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

NCT05660434

December 27, 2023

INVESTIGATOR INITIATED PROTOCOL

AROMATHERAPY & SUD

MARIAN.REVEN@HSC.WVU.EDU
WEST VIRGINIA UNIVERSITY

Table of Contents

Study Protocol

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

INSTITUTIONAL REVIEW BOARD APPROVAL NUMBER: __ 2204562633___

CHESTNUT RIDGE APPROVAL FORM: _on file 7/29/2022__

CLINICAL TRIAL NUMBER: __NCT05660434__

Common Terms List

Enroller – person who works with potential study participants to complete prescreening and explain study. This will be Investigator Marian Reven or designee.

Participant – one who is willing and able to voluntarily participate in this study.

Aroma Inhaler – A small tube-shaped device about the size of a lipstick container. It contains a pure cotton wick. This wick is impregnated with pure essential oil. This is done at the manufacturer site. An Aethereo®Stick is used for this study. See appendix B for more information.

Aromatherapy – the use of aromas usually in the form of essential oils to impact a person's feelings of health and wellbeing.

Bergamot essential oil – is a citrus essential oil extracted from the rind of the fruit Bergamot (*Citrus bergamia*). The aroma is described as sharp, fruity, powdery, and refreshing. Research shows that chemical constituents found in Bergamot (linalool and linalyl acetate) may impact nerve receptors to bring about anxiolytic effects.

Randomized Controlled Trial (RCT) – a type of study where participants are randomly assigned to either an intervention or a control group. In this way, the risk of bias is decreased. Packets are distributed in an exact order and the Enroller does not pick which participants go into groups.

Random Number Table (RNT) – used to minimize risk of bias in studies. A table of numbers generated in an unpredictable, haphazard sequence.

Master Log Sheet (MLS) – Securely maintained Excel spreadsheet used to track assignment of participants to intervention or control groups. Also used to track those who are ineligible as determined by prescreening survey.

Study Team

Principle-Investigator (PI): Marian "Marnie" Reven, marian.reven@hsc.wvu.edu or 304-479-4825

Co-Investigator (CoI): Amanda Newhouse, atorbich@hsc.wvu.edu or 304-581-1965
Assistant Professor, West Virginia University

Research Summary

Updates to Study Protocol

Update: IRB amendment 09262022 (Appendix G)

To allow Stages one, two, and three and peer recovery persons to participate.

Update: IRB Amendment 08312022 (Appendix H)

To recruit and consent participants online

Update: From QIP Audit 10252022 (Appendix I)

Annual Review with approval received 7/29/2023

8/23/2023 Per email communication with co-I Amanda Newhouse, BMed no longer using site approval forms. I have approval to proceed with recruitment when IRB approval is obtained.

Update to consent process 8/2023 (completed)
Communication with participants, begin using RedCap WVU for all surveys and emails. WVU phone and computer for all communication.

10/23/2023 Update: Will no longer include copy of consent in study packets mailed to participants. This will save on mailing costs. Participants can download and print or save to their devices. Approved 11/7/2023

11/21/23 Submitted amendment re: addition of Abigail Farris and Ella Jane Dailey CITI training certificates to the protocol

12/27/23 Amendment to add a population from Health Right, approved 2/5/2024

Study Population

Adults (>18 years) who are currently receiving treatment for SUD in the outpatient treatment program at West Virginia University Chestnut Ridge Center (WVUCRC) (n = 340 approx.).

Inclusion criteria are patients diagnosed with SUD who have completed intensive acute phase 1 treatment, and who desire to pursue continuous recovery phases (per facility protocol). All participants must be alert and oriented, provide written consent, and be able to read and write English.

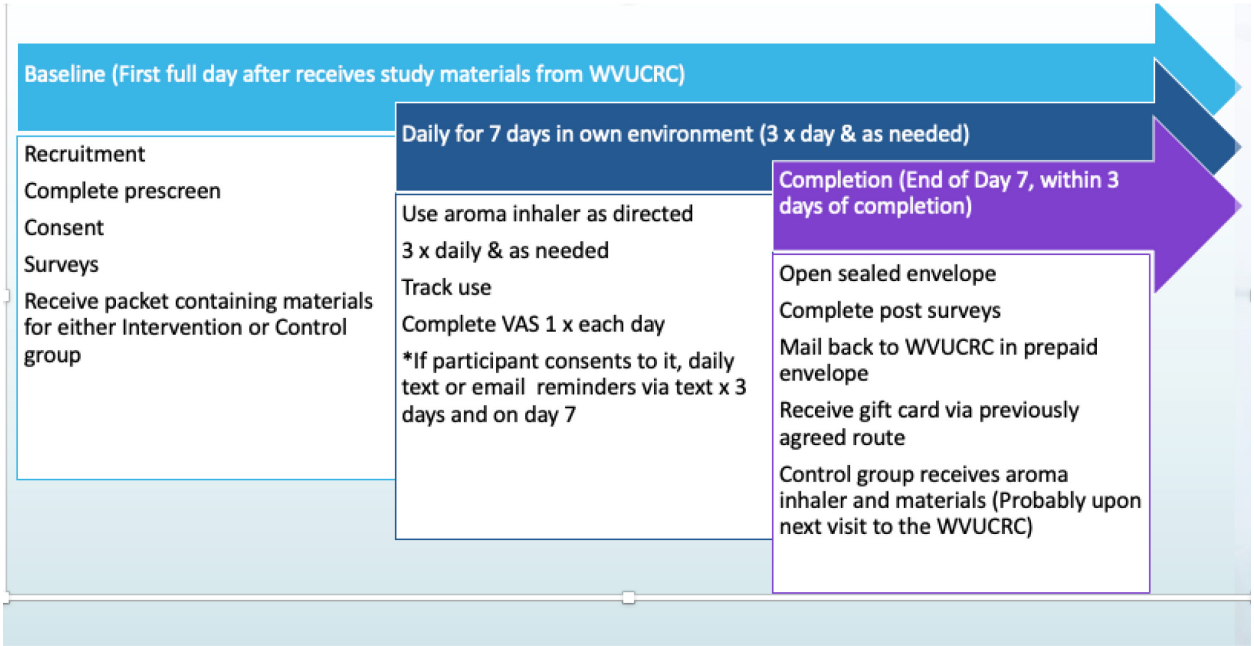
Exclusion criteria are patients diagnosed with severe mental illness (who cannot consent to participate), have a medical history of asthma or other serious respiratory disease, and known allergy to citrus. There are no exclusion criteria for gender, race, and/or ethnicity.

Anyone who meets inclusion criteria in the sample population is invited to participate. I am advertising throughout entire population of the study.

Study Design

The purpose of this study is to see if Bergamot, an aroma therapy essential oil, has any effect on comfort, ease, and stress. Participants will be asked to use a bergamot aroma inhaler, which is a small tube about the size of a lipstick container, at least three times a day for one week. Comfort, ease, and stress will be measured with self-report survey at the beginning and at the end of the week. In addition, participants will be asked to complete a daily logbook to record use of the inhaler. The study lasts for one week (7 days). The aims of this study are to explore the effects of Bergamot essential oil on comfort, ease, and stress in adults in a SUD treatment program, and to evaluate the feasibility of this type of aroma therapy intervention.

Study Duration (7 days)



Study Time Involved for Participants

Time involved in completing prescreening, informational session, & pre-surveys

	Step	**What is happening**	**Who does what**	**Approximately how much time to expect**
1	Prescreening	6 question survey	Administered by Enroller	2-3 minutes
2	Open packet & review contents Complete CONSENT	Looking at contents of packets	Enroller reviews consent & participant will either sign or decline	5-10 minutes
2a	Trying out aroma inhaler & giving directions for use	Participant opening their own aroma inhaler	Participant opens aroma inhaler. Enroller demonstrates correct use using their own inhaler	1-2 minutes
2b	Personalizing packet for each participant	Adding dates and organizing packet, going	Enroller adds dates with participant	2-4 minutes

		over logbook together	involvement. Enroller explains follow up texts or emails that participant will begin receiving the next day.	
3	Complete 3 pre-surveys	69 questions (28 GCQ, 20 Ease, 21 DASS)	Participant does this and then they are excused	5-6 minutes
			TOTAL	15-25 minutes
More time can be taken to complete these steps and participants may request to meet with the Enroller again if they still have questions.				

Time involved in study activities from day 1 to day 7 and completing post-surveys

	Step	**What is happening**	**Who does what & extra details**	**Approximately how much time to expect**
1	Using aroma inhaler 3 x day x 7 days	Participant inhales aroma from inhaler for approximately 1 minute on 3 separate occasions during each day of the study	Participant is responsible. Reminders are sent via text or email during the first 3 days of the study. This reminder should not add any extra time to the study	21 minutes
2 Intervention	Filling out daily logbook x 7 days	Participant puts an X or check mark next to the 3 spaces to document use of aroma inhaler. Also, at the end of the participant's day, Comfort is rated on a 0-10 VAS.	Participant is responsible. A place for comments is available and participants may take their time to add comments about the day (this is discretionary)	7-10 minutes

2 Control	Filling out daily logbook x 7 days	At the end of the participant's day, Comfort is rated on a 0-10 VAS.	Participant is responsible. A place for comments is available and participants may take their time to add comments about the day (this is discretionary)	Same as Intervention group
3	Completing post surveys/ logbook	Participant is completing the logbook for 7 days. Then is opening prepaid postage envelope and completing post surveys	Participant is completing these that include the GCQ, Ease, DASS, and post aromatic survey. They are then sealing the envelop and mailing back to WVU CRC (preaddressed)	5-6
			TOTALS	34-37 minutes

Background & Significance

Prevalence Information

During 2017–2019, the annual average prevalence of past-year substance use disorder in West Virginia was 13.4% (or 24,000), similar to both the regional average (15.1%) and the national average (14.7%) (SAMHSA, 2020). The population is ages 18-25. Overdose and opioid related mortality rates, comparing Appalachian and non-Appalachian portions of states, ages 15 to 64 in 2015, 59.7% of diseases of despair were related to overdose of opioids. WV has no non-Appalachian portions of the state (Meit et al., 2017). Nationally, 1.6 million people had an opioid use disorder in the past year ((2019 National Survey on Drug Use and Health, 2020).

