

2023

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

Marian E. Reven

West Virginia University, marian.reven@hsc.wvu.edu

Follow this and additional works at: <https://researchrepository.wvu.edu/etd>

Recommended Citation

Reven, Marian E., "Using Aromatherapy for Comfort, Ease, and Stress for Adults Being Treated for Substance Use Disorder in North Central Appalachia: A Randomized Controlled Trial" (2023). *Graduate Theses, Dissertations, and Problem Reports*. 11984.

<https://researchrepository.wvu.edu/etd/11984>

This Dissertation is protected by copyright and/or related rights. It has been brought to you by the The Research Repository @ WVU with permission from the rights-holder(s). You are free to use this Dissertation in any way that is permitted by the copyright and related rights legislation that applies to your use. For other uses you must obtain permission from the rights-holder(s) directly, unless additional rights are indicated by a Creative Commons license in the record and/ or on the work itself. This Dissertation has been accepted for inclusion in WVU Graduate Theses, Dissertations, and Problem Reports collection by an authorized administrator of The Research Repository @ WVU. For more information, please contact researchrepository@mail.wvu.edu.

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

Marian Reven, MSN, RN, AHN-BC, CNE, RA

Dissertation submitted
to the school of Nursing
at West Virginia University

in partial fulfillment of the requirements for the degree of

Doctor of Philosophy in Nursing

Roger Carpenter, Ph.D., RN, NE-BC, CNE, Chair

Mary Jane Smith, Ph.D., RN, FAAN

Kesheng Wang, Ph.D.

Amanda Newhouse, LICSW, PCIT Level- I Trainer, IMH-E®

Department of Nursing

Morgantown, West Virginia

2023

Keywords: Aromatherapy, essential oils, Bergamot, substance use disorder, SUD, treatment,
recovery, comfort, ease, stress

Copyright 2023 Marian Reven

Abstract

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

Marian Reven

Background: Those in treatment for substance use disorder (SUD) face significant challenges and express the need for enhanced support for comfort to be successful. There is growing interest in integrative modalities such as aromatherapy using essential oils to support health.

Purpose: The purpose of this study was two-fold. First, to see if there was an increase in comfort and ease, and a decrease in stress in those who used an aroma inhaler with *Citrus bergamia* (Bergamot) essential oil. Second, to determine the feasibility of the intervention.

Method: This study was founded upon an integrated theoretical framework combining the theory of comfort (Kolcaba, 2003) and the concept of welcoming ease (Reven, 2022a). This study used two aims to answer the research question. Aim 1 was designed to see if using an aroma inhaler (Aethereo®Stick) with bergamot essential oil for three inhalations, three times a day for seven days compared to those who did not use the aroma inhaler could increase scores for comfort and ease and decrease scores for stress in those in the intervention group. Aim 2 was designed to evaluate feasibility and acceptability. An experimental pretest posttest design with random assignment and an intention to treat design was used. The CONSORT guideline and the TREATS checklist were used to promote clear and complete reporting. Three valid and reliable instruments were used including the generalized comfort questionnaire (GCQ), the ease measure, and the depression, anxiety, and stress scale (DASS-21). Recruitment and enrollment took place between August 2022 and January 2023.

Results: The relationships and findings were coherent with concepts of the integrated theoretical framework. A sample size of 57 participants including 25 in the intervention group and 32 in the control group was obtained. There were no statistically significant changes shown in the intervention group. However, post test scores compared to baseline showed mean scores increased for comfort and ease and decreased for stress in the intervention group. In the control group, both ease and stress showed statistically significant worsening ($p < .001$; $p = .047$) respectively. Ease increased after the intervention in both statistical significance ($p = .044$) and in effect size eta squared = .093. Recruitment, enrollment, and retention rates were good with 57 volunteers in five months. Fidelity was shown with one hundred percent of participants completing the study correctly as shown by data from the logbooks. The intervention was cost effective and relatively easy to do.

Conclusions: Those in treatment for SUD face substantial challenges in everyday life and are looking for ways to help manage stress and succeed. This study showed that the use of an aroma inhaler with bergamot essential oil three times daily for one week improved scores for comfort and ease and decreased scores for perception of stress. These findings are encouraging and warrant further investigation.

Dedication

This work is dedicated to all those who bravely navigate the difficult waters of SUD treatment and recovery. Here's to your health and success! Thank you to those who work tirelessly to support success, including the healthcare team, the families, and all the support systems. May this work using essential oils and aromatherapy bring greater comfort and relief to the journey!

Acknowledgements

None of this work would exist without the wisdom and inspiration given through the Lord, Jesus Christ. Thank you, Jesus! Thank you to the love of my life, Mathew Reven, my husband, and friend, who walks with me in faith, family, and innovation. Thank you, Molly Messmer, who followed her heart and reached out to share essential oils in 2014. This simple act of sharing, done in love, forever changed the course of my life and work as a nurse and a scholar. Thank you to Dr. Roger Carpenter mentor, and friend, who recognized the potential and supported this work from beginning to end. Thank you, Dr. Mary Jane Smith, for supporting me as a scholar and colleague and contributing to the conceptual and theoretical basis for this work. Thank you to Mary McKinley who allowed me to explore use of essential oils in healthcare during the early stages. Thank you to Ross Smith who promoted excellence in nursing by his support for research and evidence-based practice. Thank you to Lya Cartwright-Stroup for being both mentor and friend and opening many doors for research at WVU. Thank you to Janelle Humphrey-Rowan and Nina Moore for joining me in foundational work in 2018 – 2020 and to Denise Joswiak for answering the phone when I needed guidance to begin using aromatherapy in healthcare. Thank you to Jill Rivard and Bill McGilvray from Plant Extracts International for their excellence in essential oil-based products. Thank you to West Virginia University for promoting excellence in nursing and evidence-based practice by investing in Magnet® status and having a Nursing Research Council. And finally, thank you to the West Virginia Nurses Association for the Rosenthal-Riter scholarship fund.

