler. Additionally, time spent completing surveys and a daily logbook may seem like it adds additional stress to the participant.

Who can I talk to if I have questions or concerns?

If you have any questions or concerns about this research or would want to withdrawal from the study, you can contact Marian Reven at marian.reven@hsc.wvu.edu from the School of Nursing at West Virginia University.

For more information, please see the Informed Consent Form.

Informed Consent for Research | Minimal Risk

Principal Investigator (PI) |	Dr. Marian Reven
Department |	School of Nursing
Sponsor or Funding Source |	West Virginia Nurses Association Rosenthal Rite Scholarship and the Ruth and Robert Kuhn Nursing Faculty Research Award
WVU IRB Protocol # |	2204562633
Study Title |	**Using Aromatherapy for Comfort, Ease, and Stress for Adults Being Treated for Substance Use Disorder in North Central Appalachia: A Randomized Controlled Trial**

Introduction

You have been asked to participate in this research study, which has been explained to you by an authorized member of the research team. This research is being conducted by Dr. Marian Reven.

Purpose

The purpose of this study is to see if using an essential oil called Bergamot will have any effect on your comfort, ease, and stress. Additionally, the purpose of this study is to gather information on the safety and effectiveness of bergamot. Bergamot is designated as generally recognized as safe by the FDA. This designation means it has been shown to be safe under the conditions of its intended use. WVU expects to enroll approximately 123 subjects.

ClinicalTrials.gov

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 the web site at any time.

Description of Procedures

1. First, you will be pre-screened using a survey that includes questions about integrative or complementary therapies (massage, yoga, acupuncture, aromatherapy with essential oils, herbs, meditation, mindfulness practices). This survey also asks questions about allergies and sense of smell because this study involves smelling aroma in the form of an essential oil called Bergamot.
2. If a severe allergy or medical condition does not allow you to participate, the prescreening form will be destroyed, and you will be excused from further participation.
3. If you qualify to be in the study, you will sign a consent form, and then receive a study packet.
4. You will be randomly assigned to one of two groups. One group will receive an aroma inhaler to use 3 x day for 7 days and complete a daily logbook. The other group will receive only the daily logbook. But those who do not get their aroma inhaler at the beginning of the study will receive it at the end of the study.
5. Both groups will do surveys before the study, the logbook every day, and surveys after the study.
6. The surveys include questions about overall comfort, ease, and stress.
7. Once consent and pre-surveys are complete, you will be shown how to use the aroma inhaler correctly.
8. The study lasts for 7 days and begins after you sign the consents and on the first full day after you receive your packet. (So, if you receive your study packet on a Tuesday, you will start the study on Wednesday).

9. At the end of 7 days, you are asked to complete post surveys and return your completed logbook to the researcher, Dr. Marian Reven, within 3 days..
10. At the end of your study time, you will receive a gift card and if you had not received the aroma inhaler, you will receive that aroma inhaler as our way of saying thank you.
11. Health related medical history data and demographic information from your medical record will be collected with your consent.
12. Permission to use your cell phone number and your email to contact you for reminders during the course of the study.

Risks and Discomforts

Potential risks or discomforts include a dislike of the scent or possibly a headache because of inhaling the essential oil fragrance from the aroma inhaler. If headache or feeling of dislike continues the participant is asked to discontinue use of the aroma inhaler and contact me, Dr. Marian Reven, at marian.reven@hsc.wvu.edu for further instructions. Logbooks will still be collected, and a post survey provided. Those who complete the study, even if they must discontinue use of the aroma inhaler before the end will receive the gift card if study materials and surveys are returned and complete.

This study does include surveys that ask questions about feelings of comfort, ease, and stress. This may cause distress to some participants. Should a participant experience or express any psychological distress or disclose information that indicates a need for urgent psychological or clinical care, the researcher will connect the participant with their provider.

While not anticipated, this research may involve side effects that are unforeseeable, uncommon, or previously unknown.

In addition, there is always the risk of uncommon or previously unknown side effect(s) or event.

Alternatives

You do not have to participate in this study.

Benefits

You may or may not directly benefit from participating in this research. The knowledge gained from this study may eventually benefit others.

Financial Considerations

You will be compensated with a $20 gift card for completing this study.

You will keep your aroma inhaler valued at $7.00

If you do not complete the study, you will still be compensated.