.

Significance to Nursing

This grant proposal is based on holistic nursing research principles (Helming et al., 2022), including work with a marginalized population of those in recovery for substance use disorder (SUD) in north central Appalachia. This study also aligns with National Institutes of Health (NIH) National Center for Complementary and Integrative Health (NCCIH) standards to advance the evidence base for integrative complementary therapies such as aromatherapy through a whole person health approach (NCCIH, 2021). The positive impact of this aromatherapy intervention is to increase comfort and ease, while reducing stress.

Background

West Virginia is at the epicenter of the opioid addiction crisis with hardly a family left untouched by the devastating consequences (Governor's Council on Substance Abuse Prevention and Treatment, 2020; Saloner et al., 2019). Compared to the rest of the United States, West Virginians are disproportionately affected by deaths due to "diseases of despair", such as drug overdose (Merino et al., 2019; SAMHSA, 2018). Those who make it into recovery programs are often plagued by anxiety and depression (Cicero & Ellis, 2017; Johannessen et al., 2019; Yang et al., 2020) with the most common concurrent mental health issues being depressive disorder, stress, and anxiety (Hutton et al., 2017; Roos et al., 2020). Relapse prevention is key (SAMHSA, 2018). It is recommended that aromatherapy (such as using an aroma stick with bergamot essential oil) has the potential to support those in recovery (Wesa, 2004).

Substance use disorder is characterized by a cluster of physiological, behavioral, and cognitive symptoms occurring when recurrent use of alcohol and/or drugs causes significant impairment, disability, and failure to meet major responsibilities (SAMHSA, 2018; World Health Organization [WHO], 1992). Those in treatment have identified that increasing the level of comfort during substance use recovery is vital (Yang et al., 2020). Integrating aromatherapy could help improve perception of comfort and ease and reduce stress which could support healthy choices and encourage recovery program progression.

Aromatherapy has long been used as a non-pharmacologic treatment alongside medical treatments for various health conditions (Armstrong et al., 2019; Buckle, 2015; Coelho et al., 2017; Herz, 2009; Lizarraga-Valderrama, 2021; Perry & Perry, 2006). Specifically, bergamot (*Citrus bergamia*) essential oil (natural plant based oil) has been reported as one of the most commonly used essential oils because of its effectiveness, low price point, and safety when used via inhalation (Chang & Shen, 2011; Han et al., 2017; Navarra et al., 2015). Bergamot essential oil has the ability to bind to GABAergic receptors and influence the hypothalamic-pituitary-adrenal axis (HPA) providing possible explanation for it anxiolytic properties (Morrone et al., 2007; Saiyudthong & Marsden, 2011). Over the decades, bergamot essential oil has been successfully among persons with mood alterations including anxiety, depression, and stress (Lizarraga-Valderrama, 2021; Mannucci et al., 2017; Perry & Perry, 2006; Scuteri et al., 2017).

Objectives

Purpose:

The purpose of the study is to examine the effect of an aromatic intervention using bergamot essential oil on comfort, ease, and stress in adults in a SUD recovery program.

Primary Objectives & Aims:

The innovation of this study is to use bergamot essential oil to improve perception of comfort and ease and reduce stress among the marginalized population in a SUD recovery program in rural Appalachia.

Specific Aim #1: Pilot test bergamot essential oil intervention with adults in a substance use disorder recovery program.
Hypothesis 1a: Participants in the intervention group will report higher scores on comfort and ease than those in the control group.
Hypothesis 1b: Participants in the intervention group will report lower scores in stress than those in the control group.

Specific Aim #2: Evaluate the feasibility and acceptability of an aromatherapy intervention by examining recruitment, enrollment and retention rates, intervention fidelity, and cost analysis.

Study Design & Methodology

The study uses a parallel-randomized control group comparison design. Data will be collected from participants daily and post intervention.
For Aim #1, descriptive and bivariate analysis will be conducted. Statistical assumptions will be tested. Sample demographics will be reported.
For Aim #2, descriptive statistics will be used as well as participant recruitment, enrollment, and retention rates. Reasons for non-participation and attrition will be recorded. Percentage of intervention consistency will be calculated, and cost of the intervention will be determined.

Risk

This study is only minimal risk because it involves aroma of a citrus essential oil named Bergamot. This essential oil is impregnated on a pure cotton wick within a manufacturer-sealed aroma inhaler. Participants are instructed and will demonstrate back to the researcher that they will use the inhaler in the prescribed fashion. Participants encounter odors and aromas during daily life and the anticipated magnitude of harm or discomfort anticipated in the

research is not greater in and of itself than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Potential risks or discomforts include a dislike of the scent or possibly a headache because of inhaling the essential oil aroma 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, Marian Reven, at marian.reven@hsc.wvu.edu for further instructions.

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.

Benefits

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

Statistical Analysis Plan

Data analysis For Aim 1, Descriptive (frequencies, means, ranges, standard deviations) and bivariate analysis will be conducted on the demographics, GCQ, Ease measure, and DASS scales. Statistical assumptions (i.e., normal distribution and homogeneity of variances etc.) will be tested. Sample demographics of patients will be reported. Fisher's exact test will be used for categorical variables; Repeated measures ANOVA and paired t-test will be used for continuous variables. Pearson's and Spearman's correlation analyses will be used to explore relationships among variables (Pallant, 2020). The statistical significance is set at a 5% (alpha = 5%). All analyses will be completed using Statistical Package for the Social Sciences (IBM SPSS).

For Aim 2, Descriptive statistics will be used to analyze Aim 2a. Participant recruitment, enrollment, and retention rates will be tabulated and reported. Reasons for non-participation and attrition will be recorded and will be used to develop strategies to address this. For Aim 2b, adherence to the intervention protocol will be calculated from responses in the logbooks. For Aim 2c, to determine the cost of the intervention implementation, all charges related to implementation are calculated. This includes costs of personnel time for administering each session, the materials, and incentives.

Sample Size

Sample size was calculated using G*Power v.3.1.9.7 on repeated measure ANOVA given α=0.05, moderate effect size (0.25), power of 80%, two groups with 2 measurements, correlation among repeated measures (0.50), a total sample size of 98 will be required. A total sample size of n=49 for intervention group and n=49 for control group is sought.

Data Safety Monitoring

Data safety will be maintained throughout the study. All information about participants will be stored in a locked cabinet inside a locked office. All electronic data will be stored on a password encrypted computer.

Safety Monitoring & Unanticipated Event Reporting

This study involves use of an aroma inhaler. This study is only minimal risk because it involves aroma of a citrus essential oil named Bergamot. This essential oil is impregnated on a pure cotton wick within a manufacturer-sealed aroma inhaler. Participants are instructed and will demonstrate back to the researcher that they will use the inhaler in the prescribed fashion.

Participants encounter odors and aromas during daily life and the anticipated magnitude of harm or discomfort anticipated in the research is not greater in and of itself than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Participants will have an informational session with a Registered Aromatherapist, Marian Reven, who will demonstrate use and care of the aroma inhaler.
The following reminder is provided in writing for participants.

*(When not in use, recap to close & store in a cool, dry place away from children and pets) It is OKAY to keep your closed inhaler in your pocket or purse and at room temperature ☺
Do not tamper with the packaging. Keep out of reach of children and animals. If you develop any adverse reactions such as a headache, stop, recap inhaler, and retry a little later. If unpleasant effects, such as headache continue, discontinue use and contact Marian Reven, Co-Investigator at marian.reven@hsc.wvu.edu

Every effort has been made to ensure the safety of all Participants and those at the study site.

1. Aroma inhalers are factory sealed
2. Tamper resistant packaging is used
3. Safety data sheets are available online and on site
4. Inhalation of essential oils such as Bergamot is considered low risk
5. Specific instructions are provided
6. A Registered Aromatherapist created and manages this study

Participants will be instructed to seek medical care if needed and are able to withdraw from the study at any time without any repercussions. Participants are already in the care of medical staff.

Study Duration & Timeline

Task	March to June 2022	May to June 2022	August to December 2022	January to March 2023	April to May 2023
Create grant documents	X				
Finalize & refine grant application and submit	X				
Submit proposal to WVU IRB, make revisions as needed		X			
Complete BMED research & recruitment form			X		
Enrollment & run study			X		
Complete enrollment & run data				X	
Dissertation defense & graduate					X

Informed Consent Process

Participation in this study is contingent upon informed and ongoing consent by each adult participant. They are free to withdraw from the study at any time without any repercussion. The following pieces of data will be collected including:

Will collect the following listed data
Name
Email address
Telephone number

Plus, the following
Data will be collected from the chart and from survey (self-report)
1. Identifier variables of Comfort, Ease, and Stress
2. Stage of treatment in the SUD treatment program (Chart)
3. Presence of anxiety and/or depression (Chart)
4. Presence of severe mental illness Dx (Chart)
5. Allergies to citrus fruits such as grapefruit, lemon, orange, or bergamot (Chart and self report)

6. Previous experience with any integrative or complementary therapies such as yoga, massage, acupuncture, aromatherapy with essential oils, herbal preparations, meditation, mindfulness practices (Self-report)
7. Pregnant and/or nursing (Self-report)
8. Severe breathing problems such as asthma, chronic bronchitis, or COPD (Chart and self-report)
9. Report of sense of smell (self-report)
10. Dx of a problem with sense of smell (Chart and self-report)
11. Current illness with cold, flu, or covid (Self-report)

Informed Consent Process

See Appendix F

Confidentiality & Privacy

Subjects in this research study will not be anonymous but all study participant data and information will be de-identified. Upon enrollment, participants will be given a unique identifier by which all study materials will be identified. A master spreadsheet will be maintained to identify each participant by name with their unique identifier. All study data will be kept securely in a locked office.