Table of Contents

Abstract	iv
Dedication	iii
Acknowledgements	iv
Chapter One	1
Statement of The Problem	1
General Background of the Problem.....	2
Purpose Statement.....	5
Research Question	6
Theoretical Framework	6
Significance.....	7
Policy and Health Initiatives	7
Summary	8
Chapter Two: Review of the Literature	10
Research question	10
Substance Use Disorder	10
Bergamot Essential Oil (BEO).....	15
Intervention Design.....	16
Theoretical and Conceptual Foundations.....	18
Nursing and Aromatics	18
Theoretical/Conceptual Framework.....	20
Concepts.....	22
Comfort	22
Ease	22
Stress	23
Stress and Aromatics.....	23
Summary	24
Chapter Three: Methods	25
Research Design.....	25
Aim 1. Test the Effects of Bergamot Essential Oil.....	25
Hypothesis 1a: Comfort and Ease	25
Hypothesis 1b: Stress.....	25
Aim 2. Determine Feasibility.....	26
2a. Recruitment, Enrollment, and Retention.....	26
2b. Assess Fidelity	26
2c. Calculate Cost	26
Research Method	26
Study Procedures	28
Study Sample and Setting	29
Sample size	30
Randomization	30
Enrollment.....	30

Aromatic Intervention Specific Considerations	31
Standard Care	32
Intervention	32
Pretest and Posttest Study Design	33
Control	32
Intervention Fidelity	34
Rationale for Method of Aromatic Intervention	35
Ethical Principles	36
Institutional Review Board (IRB)	37
Data Collection	37
Conclusion	39
Chapter Four: Results	40
Primary Objectives & Aims	40
Specific Aim #1: Pilot test bergamot essential oil intervention with adults in a substance use disorder recovery program.	40
Specific Aim #2: Evaluate the feasibility and acceptability of an aromatherapy intervention by examining recruitment, enrollment and retention rates, intervention fidelity, and cost analysis.....	41
Study Design & Methodology	41
Sample.....	41
Prescreening for Aromatic and Essential Oil Descriptive Statistics	42
Baseline Descriptive Statistics for Groups	44
Reliability of Scales	45
Specific Aim #1:	46
Hypothesis 1a:.....	46
Hypothesis 1b:	46
Paired Samples t-Test	46
Independent Samples t-Test.....	47
Two-Way Repeated Measures ANOVA.....	48
Comfort Variable Correlation	49
Ease Variable Correlations	49
2a.....	50
Recruitment.....	50
Enrollment.....	51
Retention	51
Report of Adverse Reactions	54
Conclusion	54
Chapter Five: Discussion	56
Findings of Primary Variables	56
Descriptive Findings	57
Everyday Living.....	57
Barriers to Success in SUD Treatment	58
Use of Integrative Modalities.....	58

Aromatherapy and Controlling for Bias	59
Discussion of Feasibility	59
Contribution to the Knowledge Base of Nursing.....	60
Implications.....	60
Future Research	60
Practice.....	62
Policy	63
Limitations	63
Recruitment.....	63
Challenges with SUD Population in Appalachia	64
Limitations Related to Enrollment.....	65
Conclusion	66
References	67
Appendix A: Information Collected from Study Participants	90
Appendix B	92
Diagram 1: CONSORT Flow Diagram.....	92
Appendix C: Tables 1 and 2 Prescreen Questions	93
Prescreen Question Responses (Yes/No).....	93
Appendix D: Table 3.....	97
Descriptive Statistics: Categorical Demographic Variables	97
Appendix E: Table 4	101
Group Equivalents at Baseline for Study Variables	101
Appendix F: Table 5	102
Paired Samples t-Test: Pre/Post Variables of Comfort, Ease, and Stress	102
Appendix G: Table 6.....	103
Independent Samples t-Test, Pre/Post Table: Variables of Comfort, Ease, and Stress	103
Appendix H: Table 7.....	104
Two-Way Analyses of Variance	104
Appendix I: Table 8	105
Multivariate Tests/ Wilks' Lambda	105
Appendix J: Table 9	106
Correlation Analysis of Day 1 and Day 7 VAS from Logbooks	106
Appendix K: Table 10.....	107
Comparison of Ease Measure and Subset Ease from GCQ	107
Appendix L: Table 11	108
Intervention Fidelity: Daily Use of Aroma Inhaler by Those in the Intervention Group as Recorded in the Logbook.....	108
Appendix M: Table 12	109
Daily Use of Aroma Inhaler as Recorded by Intervention Group in the Daily Logbook ...	109

Appendix N.....	110
Comments from Daily Logbook for Intervention Group.....	110
Appendix O: Post Aroma Questions	111
Appendix P: TREATS	113

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

Chapter One

Northcentral Appalachia, specifically West Virginia, is at the epicenter of the opioid abuse crisis with hardly a family left untouched by the devastating consequences of this epidemic that impacts every aspect of life (West Virginia 2020-2022 Council Substance Use Plan, n.d.; Saloner et al., 2019). Embedded within the National Center for Complementary and Integrative Health (NCCIH) 2021-2025 strategic plan is the expansion of the definition of health to include whole person health with an emphasis on why people make healthy choices (NCCIH, 2021).