For information regarding the method of payment, contact Dr. Marian Reven at marian.reven@hsc.wvu.edu .

Your information may be provided to the appropriate parties for billing and/or payment purposes. Please be advised that any compensation received for participation in a research study, including a gift card, is considered taxable income and must be reported to the Internal Revenue Service (IRS).

Your data, health information, and research results, or any and all other information related to this research study used in this research study may contribute to a new discovery or treatment. In some instances, your data, your health information, your research results, these discoveries or treatments, or any other information related to this research study, even if identifiers are removed, may be of commercial value and may be sold, patented, or licensed by the investigators and West Virginia University for use in other research or the development of new products. You will not retain any property rights nor will you share in any money or commercial profit that the investigators, West Virginia University, or their agents may realize.

Confidentiality

Any information about you that is obtained as a result of your participation in this research will be kept as confidential as legally possible. Your research records and test results, just like hospital records, may be subpoenaed by court order or may be inspected by the study sponsor or federal regulatory authorities, including the Food and Drug Administration (FDA), without your additional consent.

In addition, there are certain instances where the researcher is legally required to give information to the appropriate authorities. These would include mandatory reporting of infectious diseases, mandatory reporting of information about behavior that is imminently dangerous to you or to others, such as suicide, child abuse, etc.

In any publications that result from this research, neither your name nor any information from which you might be identified will be published without your consent.

Your information collected as part of this research, even if identifiers are removed, will not be used or distributed for future research.

HIPAA Authorization

We know that information about your health is private. We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information or share it with others.

You can decide to sign or not to sign this authorization section. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make about this research study will not have an effect on your access to medical care.

Persons/Organizations Providing the Information

Patient data will be collected from patient intake information gathered by the organization where the participant is receiving treatment.

Persons/Organizations Receiving the Information

- Health care providers who provide services to you as part of this research study.
- The members and staff of any institutional review board that oversees this research study.
- The West Virginia University Office of Human Research Protection and the West Virginia University Office of Sponsored Programs.
- West Virginia University School of Nursing

The Following Information Will Be Used

Information from your existing medical records, and new information about you that is created or collected during this study, such as: demographic data and diagnosis data as it relates to your treatment for substance use disorder only.

The Information is Being Disclosed for the Following Reasons

- Publication of study results (without identifying you)
- Other research purposes include reviewing the safety and feasibility of the aromatic intervention and developing a better understanding of disease; improving the design of future clinical trials.

You may Cancel this Authorization at Any Time by Writing to the Principal Investigator

Dr. Marian Reven, West Virginia University, 64 Medical Center Drive, Morgantown, WV 26506-9600.

Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time. To withdraw from the study, Dr. Marian Reven at marian.reven@hsc.wvu.edu.

Refusal to participate or withdraw will not affect your future care or status at West Virginia University.

In the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue your participation.

Contact Persons

If you have any questions, concerns, or complaints about this research, you can contact Dr. Marian Reven (PI) at West Virginia University School of Nursing, marian.reven@hsc.wvu.edu.

If you are hurt from being in this research, you should contact Dr. Marian Reven (PI) at 304-293-3399 Monday through Friday 9am to 5pm. If injury occurs outside of business hours and is related to your participation in this research, please contact Marian Reven (PI) at 304-293-3399.

For information regarding your rights as a participant in research or to talk about the research, contact the WVU Office of Human Research Protections (OHRP) at (304) 293-7073 or by email at IRB@mail.wvu.edu.

Signatures and Authorization

You have been given the opportunity to ask questions about the research (if applicable) and your authorization of HIPAA, and you have received answers concerning areas you did not understand. Upon signing this form, you will receive a copy.

Would you like us to contact you in the future for other studies? Yes _____ No _____

If you agree to future contact, please fill in the information below. If you do not want future contact, your participation in this study will not be impacted.

Address: _____

Email: _____

Participant Signature

I willingly consent to participate in this research.

Signature of Subject or Subject's Legal Representative

Printed Name Date

Consenting Individual Signature

The participant has had the opportunity to have questions addressed. The participant willingly agrees to be in the study.

Signature of Person Obtaining Informed Consent

Printed Name Date

The participant has provided permission to use their phone and/or email to receive reminders during the study.

Phone number_____

Email _____

In order to participate in the study a mailing address is needed, please provide

Mailing Address _____

_____