Data will be kept for a minimum of 3 years. Electronic data will be destroyed using appropriate data deletion methods to ensure data cannot be recovered. Paper documents will be destroyed by shredding and other methods as specified by WVU procedures.

No Federal Certificate of Confidentiality is used for this study.

Other Considerations

There are no conflicts of interest to report for the PI, Dr. Roger Carpenter, or Co-I's, Marian Reven, and Amanda Newhouse
.
The results of this work could be published or presented without any participant identifiers.

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.

Supplies Available for Enrolling Participants (Kept in Locked Office):

1. Supply of prescreening surveys
2. Master Log Sheet (MLS) for recording Participant name and number
3. Master Random Number Table (RNT) for randomization
4. Tote with Study Packets (including surveys*)
5. Extra forms
6. Aroma inhalers**

*Surveys Used in this Study (See Appendix A)

Surveys in this study include:

1. Prescreening survey for the aromatic elements of the study
2. Generalized Comfort Questionnaire (GCQ)
3. Ease Measure
4. Depression, Anxiety, and Stress Scale (DASS)
5. Post survey for aromatic elements of the study

**Aroma Inhalers Used in this Study (See Appendix B)

1. Company supplying: Plant Extracts International https://plantextractsinc.com/
2. Bergamot essential oil is used
3. No direct contact with essential oil is anticipated
4. No ambient odor should be present as inhalers are factory sealed and enclosed in tamper resistant packaging

Contents of Study Packets

1. Aroma inhaler
2. Aethereo®Stick Information Sheet
3. Cover letter (Appendix C)
4. Consent forms (2 copies)
5. Pre surveys (Comfort, Ease, and Stress)
6. Logbooks for Intervention or Control Groups (Appendix D)
7. Reminder paper (Appendix E)
8. 6 x 9 Postage paid return envelope
    a. Post surveys (Comfort, Ease, Stress, Post Aroma)

Prior to opening a Study Packet

1. In a private location, Enroller will determine eligibility for this study.
    a. Inclusion criteria are as follows:
        i. Older than 18 years of age
        ii. Currently enrolled in treatment
        iii. Have completed intensive phase 1 and wish to continue with treatment
        iv. Alert & oriented
        v. Able to provide written consent
        vi. Able to read & write English
    b. Exclusion criteria are as follows:
        i. Diagnosed with severe mental illness
        ii. Medical history of asthma
        iii. Other serious respiratory disease
        iv. Known allergy to citrus
2. In a private location, Enroller will prescreen using created survey tool (appendix A)
    a. Use the prescreening survey provided
    b. Read prescreening survey to participants and record answers
    c. If not contraindicated by prescreening questions, allow participant to smell the aroma inhaler (3 inches from nose)
        i. Record all reactions, “liked the smell”, “sneezed”, “said ‘yuck’” on the presurvey. Record “no negative reactions” as applicable (This is a vital component of aromatic research)
3. IF PARTICIPANT IS INELIGIBLE, thank them for their time, note on MLS that they were screened and why they were ineligible. Use the special section at the end of the MLS to make this notation. Do not use an Id # space. Write “ineligible” and the date across the top of the survey.
4. IF PARTICIPANT IS ELIGIBLE, file prescreening form in predetermined place and obtain a study packet in the order they are arranged (001-098)
    a. Enter date and name of participant on the **Random Number Table (RNT)** sheet
5. Record Unique Identifier packet number on **Master Log Sheet (MLS)**
    a. Use MLS to track Participants
    b. This Unique Identifier number is already on every document in each packet

Study Packet is Opened

6. The study packet is opened in the presence of the study participant and contents of the folder are reviewed Contents of Study Packets:
    a. Left pocket:
        i. Aroma inhaler
        ii. Welcome letter
        iii. Consent form x 2
        iv. Pre-Surveys (Comfort, Ease, and Stress)

b. Right pocket:
    i. Logbook
    ii. Reminder paper (To post as a reminder) ADD DATES
    iii. Closed postage paid envelope

7. Consent form is reviewed and signed

8. Pre-surveys for Comfort, Ease, and Stress are completed

Use of the Aethereo®Stick is reviewed (Appendix B for details about inhaler):

a. Enroller will either open or have participant open the sealed package for the Aethereo®Stick (aroma inhaler) open the outer sealed package
b. Save the package for storage
c. Pick up the inhaler and twist to the right to remove the cap
d. There is no need to shake the inhaler
e. Breath out gently
f. While holding the inhaler about 3 inches (7.62 cm) from the nose
g. Inhale through the nose using 3 sniffs as directed
h. Hold breath for about 3 seconds
i. Exhale for 3 seconds
j. Repeat 3 times and then recap and store the inhaler in a safe place away from high heat and direct sunlight, children, and pets.
k. NOTE: The Enroller will record all reactions to participant exposure to the aroma inhaler. Verbatim recording of any negative or positive response is vital. This is recorded on the Prescreening survey at the bottom of the form. Any negative or adverse reaction must be recorded. If no negative reaction, then the Enroller must write, “No negative reaction”

9. As needed use:
    a. The inhaler may be used more than 3 x daily
    b. Participants may use as needed and are asked to record all uses and reasons for uses in the provided logbook
10. Use other than instructed:
    a. If the participant uses the inhaler in some other fashion than instructed, they are asked to record this information as well (i.e. inhales x 10, inserts into nostril [which is considered safe], uses a different count to exhale etc.)
11. How Participant begins intervention:
    a. The participant begins the 7-day intervention at the beginning of their next full day of life (This allows for those who work nights etc.)
        i. ADD DATES: Participants (preferrable to have participants do this and not the Enroller) will add dates to pages of the logbook (e.g., If they received their packet and instructions on October 11, then they should begin their study on the NEXT FULL DAY, October 12, and their study would be

complete on October 18. Dates on pages should reflect the 7-days of the study, 10/12, 10/13 and so forth to 10/18)

b. Three times daily means spaced out in 3 times, which could mean morning, afternoon, and evening, or anything else that is separated by approximately 4-6 hours (while awake)
c. On day 1, 2, & 3 a text or email messages will be provided to participants to remind them to complete their diary indicating if they used the inhaler and mark how they are feeling on the VAS. They will be instructed to contact the researcher with any questions.
d. Days 4, 5, 6, & 7, participants will not receive reminders.
    i. A reminder will be sent on day 7.
    ii. After day 7, all participants will open their final survey packet included in the folder.
    iii. They will be instructed to complete the survey packet and return it and the logbook using the prepaid postage envelope.

Documents to Leave in Participant Packet:

INTERVENTION:

iv. Those randomized to the Intervention group
    1. Left pocket (in this order)
        a. Aroma inhaler
        b. Aethereo®Stick information sheet
        c. Welcome letter
        d. Copy of consent
    2. Right pocket (in this order)
        a. Logbook (with dates written in)
        b. Reminder paper
        c. Postage paid envelope (with date and instructions for return on note attached to front of the envelop)

CONTROL:

v. Those randomized to the Control group (The AROMA INHALER from Control group packets is labeled with participants ID# and kept in a secure location until they complete the study. It will have been opened and demonstrated with the participant during study introduction)
    1. Left pocket (in this order)
        a. Welcome letter
        b. Copy of consent
    2. Right pocket (in this order)
        a. Logbook (with dates written in)
        b. Reminder paper
    3. Postage paid envelope (with date and instructions for return on note attached to front of the envelope)

How Participants are Returning Study Materials:

Postage paid envelop is marked “Complete the Logbook and the surveys and return them ALL on _____.” Add date they will complete the 7-day study

e. (e.g., If they received their packet and instructions on October 11, then they should begin their study on the NEXT FULL DAY, October 12, and their study would be complete on October 19. October 19 is the date entered on the note attached to this envelope)

Timing Of Gift Card

Once the final survey is received, the $20 gift card will be issued to the intervention group and the $20 gift card and inhaler to the control group.

Frequently Asked Questions:

What if a Participant Loses Their Aroma Inhaler?

Participants are instructed to contact Marian Reven at marian.reven@hsc.wvu.edu if they lose their inhaler and arrange for a replacement.

- The study will continue during the time they are without an inhaler and resume when they have one.
- The researcher will note this occurrence, but data analysis will occur as if the days were consecutive.

What if a Participant has a Reaction?

Participants are instructed to contact Marian Reven at marian.reven@hsc.wvu.edu if they experience adverse reactions such as a headache.

- They are asked to stop using the inhaler, recap it, and retry the inhaler as directed a little later.
- If unpleasant effects, such as headache continue, discontinue use, and contact Marian Reven, Investigator at marian.reven@hsc.wvu.edu
- If participant feels any severe reaction like difficulty breathing, they are asked to seek medical care

What if a Participant Wants to Withdraw from the Study?

Participants are instructed to contact Marian Reven at marian.reven@hsc.wvu.edu if they wish to withdraw from the study.

- They are free to withdraw from the study at any time without penalty
- They can keep the aroma inhaler and all study materials
- They are asked to return the logbook if they completed it
- They will not receive the $20 gift card

References

Armstrong, M., Flemming, K., Kupeli, N., Stone, P., Wilkinson, S., & Candy, B. (2019). Aromatherapy, massage and reflexology: A systematic review and thematic synthesis of the perspectives from people with palliative care needs. *Palliative Medicine*, *33*(7), 757–769. https://doi.org/10.1177/0269216319846440

Buckle, J. (2015). *Clinical aromatherapy: Essential oils in healthcare* (3rd ed.). Elsevier.

Chang, K. M., & Shen, C. W. (2011). Aromatherapy benefits autonomic nervous system regulation for elementary school faculty in Taiwan. *Evidence-Based Complementary and Alternative Medicine*, *2011*, 1–7. https://doi.org/10.1155/2011/946537

Cicero, T. J., & Ellis, M. S. (2017). The prescription opioid epidemic: A review of qualitative studies on the progression from initial use to abuse. *Dialogues in Clinical Neuroscience*, *19*(3), 259–269.