Those in treatment have identified that relieving distress and increasing comfort during substance use recovery is vital to their success (Yang et al., 2020). Bergamot essential oil has been successfully used among persons with mood alterations (Lizarraga-Valderrama, 2021; Mannucci et al., 2017; Perry & Perry, 2006; Scuteri et al., 2017). However, to date, there is no report of using bergamot essential oil to impact comfort and ease and reduce stress among adults in substance use disorder (SUD) recovery programs. Chapter one introduces the problem of SUD, sense of smell and aromatic intervention potential in SUD, how the problem ties to the conceptual focus, the purpose, and the research question. Finally, significance and contribution to nursing science are discussed.

Statement of The Problem

Recovery from substance abuse is difficult, withdrawal from substances, particularly alcohol, opioids, and heroin impacts physical and psychological health (Patterson, 2022; SAMHSA, 2020a). The clinical problem addressed in this study was dealing with lack of

comfort, ease, and stress in adults experiencing treatment for SUD. Aromatherapy interventions may increase comfort during treatment and recovery from SUD. Therefore, the purpose of the study was to examine the effect of an aromatic intervention using bergamot essential oil on comfort, ease, and stress with adults in a SUD recovery program.

General Background of the Problem

Substance Use Disorder

Definitions of abuse and misuse of substances vary. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), SUD occurs when recurrent use of alcohol and/or drugs causes clinically significant impairment, including health problems, disability, and failure to meet major responsibilities at work, school, or home (SAMHSA, 2020b). The National Institute on Drug Abuse (NIDA) uses the term addiction to describe compulsive drug seeking despite negative consequences (NIDA, 2020). In this study, the term SUD is used in reference to those in treatment for any type of recurrent use of substances.

Substance use disorders range from mild to severe and from temporary to chronic. They typically develop gradually over time with repeated misuse, leading to changes in brain circuits governing incentive salience (the ability of substance-associated cues to trigger substance seeking), reward, stress, and executive functions like decision making and self-control. Multiple factors influence whether and how rapidly a person will develop a SUD. These factors include the substance itself, the genetic vulnerability of the user, and the amount, frequency, and duration of the misuse. A severe SUD is commonly called an addiction (SAMHSA, n.d.).

Benefits of Treatment for SUD

Benefits of treatment far outweigh the cost. Treatment is less expensive than not treating or incarceration with estimates of \$4,700 versus \$18,400 per year when methadone maintenance and imprisonment are compared. Every one dollar invested in treatment yields up to seven dollars in reduced crime related costs. Savings can exceed costs by 12:1 when healthcare costs are a factor. Reduction in interpersonal conflicts and drug related accidents as well as improved workplace productivity are realized as benefits of treatment (NIDA, 2020).

Changing Perspectives

Historically, the U.S. has had a variety of views on the nature and treatment of substance use disorders. The Harrison Narcotics Act of 1914 made it illegal for physicians to treat people with substance use disorders. The only options for care were in inebriate homes and asylums. Abusing a substance was considered a moral failing or pernicious disease characterized as causing great harm or damage often in a way that was not easily seen or noticed (*Pernicious Definition & Meaning - Merriam-Webster*, n.d.). By the 1920s, the tide had turned, and greater compassion was shown in treatment. At the same time, passionate support for the temperance movement gained traction, leading to the 18th Amendment, and prohibition. Development of what is considered the modern SUD treatment system dates to late 1950. It began with a narrow view of SUD and treatment and focused on abstinence. Those who were unwilling or unable to adhere were termed difficult or resistant (Patterson, 2022).

In response to new discoveries, substance abuse treatment has since evolved to consider new technologies, research, and theories. As the SUD treatment field has matured, new approaches continually come to light. Several areas of focus include, 1) identifying and enhancing client strengths, 2) using an individualized, person-centered approach, 3) a shift away

from labeling, 4) use of therapeutic partnerships for change, 5) use of empathy, not power and authority, 6) focus on early and brief interventions, 7) recognition of the continuum of substance misuse, 8) recognition of multiple substance use disorders, 9) acceptance of new treatment goals, 10) focus on risk reduction, and 11) integration of addiction, behavioral health, and healthcare services (SAMHSA, 2020a).

Challenges in Rural Appalachia

Those in SUD treatment programs struggle to handle everyday living. Overwhelming demands include physical exhaustion, feelings of shame and guilt, and perceived stigma from health care providers (Carpenter et al., 2021). Those who make it into recovery programs are often affected by anxiety and depression (Cicero & Ellis, 2017; Johannessen et al., 2019; Yang et al., 2020). The most common concurrent mental health issues are depressive disorder, stress, and anxiety (Hutton et al., 2017; Roos et al., 2020). Living in rural areas brings added barriers. Travel involved in treatment and peer-support activities such as Alcoholics and Narcotic Anonymous and Celebrate Recovery takes time, money, and transportation, all of which can be challenging for those with limited income and resources (Clary et al., 2020). All these factors add to the sense of stress and lack of comfort and ease that make being in treatment a challenge (Volkow & Boyle, 2018; Yang et al., 2020).

Olfaction and Aromatherapy

Based on relevant neuro pharmacological and limited clinical evidence, aromatherapy is a treatment with major but relatively unexplored potential in the field of clinical psychiatry and SUD (Van Der Watt & Janca, 2008). Olfaction is defined as the ability to smell and may be limited by structural, genetic, environmental, and disease related factors (Pinto, 2011). Smell is the most intimate of all the senses because odorant molecules are inhaled, often without choice, and influence thinking and reaction before

conscious thought can begin (Brookes, 2010). It is unknown whether the ability to smell essential oils is necessary in order for the essential oil's influence to be experienced within the mind and body (Bowles, 2020; Herz, 2009).

The use of aromatherapy to improve comfort and ease, and reduce perception of stress is thought to be therapeutically effective due to both the psychological effects of the odor and the physiological effects of inhaled volatile components; where the latter are believed to act via the limbic system, i.e. the hippocampal formation, the hypothalamus, and the pyriform cortex (Bagetta et al., 2010). Bergamot essential oil binds to GABAergic receptors and influences the hypothalamic-pituitary-adrenal axis (HPA) providing a possible explanation for anxiolytic properties (Morrone et al., 2007; Saiyudthong & Marsden, 2011). The effects of essential oils on the nervous system have been examined in a variety of settings including dental office waiting rooms (Lehrner et al., 2000), hemodialysis (Bouya et al., 2018), emergency departments (Cooke et al., 2007), and mental health treatment centers (Han et al., 2017).

Relevance of the Problem

Participating in recovery and treatment programs requires concerted effort and commitment. Many tensions fill the days of those in recovery including, but not limited to employment, demands of family, and demanding and often inflexible expectations of SUD recovery programs (Carpenter et al., 2021). It is apparent that there is a need to reduce stress and increase the sense of comfort and ease in those committed to stay in treatment.

Purpose Statement

The purpose of the study was two-fold. First, to examine the effect of the aromatic intervention using bergamot essential oil on comfort, ease, and stress in adults in a SUD recovery program. Second, to examine feasibility and acceptability of this intervention in this population.

Research Question

The research question was, “What are differences in comfort, ease, and stress for persons in treatment for substance use disorder who receive aromatic intervention and for those who do not?” This study used an experimental pretest posttest design to compare an intervention group with a control group.

Theoretical Framework

An integrated theoretical framework combining the theory of comfort (Kolcaba, 2003) and the concept of welcoming ease (Reven, 2022a) was the theoretical guidance for this study. The concepts of comfort, ease, and stress reduction were described within the integrated theoretical framework. Comfort was defined as the experience of relief (Kolcaba, 2003). Ease was defined as calmness amid distress (Reven, 2022a). Relief of stress was defined as mediating needs and relieving suffering (Kolcaba, 2003). These concepts are foundational to a holistic view in which human beings are described as whole and responsive within complex environments.

Those in treatment have identified that increasing the level of comfort during substance use recovery is vital to their success (Yang et al., 2020). Integrating aromatherapy could help improve the perception of comfort and ease, and reduce stress, and support recovery program progression. The theoretical framework addressed the purpose and guided the research question based on the concepts of comfort, ease, and stress reduction. The concepts were operationalized using appropriate instruments. It was expected that querying the intervention through the integrated theoretical framework would contribute to the knowledge base of nursing.

Significance

M. C. Smith (2019) identifies health, healing, and wellbeing as areas of study that can contribute to the knowledge base of nursing. It was proposed that an aromatic intervention such as an environmental agent to impact comfort, ease, and stress, may facilitate health, healing, and wellbeing for adults engaged in treatment for SUD. Health, healing, and wellbeing were described as the dynamic and transformative experience and manifestation of living and dying (Smith, 2019). Health implies optimal functioning. Healing suggests being whole, sound, and flourishing. Wellbeing, also known as well-becoming affirms the subjective, ever-changing nature of the experience and the potential for health and healing throughout the life process despite chronic disease, illness, or limitations (Smith, 2019). Health in this perspective is tied to the persons connectedness with the environment in which there is continuous change. Therefore, adding aromatherapy to a person's environment may enhance health and wellbeing.

Caring as the focus of the discipline of nursing forms the framework for fostering health, healing, and wellbeing and goes beyond the absence of disease (Newman et al., 1991). This was taken into consideration by exploring comfort, ease, and stress as concepts important to health-promoting environments such as those incorporating aromatherapy. This description of the conceptual foundation of the study makes explicit the contribution to the knowledge base of nursing. Core nursing concepts of health, healing, and wellbeing provided the lens through which the problem of SUD treatment and recovery care were viewed.

Policy and Health Initiatives

While there is limited clinical evidence, complementary and integrative medicine is widely used. Almost eighteen percent of adult Americans use natural products like essential oils (NCCIH, 2020). There is growing interest in “whole person” health with a view toward use of

multiple modalities such as mindfulness (NCCIH, 2021; Zullig et al., 2018). Findings from this research could inform stakeholders and policy makers at multiple levels. Aromatic interventions are readily available, low-cost ways to support adults in treatment for SUD.

In the US, both the Joint Commission (TJC) and the Institute for Healthcare Improvement (IHI) triple aim initiative call for organizations to improve patient care and control cost (IHI, 2018; TJC, 2018). In 1999 the World Health Organization (WHO) began looking into traditional, complementary, integrative medicine (TCIM) practices all over the globe. Since then, 179 member states have reported practices, challenges, and attempts to integrate TCIM with conventional medicine (WHO TC&M Global Report, 2019). Not surprisingly, many enlightened states are fast adopting a more balanced approach that includes TCIM in care for aging and chronically ill populations. They are turning to integrative practices such as aromatherapy to foster wellbeing, improve resilience, and support health. Finally, while national and global initiatives are underway to explore and increase use of modalities such as aromatherapy, there is a paucity of well-developed studies on which to draw conclusions and create policy (*Aromatherapy With Essential Oils (PDQ®)–Patient Version - National Cancer Institute*, 2007).