Coelho, A., Parola, V., Cardoso, D., Bravo, M. E., & Apóstolo, J. (2017). Use of non-pharmacological interventions for comforting patients in palliative care: A scoping review. *JBI Evidence Synthesis*, *15*(7), 1867–1904. https://doi.org/10.11124/JBISRIR-2016-003204

Governor's Council on Substance Abuse Prevention and Treatment. (2020). *West Virginia 2020-2022 substance use response plan*. West Virginia Department of Health & Human Resources Office of Drug Control Policy. https://dhhr.wv.gov/office-of-drug-control-policy/news/Documents/FINAL%20-%20West%20Virginia%202020_2022%20Council%20Substance%20Use%20Plan_January%2020,%202020%20(as%20filed).pdf

Han, X., Gibson, J., Eggett, D. L., & Parker, T. L. (2017). Bergamot (Citrus bergamia) essential oil inhalation improves positive feelings in the waiting room of a mental health treatment center: A pilot study. *Phytotherapy Research*, *31*(5), 812–816. https://doi.org/10.1002/ptr.5806

Helming, M. A. B., Avino, K., Shields, D., Rosa, W., & Dossey, B. M. (Eds.). (2022). *Dossey & Keegan's holistic nursing: A handbook for practice* (8th ed.). Jones & Bartlett Learning.

Herz, R. S. (2009). Aromatherapy facts and fictions: A scientific analysis of olfactory effects on mood, physiology and behavior. *International Journal of Neuroscience*, *119*(2), 263–290. https://doi.org/10.1080/00207450802333953

Hutton, H., Lesko, C. R., Chander, G., Lau, B., Wand, G. S., & McCaul, M. E. (2017). Differential effects of perceived stress on alcohol consumption in moderate versus heavy drinking HIV-infected women. *Drug and Alcohol Dependence*, *178*, 380–385. https://doi.org/10.1016/j.drugalcdep.2017.05.021

Johannessen, D. A., Nordfjærn, T., & Geirdal, A. Ø. (2019). Change in psychosocial factors connected to coping after inpatient treatment for substance use disorder: A systematic review. *Substance Abuse Treatment, Prevention, and Policy*, *14*(1), 16. https://doi.org/10.1186/s13011-019-0210-9

Kalayasiri, R., Maneesang, W., & Maes, M. (2018). A novel approach of substitution therapy with inhalation of essential oil for the reduction of inhalant craving: A double-blinded randomized controlled trial. *Psychiatry Research*, *261*, 61–67. https://doi.org/10.1016/j.psychres.2017.12.015

Lizarraga-Valderrama, L. R. (2021). Effects of essential oils on central nervous system: Focus on mental health. *Phytotherapy Research*, *35*(2), 657–679. https://doi.org/10.1002/ptr.6854

Mannucci, C., Navarra, M., Calapai, F., Squeri, R., Gangemi, S., & Calapai, G. (2017). Clinical pharmacology of citrus bergamia: A systematic review: Systematic review of citrus bergamia clinical studies. *Phytotherapy Research*, *31*(1), 27–39. https://doi.org/10.1002/ptr.5734

Meit, M., Heffernan, M., Tanenbaum, E., & Hoffman, T. (2017). *Appalachia diseases of despair* (p. 23) [Policy Analysis and Research]. Appalachian Regional Commission. https://www.arc.gov/wp-content/uploads/2020/06/AppalachianDiseasesofDespairAugust2017.pdf

Merino, R., Bowden, N., Katamneni, S., & Coustasse, A. (2019). The opioid epidemic in West Virginia. *The Health Care Manager*, *38*(2), 187–195. https://doi.org/10.1097/HCM.0000000000000256

Morrone, L. A., Rombolà, L., Pelle, C., Corasaniti, M. T., Zappettini, S., Paudice, P., Bonanno, G., & Bagetta, G. (2007). The essential oil of bergamot enhances the levels of amino acid neurotransmitters in the hippocampus of rat: Implication of monoterpene hydrocarbons. *Pharmacological Research*, *55*(4), 255–262. https://doi.org/10.1016/j.phrs.2006.11.010

Navarra, M., Mannucci, C., Delbò, M., & Calapai, G. (2015). Citrus bergamia essential oil: From basic research to clinical application. *Frontiers in Pharmacology*, *6*. https://doi.org/10.3389/fphar.2015.00036

NCCIH. (2021). *NCCIH strategic plan fiscal year 2021–2025*. https://www.nccih.nih.gov/about/nccih-strategic-plan-2021-2025

Pallant, J. (2020). *SPSS survival manual: A step by step guide to data analysis using IBM SPSS*. https://www.taylorfrancis.com/books/9781003117407

Perry, N., & Perry, E. (2006). Aromatherapy in the management of psychiatric disorders. *CNS Drugs*, *20*(4), 257–280. https://doi.org/10.2165/00023210-200620040-00001

Redstone, L. (2015). Mindfulness meditation and aromatherapy to reduce stress and anxiety. *Archives of Psychiatric Nursing*, *29*(3), 192–193. https://doi.org/10.1016/j.apnu.2015.03.001

Roos, C. R., Kiluk, B. D., McHugh, R. K., & Carroll, K. M. (2020). Evaluating a longitudinal mediation model of perceived stress, depressive symptoms, and substance use treatment outcomes. *Psychology of Addictive Behaviors*, *34*(6), 660–668. https://doi.org/10.1037/adb0000581

Saiyudthong, S., & Marsden, C. A. (2011). Acute effects of bergamot oil on anxiety-related behaviour and corticosterone level in rats. *Phytotherapy Research*, *25*(6), 858–862. https://doi.org/10.1002/ptr.3325

Saloner, B., Landis, R., Stein, B., & Barry, C. L. (2019). The Affordable Care Act in the heart of the opioid crisis: Evidence from West Virginia. *Health Affairs (Project Hope)*, *38*(4), 633–642. https://doi.org/10.1377/hlthaff.2018.05049

SAMHSA. (2018). *SAMHSA releases national survey on drug use and health*. Capitol Connector. https://www.thenationalcouncil.org/capitol-connector/2018/09/samhsa-releases-national-survey-on-drug-use-and-health/

SAMHSA. (2020). *Behavioral health barometer: West Virginia, volume 6. Indicators as measured through the 2019 national survey on drug use and health and the national survey of substance abuse treatment services* (p. 45) [HHS Publication No. SMA–20–Baro–19–WV]. https://store.samhsa.gov/

Scuteri, D., Morrone, L. A., Rombolà, L., Avato, P. R., Bilia, A. R., Corasaniti, M. T., Sakurada, S., Sakurada, T., & Bagetta, G. (2017). Aromatherapy and aromatic plants for the treatment of behavioural and psychological symptoms of dementia in patients with Alzheimer's disease: Clinical evidence and possible mechanisms. *Evidence-Based Complementary and Alternative Medicine*, *2017*, 1–9. https://doi.org/10.1155/2017/9416305

Wesa, K. M. (2004). *Recommendations and guidelines regarding the preferred research protocol for investigating the impact of an optimal healing environment on patients with substance abuse*. *10*(S1), S-193-S-199.

World Health Organization (Ed.). (1992). *The ICD-10 classification of mental and behavioural disorders: Clinical descriptions and diagnostic guidelines*. World Health Organization.

Yang, Y., Perkins, D. R., & Stearns, A. E. (2020). "I started to feel better now": Qualitative findings from client narratives on early recovery in inpatient substance use treatment. *International Journal of Mental Health & Addiction*, *18*(4), 1048–1066. https://doi.org/10.1007/s11469-019-00107-z

Appendix A

PRESCREEN SURVEY

To be completed by the Enroller:

1. Please answer the following questions about aversion (dislike) or allergy.
    a. Do you have a strong aversion to smells of citrus and/or citrus fruit(s) themselves (such as grapefruit, orange, lemon, or bergamot). Yes/No (If no, please go to the next question)
        i. Do you have any allergies to citrus? Yes/No (If no, answer next question)
        ii. This study uses the pure essential oil of Bergamot. Have you ever smelled this fruit or essential oil? Yes/No
        iii. If yes, you have smelled Bergamot fruit or essential oil, do you dislike the smell? Yes/No
        iv. If yes, you dislike the smell of Bergamot essential oil, you are excused from participation in this study.

    If yes, you have a strong dislike or allergy to Bergamot fruit or essential oil, you are not eligible to participate in this study.

    If no strong aversion or allergy to Bergamot, proceed with the following questions.

2. Do you or have you ever been told by a doctor that you have any of the following medical or health conditions? Yes/No (If No, go to question 3)
    a. ___ Severe breathing problems such as asthma, chronic bronchitis, or a chronic obstructive pulmonary disease (COPD)
    b. ___ Pregnant or the possibility of becoming pregnant and/or breastfeeding
    c. ___ Allergies to citrus fruits such as grapefruit, lemon, orange, or bergamot

    If yes to any responses to question 2, you are not eligible to participate in this study.

3. Have you ever tried any integrative or complementary therapies (examples include; massage, yoga, acupuncture, aromatherapy with essential oils, herbs, meditation, mindfulness practices etc.) Yes/No (If Yes, please answer the following. If No, go to question 5)
    a. If yes, list which ones? _____
    b. If yes, what was your main reason for using complementary therapies? Choose all that apply
        i. ___Pain
        ii. ___Anxiety
        iii. ___Relaxation
        iv. ___Stress relief

v. ___Other, please write in _____

c. If there is a specific therapy used for a specific symptom, please write the therapy beside the symptom listed above.
d. On a scale of 0 to 10 with 0 being not at all effective and 10 being very effective, how effective was the therapy noted above for relief of the symptom? (Example: Pain, massage, 7/10)

4. Was one of the complementary therapies you have tried aromatherapy or essential oils? Yes/No (If Yes, please answer the following. If No, go to question 5)
    a. No, I have not used aromatherapy or essential oils. (Proceed to question 5)
    b. Yes, I have used essential oils and have tried (please list the essential oils you have tried) _____
    c. Of those essential oils you have tried, which one or ones would you consider to be your favorite(s) _____
    d. Of those essential oils you have tried, which one or ones would you consider to be your least favorite(s) _____
    e. Have you ever tried Bergamot essential oil? Yes/ No
        i. If yes, why did you try it? _____
        If yes, what, if any effect, did you think it had? _____

5. Do you have difficulty smelling or recognizing odors? Yes/No
    a. If yes, do you think your problems with smelling are because of allergies or stuffy nose and congested sinuses? Yes/No
        i. Are you currently feeling sick with a cold, the flu, or with COVID? Yes/No
    b. If yes, you have problems with your sense of smell, have you ever been *told by a doctor* that you have a problem with your sense of smell? Yes/No
        i. If yes, have you ever been diagnosed or told by a doctor that you have *anosmia*, which is a total loss of the sense of smell? Yes/No
            1. Was this loss of smell related to COVID or some other illness? Yes/No

    If yes, approximately when did the loss of smell begin ____

END OF SURVEY

Participant is not eligible to participate in this study
If they answered “Yes” to either or both of the following questions:
Question 1. "I am allergic to or have a strong aversion to smells of citrus and/or citrus fruit(s) themselves (such as grapefruit, orange, lemon, bergamot)”
Question 2. “Do you or have you ever been told by a doctor that you have any of the following medical or health conditions”, and/or

ENROLLER: Record all reactions to the smell of Bergamot during prescreening. If no negative reaction, write “No negative reaction” _____

Once complete, either excuse participant if they are not eligible or proceed by obtaining a packet and opening study materials.

COMFORT SURVEY

Thank you VERY MUCH for helping us understand your **comfort**. Below are statements that relate to your comfort right now. Six numbers are provided for each question; please circle the number you think most closely matches your feeling. Your responses should describe your comfort right now.

	Right now…	**Strongly Disagree**					**Strongly Agree**
1.	My body is relaxed right now	1	2	3	4	5	6
2.	I feel useful because I am working hard	1	2	3	4	5	6
3.	There are those I can depend on when I need help	1	2	3	4	5	6
4.	My condition gets me down	1	2	3	4	5	6
M5.	I feel confident	1	2	3	4	5	6
6.	I feel dependent on others	1	2	3	4	5	6
7.	I feel my life is worthwhile right now	1	2	3	4	5	6
8.	I am inspired by knowing that I am loved	1	2	3	4	5	6
9.	No one understands me	1	2	3	4	5	6
10.	My pain is difficult to endure	1	2	3	4	5	6
11.	I am inspired to do my best	1	2	3	4	5	6
12.	I am unhappy when I am alone	1	2	3	4	5	6
13.	My faith helps me not to be afraid	1	2	3	4	5	6
14.	I do not feel healthy right now	1	2	3	4	5	6
15.	I am afraid of what is next	1	2	3	4	5	6
16.	I am being treated fairly	1	2	3	4	5	6
17.	I have experienced changes which make me feel uneasy	1	2	3	4	5	6
18.	I am very tired	1	2	3	4	5	6
19.	I can rise above my pain	1	2	3	4	5	6
20.	The mood around here uplifts me	1	2	3	4	5	6
21.	I am content	1	2	3	4	5	6

22.	My beliefs give me peace of mind	1	2	3	4	5	6
23.	I feel out of control	1	2	3	4	5	6
24.	I feel safe	1	2	3	4	5	6
25.	I feel peaceful	1	2	3	4	5	6
26.	I am depressed	1	2	3	4	5	6
27.	I have found meaning in my life	1	2	3	4	5	6
28.	I need to feel good again	1	2	3	4	5	6

EASE MEASURE

Ease Measure: Please circle the number (**never; sometimes; frequently; always**) to indicate your degree of agreement with each statement as a descriptor of what is generally happening in your everyday life.

	Never	Sometimes	Frequently	Always
1. I can let go of my daily stress.	1	2	3	4
2. I am comfortable in knowing what to do when in a difficult situation.	1	2	3	4
3. I feel comfort when I share my everyday experiences.	1	2	3	4
4. I am at peace with myself.	1	2	3	4
5. I can handle situations in a calm manner.	1	2	3	4
6. I struggle to get though my day.	1	2	3	4
7. I can go to a place of tranquility when needed.	1	2	3	4
8. I accept things I cannot change.	1	2	3	4
9. I take time to rest during my busy day.	1	2	3	4
10. I feel safe.	1	2	3	4
11. I am content with my life.	1	2	3	4
12. I experience moments of joy.	1	2	3	4

13. I take time for soothing activities.	1	2	3	4
14. I am uncomfortable in everyday situations.	1	2	3	4
15. I have sadness during my day.	1	2	3	4
16. I am nervous during everyday circumstances.	1	2	3	4
17. I worry about what is happening in my life.	1	2	3	4
18. I experience my day going smoothly.	1	2	3	4
19. I can let go of restrictive circumstances.	1	2	3	4
20. I have energy to face whatever comes my way.	1	2	3	4

STRESS SURVEY

Please read each statement and circle a number 0, 1, 2, or 3, which indicates how much this statement applied to you over the past week. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:

0 Did not apply to me at all
1 Applied to me to some degree, so some of the time
2 Applied to me to a considerable degree or a good part of the time
3 Applied to me very much or most of the time

1. I find it hard to wind down	0	1	2	3
2. I was aware of my dry mouth	0	1	2	3
3. I couldn't seem to experience any positive feelings at all	0	1	2	3
4. I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5. I found it difficult to work up the initiative to do things	0	1	2	3
6. I tend to over-react to situations	0	1	2	3
7. I experienced trembling (e.g. in the hands)	0	1	2	3

8.	I felt that I was using a lot of nervous energy	0	1	2	3
9.	I was worried about situations where I might panic and make a fool of myself	0	1	2	3
10.	I felt that I had nothing to look forward to	0	1	2	3
11.	I found myself getting agitated	0	1	2	3
12.	I found it difficult to relax	0	1	2	3
13.	I felt down-hearted and blue	0	1	2	3
14.	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15.	I felt I was close to panic	0	1	2	3
16.	I was unable to become enthusiastic about anything	0	1	2	3
17.	I felt I wasn't worth much as a person	0	1	2	3
18.	I felt that I was rather touchy	0	1	2	3
19.	I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)	0	1	2	3
20.	I felt scared without any good reason	0	1	2	3
21.	I felt that life was meaningless	0	1	2	3

POST SURVEY

Please answer the following regarding the intensity or strength of the aroma inhaler.

1. On a scale of 1 to 10 rate overall how enjoyable the aroma of the inhaler was (0 being not enjoyable at all and 10 being very enjoyable)

0	1	2	3	4	5	6	7	8	9	10

2. On a scale of 1 to 10 rate the <u>usual</u> strength smell of the aroma inhaler (0 being no strength and very weak to 10 the strongest it could be)

0	1	2	3	4	5	6	7	8	9	10

3. How likely are you to continue to use this aroma inhaler (1 being not at all likely and 10 being very likely)?

0	1	2	3	4	5	6	7	8	9	10

4. Any other thoughts you wish to share about this experience?

Thank you for taking the time to complete this study, please return this and all other surveys and the logbook in the prepaid envelope. Once this is received, a gift card will be sent.
If you have any further questions, please contact Marian Reven at marian.reven@hsc.wvu.edu

Appendix B

SAFETY DATA SHEET

Plant Extracts International Inc.
600 11th Avenue South, Hopkins, Minnesota 55343-7840 USA
Telephone 877-999-H2EO (877-999-4236) or 952-935-9903
Fax 877-329-H2EO (877-329-4236) or 952-935-2075
www.plantextractsinc.com info@plantextractsinc.com

Nurse/Practitioner Safety Data Sheet	BERGAMOT ESSENTIAL OIL SDS #004
Company Name: **Plant Extracts International Inc.** 600 11th Avenue South Hopkins MN 55343	**Product Name:** Bergamot Essential Oil **Source:** *Citrus bergamia (bergapten-free)* **Physical state:** Essential oil **Major constituents:** limonene, linalyl, acetate, linalool
For reference in handling: – Bath Salts – Aethereo®Sticks – Massage Oils – Mask Sprays – AromaDiscs (for use with fan diffuser) – Quantities of 30 mL (1 oz.) or less*	**Handling and Storage:** Store in sealed containers in cool, dry area. Avoid exposure to heat, light, and moisture. *For larger quantities refer to manufacturer's or formulator's SDS
Aroma: Spicy/citrus/floral **Physical data:** Solubility: 20 mg/L in water; soluble in most organic solvents. **Toxicological Information:** Ingestion: May be harmful if swallowed Contact with eyes: Irritating to eyes Contact with skin: Use in <3% dilution in fractionated coconut oil	**Health and Hazard Data:** **Eyes:** Will cause irritation. Flush with milk or water. Contact physician if needed. **Skin:** Wash affected areas thoroughly with water and soap. Contact physician if needed. **Ingestion:** Rinse mouth with milk or water. Do not induce emesis. Contact a physician immediately. **Inhalation:** For use in personal inhalers or for room diffusion.
Spill, leak, and disposal procedures: Soak up with inert absorbent/paper and dispose according to regulations	**Emergency First Aid Procedure:** Follow normal first aid procedure. Contact doctor or poison control as needed.
Ecological information: The product is not harmful in the local environment in the quantities available. Limited potential for bio-accumulation.	– This product is for external use, and low level inhalation. It is not intended for enteral ingestion. – Keep away from eyes.
Exposure Scenarios: Bath Salts: 0.154 mL per average bath Aethereo®Sticks: 0.83 µL per average inhalation Massage Oils: 0.2 mL per average treatment AromaDiscs: 0.17 µL per average inhalation Mask Sprays: 1.82 µL per hour @ average respiration rate.	– Plant Extracts International disclaims any warranty expressed or implied as well as any liability for any injury or loss arising from the use of this information or the material described. – These data are condensed from the manufacturer's Safety Data Sheet for this product. – It is the responsibility of the user to determine appropriate precautions for the safe handling and use of this product. – This safety data is specific to the product designated above, as supplied by Plant Extracts International Inc.