Summary

Challenges caused by SUD are profound. This is found particularly in Appalachia where hardly a family is left untouched by the damaging consequences of the opioid addiction crisis. Adults engaged in treatment for SUD experience a perplexing combination of cognitive, behavioral, and medication-based interventions. In the proposed study, an aromatic intervention was integrated within the treatment package. Environmental interventions, such as aromatherapy,

that facilitate health, healing, and wellbeing may support persons in treatment. Over the decades, bergamot essential oil has been used successfully among persons with mood alterations including anxiety, depression, and stress. The proposed study was designed to examine comfort, ease, and stress. Potential contributions to expand the knowledge base of nursing practice included examining feasibility of using bergamot essential oil by adults in treatment for SUD. The innovation of this study was the use of bergamot essential oil to reduce stress and improve comfort and ease among the adult population in SUD recovery programs in rural northcentral Appalachia.

Chapter Two: Review of the Literature

The purpose of this study was to examine the effect of an aromatic intervention using bergamot essential oil on comfort, ease, and stress in adults in a SUD recovery program. A literature review was conducted on EBSCO Host using the databases of CINAHL Complete, Academic Search Complete, APA PsycArticles, Health Source/Academic Edition, and Medline as well as PubMed and Google Scholar with date ranges from 2012 through 2020. Additionally, references and resources were mined from U. S. state and federal government publications. The following terms were searched in various combinations including addiction or drug abuse or substance abuse, addiction treatment, SUD and SUD treatment, opioid use disorder (OUD) and OUD treatment, mental health treatment, and aromatherapy or essential oils. The terms nursing or nurses were added as well as comfort, ease, and stress. Careful attention was given to the aromatic intervention including how and why it was used in the method outlined in this study. Findings from this review are synthesized in the chapter.

Research question

The research question was what are differences in comfort, ease, and stress for persons in a SUD program who receive aromatic intervention and for those who do not?

Substance Use Disorder

Substance use disorders pose physical and psychological health consequences for millions around the world. Over 35 million people worldwide suffer from substance use disorders while only 1 in 7 receive treatment (UNODC, 2019). Motivation for change is key for recovery in SUD. Individuals and treatment program professionals desire additional therapeutic approaches to impact successful recovery program progression (Baird, 2014).

Risk for SUD is related to complex interactions between personal, biological, and environmental factors. While major emphasis has been placed on the dopaminergic system explaining the rewarding effect of drugs, it is also clear that neurotransmitters such as opioids, cannabinoids, Gamma-aminobutyric acid (GABA) (an amino acid that serves as a primary inhibitory neurotransmitter in the brain) and serotonin contribute to the pleasurable response to drugs. When an individual no longer has those drugs in their system in sufficient quantities, a feeling of withdrawal and letdown occurs, often accompanied by a loss of pleasure in activities (anhedonia), an increased sensitivity to stress, and anxiety (Volkow & Boyle, 2018).

Effects of stress on the hypothalamus-pituitary-adrenal axis (HPA) has also been examined in animal studies. Given that uncontrollable stress made animals more sensitive to cocaine, Goeders, and colleagues (2003) hypothesized that this may have resulted from the stress-induced activation of the HPA axis. Relapse, also known as reinstatement, also appears related to the HPA axis and interventions designed to reduce activation of this axis may result in more effective and efficient treatments for substance abuse in humans (Goeders, 2003). Bergamot essential oil can bind to GABAergic receptors and influence the HPA axis providing possible explanation for its anxiolytic properties (Morrone et al., 2007; Saiyudthong & Marsden, 2011).

Substance Use Disorder Treatment

Treatment for SUD continues to evolve. Organizations like alcoholics and narcotics anonymous (AA and NA) provide a warm and friendly environment with a spirituality-based approach to recovery (Patterson, 2022). Medication assisted treatment (MAT), used along with counseling and behavioral therapies helps to treat and sustain recovery (SAMHSA, n.d.). Motivation-based interventions based on the Transtheoretical Model (TTM) of the Stages of

Change (SOC) (Prochaska & Velicer, 1997), incorporate motivational interviewing (MI) that focuses on helping clients resolve ambivalence and enhance motivation to change health-risk behaviors, including substance misuse (SAMHSA, 2020a).

Future Non-Pharmacological Therapies

Alternative nonpharmacological strategies to treat SUD include vaccines and other biologics, neural stimulation technologies, such as transcranial magnetic stimulation (TMS), transcranial direct current stimulation (tDCS), deep-brain stimulation, and peripheral stimulation devices; and behavioral interventions (Volkow & Boyle, 2018). On the heels of the country's deadliest year for drug overdoses (2019), the West Virginia University Rockefeller Neuroscience Institute launched a clinical trial to investigate the use of focused ultrasound technology to treat those with opioid use disorder (*WVU Today / WVU Addresses Addiction Crisis with Novel Ultrasound Treatment*, n.d.). Volkow and Boyle (2018) describe research related to efficacy of behavioral interventions for SUD. These represent the only interventions for stimulant, cannabis, and hallucinogen use disorders. Understanding the neurobiological mechanisms is key to guide future refinement of this treatment approach (Volkow & Boyle, 2018).

Treatment Challenges

Adults in treatment for SUD face many challenges. Most battle negative emotional states such as anxiety and depression, which are seen as predictors of relapse (Saloner & Karthikeyan, 2015). Reduction of measurable symptoms such as withdrawal and abstinence from use of substances is not equivalent to personal recovery. Those progressing through treatment admit that they learn to deal with feelings and emotions without using substances and this takes courage and energy because they want to be healthy (Yang et al., 2020). Participating in

treatment requires great commitment and involves tension created by demands of employment, family, and expectations of treatment programs (Carpenter et al., 2021).

Drug counselor's attitudes toward nonpharmacologic treatments of chronic pain tend to favor those interventions with proven higher levels of efficacy. Conversely, they found modalities such as aromatherapy to have the least efficacy and limited reason for consideration (Oberleitner et al., 2016). Some voice caution about the use of aromatherapy for addiction saying there have been many untested and strange treatments in mental healthcare and caution that all interventions, including aromatherapy, should be subjected to tests of evidentiary rigor (Miller & Walker, 1997). Additionally, psychosocial treatments such as those involving mindfulness and aroma may be more costly to evaluate than are pharmacotherapies (Miller & Walker, 1997).

Substance use disorder treatment approaches include MAT, 12-step programs, behavior modification, and counseling. However, the role of the registered nurse working in SUD treatment is one that is not well understood. With caring as the focus of the discipline of nursing, nurses are poised to provide multifaceted caring modalities that go beyond medicine and psychiatry. Nurses bring knowledge of the complexity of disease and appreciation for the psychosocial and spiritual lives of individuals (IntNSA, 2011). From the patient's perspective, caring encounters and supportive caring relationships have been described as essential for recovery (Johansson & Wiklund-Gustin, 2016). Support for use of aromatics in nursing to foster healing environments is found in the literature (Smith & Kyle, 2008).

Aromatics and Essential Oils

Essential oil (EO) is the term used to describe the oil contained within plant material that when pressed or heated, separates from the water and pulp of the plant to become distinct and concentrated oil (Battaglia, 2003; Buckle, 2015a; Farrar & Farrar, 2020; Price & Price, 2012;

Tisserand & Young, 2014). Aromatic plant material is found in the flowers, stems, leaves, needles, bark, resins, wood, roots, and fruits of plants. The oil is used by the living plant for defense (a foul taste so insects and animals will avoid it) or to attract (for pollination and procreation). Large quantities of plant material are required to create very small amounts of EO. Most EOs are distilled using heat that separates the oils from the water by an evaporative and cooling process. Some citrus fruits such as lemons, limes, and bergamot, are pressed to release oils.

Aromatic Applications

Essential oils used in aromatic medicine are distinct from those used in the pharmaceutical, perfumery, and food flavoring industry (Battaglia, 2003; Buckle, 2015a; Farrar & Farrar, 2020; Price & Price, 2012; Tisserand & Young, 2014). Essential oils used in aromatherapy come from natural products that are the result of cultivation, harvest, and extraction occurring in settings where nothing is added or manipulated. In other words, unlike a pharmaceutical such as aspirin, where the precursor to the active ingredient acetylsalicylic acid found in the leaves of the willow tree is isolated and recreated in the lab, EOs are unique batch by batch. This means that when lavender EO is used in an experiment, that lavender may be very different from the lavender used in another study. Researchers wishing to research whole essential oils have the added responsibility to clearly identify the oil used (Buckle, 2015a; Price & Price, 2012; Tisserand Institute, n.d.).

Research Using Essential Oils

Essential oil research done *in vitro* is designed to discover what response occurs with which EO, at what dose and length of action, and other factors. This can involve the whole essential oil or specific chemicals or constituents. Whole essential oil research involving

bergamot has been done to examine effects on anxiety, corticosterone and amino acid neurotransmitter levels, and behavior in rats (Morrone et al., 2007; Rombolà et al., 2017; Rombolà et al., 2009; Saiyudthong & Marsden, 2011). Linalool, an important constituent found in bergamot, has been a focus of research in mice for anxiety, social interaction, and aggression (Harada et al., 2018; Linck et al., 2010).

Research using whole essential oils via inhalation on mood and feelings of wellbeing may be termed nonpharmacologic (Bowles, 2020). Studies in humans of essential oils such as *Lavandula angustifolia* (Lavender) and *Citrus bergamia* (Bergamot [BEO]) show promise for reducing anxiety and promoting overall wellbeing (Buckle, 2015b; Chang & Shen, 2011; Han et al., 2017; Kerkhof-Knapp Hayes, 2015; Price & Price, 2012; Reven et al., 2020). Both Lavender and BEO share similar chemistry of linalool and linalyl acetate. One rationale for the choice to use BEO in this study arose from the desire to use a refreshing scent as opposed to a floral scent.

Essential oils are distinct from drugs. Drugs are defined by the United States Food and Drug Administration (FDA) as substances recognized by an official pharmacopeia or formulary that are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. (FDA Drug Glossary of Terms, 2017). The intent of this study was to examine perceived effects of inhalation of BEO and was not intended to diagnose, treat, cure, or mitigate disease.

Bergamot Essential Oil (BEO)

Bergamot EOs may have over 100 components (Valussi et al., 2021). Unlike other citrus essential oils whose composition is dominated by monoterpenes (usually between 90% and 98%) mainly (+)-limonene, but also terpinene and β -pinene, bergamot has other components that make it unique. Bergamot has a high percentage of oxygenated terpenes, specifically linalool and linalyl acetate. The main components, making up approximately 90% of bergamot EO, are

limonene, linalyl acetate (29%), linalool (9%), β -pinene, and γ -terpinene (Tisserand & Young, 2014; Valussi et al., 2021).