October 2020

Plant Extracts International Inc.
600 11th Avenue South, Hopkins, Minnesota 55343-7840 USA
Telephone 877-999-H2EO (877-999-4236) or 952-935-9903
Fax 877-329-H2EO (877-329-4236) or 952-935-2075
www.plantextractsinc.com info@plantextractsinc.com

BERGAMOT ESSENTIAL OIL
SAFETY DATA SHEET #004 - MANUFACTURING

1. Company/Product Identification

Company:	Plant Extracts International Inc. 600 11th Avenue South, Hopkins MN 55343 Telephone 877-999-4236 Fax 877-329-4236
E-mail Address:	info@plantextractsinc.com
Identified Uses:	Manufacture of essential oil products
Natural Product:	Yes
Chemical Identity:	Essential oil
Commercial Name:	Bergamot Essential Oil
FEMA:	2153
Scientific Name/Plant of Origin:	Essential oil from the peel of *Citrus bergamia* (bergapten-free)
Major Constituents:	limonene, linalyl acetate, linalool

2. Hazard Identification

Pictograms/Signal words:	 Warning
Hazard Statements:	H226 – flammable liquid H303 – may be harmful if swallowed H316 – causes mild skin irritation H320 – causes eye irritation
Precautionary Statements:	P210 – keep away from heat/sparks/open flame P233 – keep container tightly closed P235 – keep cool P313 – if severe irritation occurs/persists: get medical advice/attention P370 + P378 – in case of fire: use dry sand, dry chemical or alcohol-resistant foam for extinction

3. Composition/Information on Ingredients

Ingredient(s):	Essential oil of *Citrus bergamia*
CAS Nr.:	8007-75-8
CTFA Nr.:	296-429-8
Concentration:	100%

4. First Aid Measures

General Indications:	Remove contaminated clothing.
Inhalation:	If dizzy or lightheaded from exposure, leave the area until normalcy is regained.
Skin Exposure:	Wash skin with soap and warm water.
Eye Exposure:	Use eyeglass with milk, if available; otherwise flush with water.
Ingestion:	Administer milk, or charcoal tablets if available.
Main Hazard:	None identified.
Health Effects-Eyes:	May cause conjunctival irritation.

October 2020

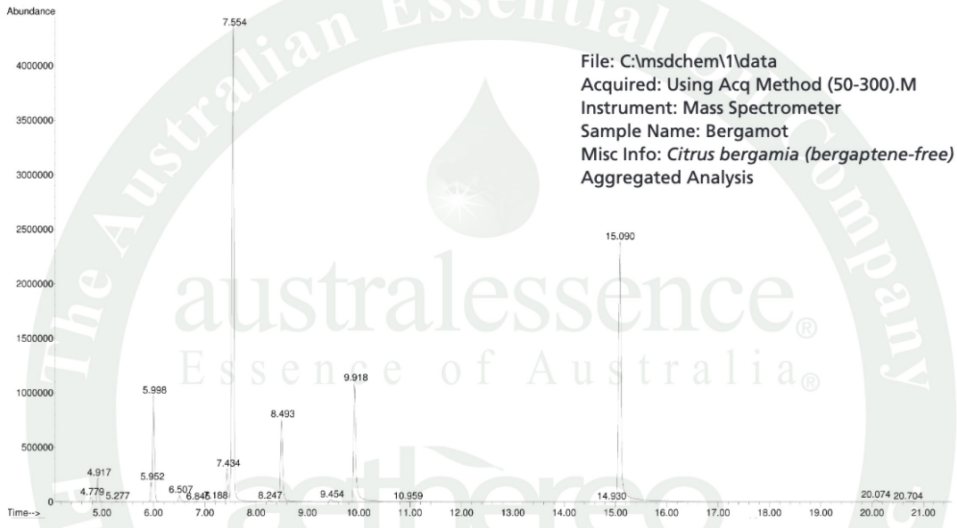
The Australian Essential Oil Company & Plant Extracts International Inc.

ANALYTICAL DATA SHEET

Bergamot

Citrus bergamia (bergaptene-free)

Gas Chromatographic Trace



Constituent Mass Balance

RT (min)	Area%	Component
4.779	0.29	alpha-thujene
4.917	1.46	alpha-pinene
5.277	0.05	camphene
5.952	1.00	sabinene
5.998	7.20	beta-pinene
6.507	0.64	myrcene
6.845	0.04	alpha-phellandrene
7.188	0.11	alpha-terpinene
7.434	2.39	para-cymene
7.554	38.36	limonene
8.247	0.12	trans-beta-ocimene
8.493	6.69	gamma-terpinene
9.454	0.28	terpinolene
9.918	11.70	linalool
14.930	0.04	trans-sabinene hydrate acetate
15.090	29.20	linalyl acetate
20.074	0.25	beta-caryophyllene
20.704	0.1	trans-alpha-bergamotene

Mass balance: 100% (w/w)

Physical Data

Relative Density @ 25°C: 0.848
Refractive Index @ 25°C: 1.4735
Optical Rotation @ 25°C: +62.47°

Date of Manufacture

Date of GC run for specific batch

Product Life

3 years from the date of analysis, when stored under appropriate conditions

GC and Run Parameters

Hewlett Packard HP 6890 Series GC System
Detector: HP5973 Mass Selective Detector
Column: HP-5 (30 m x 0.32 mm x 0.25 µm film thickness)
Temperature Program: 0-2 min @ 50°C, 50 - 300°C @ 4°C/min
Carrier Gas: Helium
Injection: 1.0 µL (1:100 dilution in MeOH)

A mass balance (weight for weight) of 100% indicates a pure and natural essential oil.
These data are aggregated from the last five batch analyses.
Specific batch data is available from the relevant certificate of analysis.

[Code of Federal Regulations]
[Title 21, Volume 3]
[CITE: 21CFR182.20]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B - FOOD FOR HUMAN CONSUMPTION (CONTINUED)

PART 182 -- SUBSTANCES GENERALLY RECOGNIZED AS SAFE

Subpart A - General Provisions

Sec. 182.20 Essential oils, oleoresins (solvent-free), and natural extractives (including distillates).

Essential oils, oleoresins (solvent-free), and natural extractives (including distillates) that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Common name	Botanical name of plant source
Alfalfa	Medicago sativa L.
Allspice	Pimenta officinalis Lindl.
Almond, bitter (free from prussic acid)	Prunus amygdalus Batsch, Prunus armeniaca L., or Prunus persica (L.) Batsch.
Ambrette (seed)	Hibiscus moschatus Moench.
Angelica root	Angelica archangelica L.
Angelica seed	Do.
Angelica stem	Do.
Angostura (cusparia bark)	Galipea officinalis Hancock.
Anise	Pimpinella anisum L.
Asafetida	Ferula assa-foetida L. and related spp. of Ferula.
Balm (lemon balm)	Melissa officinalis L.
Balsam of Peru	Myroxylon pereirae Klotzsch.
Basil	Ocimum basilicum L.
Bay leaves	Laurus nobilis L.
Bay (myrcia oil)	Pimenta racemosa (Mill.) J. W. Moore.
Bergamot (bergamot orange)	Citrus aurantium L. subsp. bergamia Wright et Arn.
Bitter almond (free from prussic acid)	Prunus amygdalus Batsch, Prunus armeniaca L., or Prunus persica (L.) Batsch.
Bois de rose	Aniba rosaeodora Ducke.
Cacao	Theobroma cacao L.

AETHEREOSTICK INFORMTION SHEET

Aethereo®Sticks are a simple, portable, economical and effective way to enjoy the aromatherapeutic benefits of essential oils - wherever you are.

Long-lasting and safe for all ages, AethereoSticks are enjoyed by people at home, at work or school, and while traveling. AethereoSticks are widely used in hospitals for adjunctive symptom management and general well-being. Providing single-person exposure, they offer the ultimate in personal, private diffusion.

What is in an AethereoStick?

AethereoSticks are available in a wide range of undiluted essential oils and scientifically formulated essential oil blends. These precious plant materials can help with symptom relief and help to create a healing environment, which supports our natural abilities to balance, restore, and maintain overall wellness.

How do you use an AethereoStick?

Unscrew the outer cap. Hold the AethereoStick a few inches from your nose and take three or four slow, deep breaths. Enjoy. Repeat as desired.

How long will an AethereoStick last?

AethereoSticks are given a nominal one year expiry date when sealed and unopened. When AethereoSticks are unsealed, opened, and in use, trials indicate that a product life of about three months can be expected, depending upon frequency of use. Due to variations in aroma intensity, some will be effective for much longer than three months, and some for less. The variables to which the product may be exposed after opening will influence the length of time the essential oil in the AethereoStick remains available.

Built-in clip for optional hands-free use

At the request of our health care customers, we have redesigned the inner cylinder to incorporate a patent-pending built-in clip for hands-free use in hospitals. Simply remove the outer cap and slide the clip onto clothing or gown. Perfect for when the user is unable to hold the AethereoStick – including peri-op, sedation, infusion, memory care, hospice and palliative care. Or use it in hand, removing the outer cap and holding the inner cylinder a few inches from your nose.

Plant Extracts International Inc.

Minneapolis, Minnesota USA | www.plantextractsinc.com | info@plantextractsinc.com

PLANT EXTRACTS INTERNATIONAL
PRODUCT LIFE/EXPIRY INFORMATION

Every Plant Extracts International product carries information indicating the date of manufacture *(for example, "Made 06.16.21")* rather than the date of expiry; and our product stock number *(for example, # 642)*. In addition, bottles of undiluted essential oil are marked with the Lot (Batch) #.