Safety of BEO is important to consider. Bergaptens, the furanocoumarins (FCO) found in bergamot, are responsible for phototoxic effects of topically applied BEO. Bergamot FCO (Bergapten free) is safe to use on the skin, whereas BEO that has only been cold-pressed is phototoxic when applied to the skin at 0.4% and greater (Tisserand & Young, 2014). In this study, the BEO is contained within a prepackaged inhaler tube and impregnated within a wick. The inhaler is factory sealed thus minimizing risk to participants related to phototoxicity.

Nomenclature and type of BEO used in this study were considered. Essential oils are identified by their binomial or botanical names. Bergamot may be identified by the name *Citrus bergamia* Risso & Poit (Tisserand & Young, 2014). Though there is debate about naming of this hybrid fruit, *Citrus bergamia* is a name recognized throughout most of the world. Data and percentages used in this study refer to Calabrian BEOs. The BEO used in this study comes from Plant Extracts International (<https://plantextractsinc.com/>) and specific components are provided in Supplement: Protocol Manual.

Intervention Design

To properly design the aromatic intervention, it was appropriate to go to the literature to discover how aromatic interventions have been applied in previous studies. Key points included rationale for intermittent and short time frame inhalation, use of logbooks, community setting, and inhalation as the method for administration. Aromatic interventions incorporating essential oils are typically applied either by topical or inhalation methods. Almost all palliative care studies involving aromatics involved multiple administrations ranging from massage with

essential oils for one hour weekly for three weeks (Wilkinson, 1995; Wilkinson et al., 1999), weekly for four weeks (Soden et al., 2004; Wilcock et al., 2004), 15 to 20 minutes daily for five days (Lai et al., 2011), and 5 minute sessions three times weekly for four weeks (Ovayolu et al., 2014). Hemodialysis studies featured multiple examples of intermittent, short interval use of inhalation (Bouya et al., 2018). According to the Tisserand Institute, it is not advisable to intensely inhale essential oils for extended periods of time. It is better to use them intermittently <https://tisserandinstitute.org/safety-guidelines/#:~:text=If%20you%20are%20diffusing%20essential,then%2030%2D60%20minutes%20off.>

Use of a logbook to support increased protocol adherence is found in the literature. Most researchers based their choice for a particular measurement frequency on the dynamics of the variable of interests. Researchers argued that increasing the measurement frequency would increase participant burden; while some reported that increasing the measurement frequency decreased participant burden, as they did not forget (Janssens et al., 2018). The median measurement frequency was 5 times a day with an interquartile range between 3 and 10 times a day, and total range between 1 and 50 times a day.

Home or community use of aromatic interventions is supported by the literature. Pleasant odors can induce a positive mood in a person. Essential oils administered in the center-based sessions and aromatic spray used in the self-administered home-based sessions exposed the older persons to pleasant aromas. Their mood was lifted after inhaling the essential oils and aromatic spray, resulting in decreased depression, anxiety, and stress scores. The positive effect of the program was also supported by the increased use of aromatherapy and aromatic spray by the participants in the intervention group after the completion of the program (Tang & Tse, 2014).

Inhalation as the method of administration has been used in multiple studies for sleep (Cannard, 1996; Yildirim et al., 2020), for anxiety and stress relief (Bouya et al., 2018; Cho et al., 2017; Hur et al., 2014; Johnson et al., 2017; Liu et al., 2013; Nesami et al., 2018; Reven et al., 2020; Tang & Tse, 2014), in the peri anesthesia area (Nord & Belew, 2009), pain relief (Tang & Tse, 2014), and hemodialysis (Bouya et al., 2018). When inhaled, the scent molecules in essential oils travel from the olfactory nerves directly to the brain and especially impact the amygdala, the emotional center of the brain (Bowles, 2020; Herz, 2009, 2016).

Theoretical and Conceptual Foundations

Nursing and Aromatics

To properly frame this nursing study of aromatics in those in treatment for SUD, it was appropriate to go to the literature to discover historical perspectives and theoretical foundations for use of aromatic oils in nursing. Comfort and stress relief as they relate to human health and wellbeing are complex. Foundations of aromatics in nursing and their place in comfort and stress relief can be traced back as far as Nightingale. There is also record of orders for tincture of myrrh. Prominent aromatic specialist nurse, Madame Marguerite Maury (1895 – 1968), classified essential oils and established the first aromatic clinics in Paris, England, and Switzerland (Gnatta et al., 2016; Smith & Kyle, 2008).

Theoretical foundations for aromatics in nursing are seen in three major nursing theorists' work including Nightingale, Watson, and Rogers (Smith & Kyle, 2008). Nightingale had a clear purpose to facilitate health and healing by putting the person in the best condition for natural processes to flourish. Elements seen in the seminal work

Notes on Nursing are seen in ventilation and cleanliness, sensory variety, rest, and relaxation (Nightingale, 1969). An example of ventilation can be seen in bergamot via diffusion (misted into the air of a room or area) has been used in the lobby of a mental health clinic in Utah, U.S. Fifteen minutes of BEO exposure improved participants positive feelings (Han et al., 2017). Conversely, smelling BEO during clinic visits, autistic children showed no anxiolytic effects and may have experienced more anxiety (Hawkins, 2018). Use of BEO with an uplifting scent and anxiolytic chemical profile are welcome additions to SUD recovery treatment. Use of aroma inhalers represents a unique delivery system in this population.