While expiry dates are not always absolute or consistent because of differences in materials, use, and storage, we are often asked to provide them – thus the following:

In relation to expiry dates, the following information gives greater detail.

BOTTLED ESSENTIAL OILS

Unopened bottles of undiluted essential oil are given a minimum of one year expiry date.
When a bottle of undiluted essential oil is opened for use, relevant hospital policy regarding expiry, safe use, and disposal of unused contents applies.

FORMULATED PRODUCTS

Formulated products in a carrier base, such as massage oils, bath salts, and multi-purpose sprays, are given a minimum of one year expiry date when unopened. When a formulated product is opened for use, relevant hospital policy regarding expiry, safe use, and disposal of unused contents applies.

AETHEREOSTICKS

AethereoSticks are given a minimum of one year expiry date when sealed and unopened.
When AethereoSticks are unsealed, opened, and in use, trials indicate that a product life of about three months can be expected, depending upon frequency of use. Due to variations in aroma intensity, some will be effective for much longer than three months, and some for less. The variables to which the product may be exposed after opening will influence the length of time the essential oil in the AethereoStick remains available.

We recommend purchasing our products in quantities that give you a few weeks supply at most. Our just-in-time manufacturing practices make it unnecessary to overstock, assuring that your inventory is always as fresh as possible. This eliminates situations where newer stock may get put in front and older stock continues to age. Storage conditions can also play a role – stored in sunlight or a warm room, products will not be effective for as long. Ordering frequently will ensure that you have the freshest and most efficacious products.

July 2021

Appendix C

Cover Letter (Formatted per IRB)

Dear Participant,

This letter is to inform you about the research project *Using aromatherapy for comfort, ease, and stress for adults being treated for substance use disorder in north central Appalachia: A randomized controlled trial.* This project is being conducted by Marian Reven, MSN, RN in the Adult Health Department at the WVU School of Nursing. This study is done to fulfill the requirements of earning my PhD in nursing philosophy at WVU.

For this study, you will either be asked to answer survey questions, use an aroma inhaler, and fill out a daily logbook or asked to answer surveys, and fill out a daily logbook. The study has one group that uses the aroma inhaler and one group that does not, and this is randomly assigned. The study lasts for 7-days. The survey questions focus on comfort, ease, and stress.

The day you receive your materials, you will complete the consent form and take the surveys. At the beginning of the following day, you will begin to use the aroma inhaler or continue with treatment as usual. Each day during the 7 days, you will use the logbook to track your progress. With your consent, I will send a reminder text message to your cell phone for the first 3 days of the study and at the end. You will receive a $20 gift card and an aroma inhaler valued at $7 for completion of this study.

Your participation in this project will be kept as confidential as legally possible. All data will be reported in the aggregate (all together). Your participation is entirely voluntary. You may skip any question that you do not wish to answer, and you may stop participating at any time. The West Virginia University Institutional Review Board's approval of this project is on file with the WVU Office of Human Research Protections.

If you have any questions about this research project, please feel free to contact me at marian.reven@hsc.wvu.edu. Additionally, you can contact the WVU Office of Human Research Protections at 304-293-7073. Thank you for your participation.

Sincerely,

Marian Reven, MSN, RN

For more information, please see the informed consent.

Appendix D

Logbooks for Intervention & Control Groups

ID#_____

AROMA INHALER STUDY

LOGBOOK

INTERVENTION GROUP

Directions for using your aroma inhaler and this logbook:
Follow these steps to use your aroma inhaler:

1. Hold the aroma inhaler by the base
2. Twist off the cap. The inner part of the aroma inhaler with the essential oil-soaked cotton wick is part of a closed system and is not intended to be opened. All you need to do is twist off the cap
3. Hold the aroma inhaler within 3 inches of your nose
4. Breath in gently through your nose for 3 seconds
5. Hold your beath for about three seconds and then exhale gently through your mouth
6. Repeat this 3 times* and then replace the cap and store your aroma inhaler in a cool, dry place away from children or pets. (You may repeat this breathing cycle more than 3 times each day, please remember to make a note of this in the comments section about when and why you did)
7. Use at least 3 times a day, and if you want to, use it more, but this should be recorded on the daily logbook page

Follow these steps to use your Logbook:
Use your logbook to track how you are using your aroma inhaler and how you are feeling

1. Use a new page of the logbook for each of the seven days of the study
2. If you forget or purposely do not do the aroma inhaler, please make a note with a brief reason why
3. Do not stop the study because you miss a step of using the inhaler or recording in the logbook
4. Keep your logbook in a secure place as we will collect it at the end of the study
5. Do not write important or private information that does not have to do with using your aroma inhaler in this logbook
6. Do not write your name on the logbook
7. All information provided in the logbook will be kept confidential
8. **Return within 3 days of completion**

*NOTE: If you develop any uncomfortable symptoms such as a headache, stop using the aroma inhaler, recap, and retry a little later. If unpleasant symptoms continue the next time, discontinue use and contact Marian Reven, the Principal Investigator (PI), at marian.reven@hsc.wvu.edu.

Day 1

Please indicate each time you use your inhaler today (approximate time of day)

____ I used my aroma inhaler as directed for the first time today
____ I used my aroma inhaler as directed for the second time today
____ I used my aroma inhaler as directed for the third time today

Any additional comments:
If you used your aroma inhaler any extra times, please indicate when and brief reason why (example: 2:30p, feeling stressed, and it seemed to help)

One time at the end of each day, after using the inhaler throughout your day, place an X on the line under "I feel as comfortable as possible today"

I feel as comfortable as possible today

Strongly disagree	Strongly agree

Comments:

If you have any questions or comments, contact Marian Reven at marian.reven@hsc.wvu.edu.
Thank you

Day 2

Please place a check mark or X on the line each time you use your inhaler today

____ I used my aroma inhaler as directed for the first time today
____ I used my aroma inhaler as directed for the second time today
____ I used my aroma inhaler as directed for the third time today

Comments: (example: I used my aroma inhaler an extra time today because…)

One time each day place an X on the line under "I feel as comfortable as possible today"

I feel as comfortable as possible today

Strongly disagree	Strongly agree

Comments:

If you have any questions or comments, contact Marian Reven at marian.reven@hsc.wvu.edu.

Thank you

Day 3

Please place a check mark or X on the line each time you use your inhaler today

____ I used my aroma inhaler as directed for the first time today
____ I used my aroma inhaler as directed for the second time today
____ I used my aroma inhaler as directed for the third time today

Comments: (example: I used my aroma inhaler an extra time today because…)

One time each day place an X on the line under "I feel as comfortable as possible today"

I feel as comfortable as possible today

Strongly disagree	Strongly agree

Comments:

If you have any questions or comments, contact Marian Reven at marian.reven@hsc.wvu.edu.

Thank you

Day 4

Please place a check mark or X on the line each time you use your inhaler today

____ I used my aroma inhaler as directed for the first time today
____ I used my aroma inhaler as directed for the second time today
____ I used my aroma inhaler as directed for the third time today

Comments: (example: I used my aroma inhaler an extra time today because…)

One time each day place an X on the line under "I feel as comfortable as possible today"

I feel as comfortable as possible today

Strongly disagree	Strongly agree

Comments:

If you have any questions or comments, contact Marian Reven at marian.reven@hsc.wvu.edu.

Thank you

Day 5

Please place a check mark or X on the line each time you use your inhaler today

____ I used my aroma inhaler as directed for the first time today
____ I used my aroma inhaler as directed for the second time today
____ I used my aroma inhaler as directed for the third time today

Comments: (example: I used my aroma inhaler an extra time today because…)

One time each day place an X on the line under "I feel as comfortable as possible today"

I feel as comfortable as possible today

Strongly disagree	Strongly agree

Comments:

If you have any questions or comments, contact Marian Reven at marian.reven@hsc.wvu.edu.

Thank you

Day 6

Please place a check mark or X on the line each time you use your inhaler today

____ I used my aroma inhaler as directed for the first time today
____ I used my aroma inhaler as directed for the second time today
____ I used my aroma inhaler as directed for the third time today

Comments: (example: I used my aroma inhaler an extra time today because…)

One time each day place an X on the line under "I feel as comfortable as possible today"

I feel as comfortable as possible today

Strongly disagree	Strongly agree

Comments:

If you have any questions or comments, contact Marian Reven at marian.reven@hsc.wvu.edu.

Thank you

Day 7

Please place a check mark or X on the line each time you use your inhaler today

____ I used my aroma inhaler as directed for the first time today
____ I used my aroma inhaler as directed for the second time today
____ I used my aroma inhaler as directed for the third time today

Comments: (example: I used my aroma inhaler an extra time today because…)

One time each day place an X on the line under "I feel as comfortable as possible today"

I feel as comfortable as possible today

Strongly disagree	Strongly agree

Comments:

If you have any questions or comments, contact Marian Reven at marian.reven@hsc.wvu.edu.

Thank you

- Thank you for completing your seven-day aroma inhaler study!
- Please place your survey and logbook in the envelope provided and seal it
- Return this envelope to the Chestnut Ridge Center within 3 days of completion
- Receive a $20 gift card
- Keep the aroma inhaler and all other study materials as our way of saying thank you!

ID#_____

AROMA INHALER STUDY

LOGBOOK

CONTROL GROUP

Follow these steps to use your Logbook:
Use your logbook to track your comfort on each of the seven days of the study

Day 1

One time each day place an X on the line under "I feel as comfortable as possible today"

I feel as comfortable as possible today

Strongly disagree	Strongly agree

Comments:

If you have any questions or comments, contact Marian Reven at marian.reven@hsc.wvu.edu.

Thank you

Day 2

One time each day place an X on the line under “I feel as comfortable as possible today”

I feel as comfortable as possible today

Strongly disagree	Strongly agree

Comments:

If you have any questions or comments, contact Marian Reven at marian.reven@hsc.wvu.edu.

Thank you

Day 3

One time each day place an X on the line under “I feel as comfortable as possible today”

I feel as comfortable as possible today

Strongly disagree	Strongly agree

Comments:

If you have any questions or comments, contact Marian Reven at marian.reven@hsc.wvu.edu.

Thank you

Day 4

One time each day place an X on the line under “I feel as comfortable as possible today”

I feel as comfortable as possible today

Strongly disagree	Strongly agree

Comments:

If you have any questions or comments, contact Marian Reven at marian.reven@hsc.wvu.edu.

Thank you

Day 5

One time each day place an X on the line under “I feel as comfortable as possible today”

I feel as comfortable as possible today

Strongly disagree	Strongly agree

Comments:

If you have any questions or comments, contact Marian Reven at marian.reven@hsc.wvu.edu.

Thank you

Day 6

One time each day place an X on the line under “I feel as comfortable as possible today”

I feel as comfortable as possible today

Strongly disagree	Strongly agree

Comments:

If you have any questions or comments, contact Marian Reven at marian.reven@hsc.wvu.edu.

Thank you

Day 7

One time each day place an X on the line under “I feel as comfortable as possible today”

I feel as comfortable as possible today

Strongly disagree	Strongly agree

Comments:

If you have any questions or comments, contact Marian Reven at marian.reven@hsc.wvu.edu.

Thank you

- Thank you for completing your logbook for the seven-day aroma inhaler study!
- Please place your survey and logbook in the envelope provided and seal it
- **Return this envelope to the Chestnut Ridge Center within 3 days of completion**
- Receive a $20 gift card
- You will receive the aroma inhaler and all other study materials as our way of saying thank you!

Appendix E

Reminder Paper

SEVEN DAY AROMA INHALER STUDY

(Please post this in a place where you will see it each day as a reminder to use your aroma inhaler and logbook) **Thank you for your participation** ☺

How to use & store your aroma inhaler*

DIRECTIONS: To use 3 times daily and as desired:

1. Uncap Inhaler

    Hold within 3 inches of the nose

2. Gently breath in through your nose and hold for 3 seconds, gently exhale through your mouth

    Repeat 3 times each day and as desired (Use the comments section of the logbook to record extra use and thoughts about using your aroma inhaler)

3. Recap Inhaler & Record all uses & reactions to the inhaler in the Logbook**

4. Keep your aroma inhaler and logbook in a safe place. The aroma inhaler is yours to keep.

    **The logbook is returned at the end of this study

*(When not in use, recap to close & store in a cool, dry place away from children and pets) It is OKAY to keep your closed inhaler in your pocket or purse and at room temperature ☺

Do not tamper with the packaging. Keep out of reach of children and animals. If you develop any adverse reactions such as a headache, stop, recap inhaler, and retry a little later. If

unpleasant effects, such as headache continue, discontinue use and contact Marian Reven,

Investigator at marian.reven@hsc.wvu.edu

Thank you!

Appendix F

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. Roger Carpenter (Marian Reven Dissertation work)
Department |	School of Nursing
Sponsor or Funding Source |	TBD
WVU IRB Protocol # |	Pending
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 to fulfill the requirements for a [PhD] in [Philosophy of Nursing] from the Department of Nursing at West Virginia University. This research is being conducted under the supervision of Dr. Roger Carpenter.

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. WVU expects to enroll approximately 98 subjects.

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 groups 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 on the day after you sign the consents and receive your packet. (So, if you sign up on a Tuesday, you will start the study on Wednesday).
9. At the end of 7 days, you are asked to place your completed logbook and post surveys in a postage paid envelope and return them to the Chestnut Ridge Center within 3 days.
10. Once the post survey is received, 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 including stage of treatment in the SUD treatment program, Presence of medical diagnoses of anxiety and/or depression, and presence of severe mental illness.
12. Your permission to use your cell phone number to contact you via text message for reminders on days 1 through 3 and at the end of the study is requested (Optional).

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, 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 not be compensated.

For information regarding the method of payment, contact 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.

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 and data from the WVU Chestnut Ridge/West Virginia University Hospitals/ WVU Medicine/ WVU will be collected.

Persons/Organizations Receiving the Information

- This study will be conducted at the West Virginia University Chestnut Ridge Center (WVUCRC), outpatient substance use disorder treatment and recovery program in north central Appalachia located at 930 Chestnut Ridge Rd., Morgantown, West Virginia, 26505.
- Health care providers who provide services to you as part of this research study.
- (Sponsor name, if applicable) and the people and companies that they use to oversee, manage, or conduct the research.
- 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.
- If applicable, 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. Roger Carpenter, 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, contact Dr. Roger Carpenter at rcarpenter@hsc.wvu.edu or 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. Roger Carpenter (PI) at West Virginia University School of Nursing, rcarpenter@hsc.wvu.edu or Marian Reven (Co-I) West Virginia University School of Nursing, marian.reven@hsc.wvu.edu.

If you are hurt from being in this research, you should contact Dr. Roger Carpenter at 304-293-1410 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 (Co-I) at 304-479-4825.

For information regarding your rights as a participant in research or to talk about the research, contact the WVU Office of Human Research Protection (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 cell phone to send text messages

Phone number_____

Appendix G (IRB Update allowing Stages one, two, three, and peer recovery recruitment)

WestVirginiaUniversity.
OFFICE OF HUMAN RESEARCH PROTECTIONS
886 Chestnut Ridge Road Morgantown, WV 26506

Approval of Protocol Amendment

09/26/2022

To: Roger Carpenter

From: WVU Office of Human Research Protections

Protocol Type: Expedited

Approval Date: 09/26/2022

Submission Type: Amendment

Expiration Date: 07/28/2023

Funding: N/A

WVU Protocol #: 2204562633A002

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

---

The West Virginia University Institutional Review Board has reviewed your request for modifications to the Expedited protocol 2204562633A002, in accordance with 45 CFR 46, 21 CFR 50, and 21 CFR 56 (when applicable). The amendment wording is as follows:

- Amendment wording: During a Zoom meeting between the enroller (study personnel) and the participant, the following changes include: Consent form amended to delete an item of data collection (p. 3, #11, presence of severe mental illness, will not be collected), pre-surveys are done online, given by Qualtrics: Comfort, Ease, and Stress. A demographic data collection form has been submitted as an attachment for clarity on self-report and chart data collected (this is not added to the study packets for participants). All study materials will be mailed to participants instead of in-person enrollment. The initial prescreening of sniffing the bergamot aroma inhaler will occur in the participant's home. Once the participants receive their study materials in the mail, another meeting or phone call will be done between the participant and the enroller (study personnel). In addition, the recruitment population has been widened to include all phases of treatment, including peer recovery coach program (all part of West Virginia University Chestnut Ridge Center (WVUCRC)

The following documents were reviewed and approved for use as part of this submission. Only the documents listed below may be used in the research. Please access and print the files in the Notes & Attachments section of your approved protocol.

Appendix H (IRB approval to recruit online complete consent online)

WestVirginiaUniversity.
OFFICE OF HUMAN RESEARCH PROTECTIONS
886 Chestnut Ridge Road Morgantown, WV 26506

Approval of Protocol Amendment

08/31/2022

To: Roger Carpenter

From: WVU Office of Human Research Protections

Protocol Type: Expedited

Submission Type: Amendment

Funding: N/A

Approval Date: 08/31/2022

Expiration Date: 07/28/2023

WVU Protocol #: 2204562633A001

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

---

The West Virginia University Institutional Review Board has reviewed your request for modifications to the Expedited protocol 2204562633A001, in accordance with 45 CFR 46, 21 CFR 50, and 21 CFR 56 (when applicable). The amendment wording is as follows:

- Amendment wording: Requesting to be able to get consents electronically also. Many participants are being recruited from groups that meet online, and they are from a distance. The potential participants requested being about to consent online.

The following documents were reviewed and approved for use as part of this submission. Only the documents listed below may be used in the research. Please access and print the files in the Notes & Attachments section of your approved protocol.

- CONSENT WVU with HIPAA AT and SUD 2.pdf
- 8-29-22 CONSENT Electronic consent document.docx
- Response to IRB Specific Minor Revisions Requested 07262022.docx
- 2 COMFORT SURVEY.docx
- 3 EASE MEASURE.docx
- 5 POST SURVEY.docx

Appendix I (QIP Audit letter from IRB)

WestVirginiaUniversity.
OFFICE OF HUMAN RESEARCH PROTECTIONS
886 Chestnut Ridge Road Morgantown, WV 26506

Approval of Protocol Amendment

10/25/2022

To: Roger Carpenter

From: WVU Office of Human Research Protections

Protocol Type: Expedited

Approval Date: 10/25/2022

Submission Type: Amendment

Expiration Date: 07/28/2023

Funding: N/A

WVU Protocol #: 2204562633A003

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

---

The West Virginia University Institutional Review Board has reviewed your request for modifications to the Expedited protocol 2204562633A003, in accordance with 45 CFR 46, 21 CFR 50, and 21 CFR 56 (when applicable). The amendment wording is as follows:

- Amendment wording: Response to a QIP

The following documents were reviewed and approved for use as part of this submission. Only the documents listed below may be used in the research. Please access and print the files in the Notes & Attachments section of your approved protocol.

- QIP Response AT and SUD Audit.docx
- CONSENT WVU with HIPAA AT and SUD 4 CT.pdf
- citiCompletionCertificate_10915189_51619788.pdf
- AMEND_Aromatherapy Study ammend to prot for IRB 2.docx
- AMEND_Aromatherapy Study ammend to prot for IRB 2.docx
- 7 Aromatherapy study flier updated 09242022.docx
- Demographic Data Collection.docx
- Updates to AT and SUD Protocol data collection 09242022.docx