Watson describes caring as an ontology (a way of being) and an ethic of relationship and connectedness. Watson specifically identifies aromatherapy as a postmodern transpersonal caring art (Smith & Kyle, 2008). This dynamic is seen in welcoming ease in the stories of those for whom aromatics brought ease in the midst of distress. Aromatics introduced by the nurse after realizing the needs of the patient bring comfort which is located at the heart of nursing (Reven, 2022a). Use of aromatics coupled with touch is considered a sacred art-act and has been studied in palliative care often using Roman chamomile (*Chamaemelum nobile*) and Lavender (Armstrong et al., 2019; Candy et al., 2020; Owayolu et al., 2014; Wilkinson, 1995; Wilkinson et al., 1999).

Rogers' science of unitary human beings also aligns with aromatic practices in nursing. Each essential oil, like the plant from which they were derived, may be viewed as possessing a pattern of unique vibrational frequencies. This resonance carries through in topical and olfactory delivery methods and would appear most applicable in instances when the nurse and patient can cocreate a blend for inhalation or massage (Smith & Kyle, 2008). Use of massage and

aromatherapy in a setting where patients can choose from a variety of oils and combinations is described (Kyle, 2006; Serfaty et al., 2012; Soden et al., 2004; Wilkinson et al., 2007).

Theoretical/Conceptual Framework

An integrated theoretical framework combining the theory of comfort (Kolcaba, 2003) and the concept of welcoming ease (Reven, 2022a) was used as theoretical guidance for this study. The concepts of comfort, ease, and stress reduction were described within the integrated framework. Comfort was defined as the experience of relief (Kolcaba, 2003). Ease was defined as calmness amid distress (Reven, 2022a). Relief was defined as mediating needs and relieving suffering (Kolcaba, 2003).

Many believe that comfort is a highly desired and necessary outcome of all health care encounters no matter the setting (Gnatta et al., 2016; Kasar et al., 2020; Kolcaba, 2003; Kolcaba & Kolcaba, 1991; Nord & Belew, 2009; Tillett & Ames, 2010). Those with advanced cancer experience enhanced wellbeing, respite, and escapism from aromatherapy, massage, and reflexology when delivered in consultation with skilled therapists (Armstrong et al., 2019). Indeed, aroma and touch can have rapid therapeutic effects that can be used to decrease stress levels, enhance parasympathetic responses, and improve patients' comfort (Buckle, 1998, 2015b).

Evidence of the effectiveness of massage and aromatherapy in reducing anxiety, pain, and improving quality of life was inconclusive when compared to reflexology (Candy et al., 2020). Comfort using aromatherapy during trigger point injections for myofascial pain syndrome (MPS) should be considered a low cost, noninvasive, and easily applicable modality that reduces anxiety and stress (Kasar et al., 2020). Both

patient and caregiver found aromatherapy comforting in home hospice settings (Louis & Kowalski, 2002).

Aromatherapy is one more tool that nurses can consider in the peri anesthesia setting for symptom management and enhanced comfort (Nord & Belew, 2009). Enhanced comfort was seen in community dwelling adults with a multimodal approach with aromatherapy and education about pain management (Tang & Tse, 2014). There have been no studies or published anecdotal evidence demonstrating harm from essential oils to mother and fetus (Tillett & Ames, 2010).

In the comfort theory, comfort is defined as “the state of having met basic human needs for ease, relief, and transcendence” (Kolcaba, 2001, p. 88). This definition provides substantive foundation for the theory as grounded within the focus of the discipline of nursing. A coherent model provides further structural merit as the concept is logically and parsimoniously described. Functional adequacy is seen in the simplicity of the theory. Kolcaba notes that concepts from this theory have been applied in multiple practice settings and are profound yet simple enough to be easily grasped even by nursing students (Kolcaba, 2001).

The concept of welcoming ease grew out of work done during a doctoral seminar in theory (Reven, 2022a). It developed out of finding comfort arising in practice during a nurse-patient encounter. The nurse-patient encounter described in this concept reflects caring in the human health experience, which is the focus of the discipline of nursing (Newman et al., 1991). Welcoming ease is a human health experience defined as comfort in the midst of anguish, where comfort is facilitated through a fully present regard. In welcoming ease, both comfort and anguish refer to the patient, the family, and the nurse, while a fully present regard is brought into

the setting by the nurse. This concept is important for nursing science because it is grounded in nurse-patient encounters foundational to caring in practice.

Concepts

Comfort

Three variables, comfort, ease, and stress were queried in this study. Three distinct tools and a visual analogue scale were used to enhance reliability. Comfort as it relates to those with SUD working to succeed in treatment and recovery has been described in the literature. Comfort was associated with catharsis of crying and in the honest expression of emotions that prompts a sense of release and liberation. Comfort is described as a diminishment of pain and a sense of peace (Yang et al., 2020). Experiencing support in both in person and online environments has been associated with a sense of comfort (Bliuc et al., 2017; D’Agostino et al., 2017) In this study, comfort was conceptualized as the experience of relief.

Ease

Ease as it relates to those in treatment for SUD was equated with feelings of comfort, wellbeing, and decreased stress (Patterson, 2022; SAMHSA, 2020a; Volkow & Boyle, 2018). The word “ease” used with the prefix “dis” signifies the wide category known as “disease” the antonyms of which are health and wellness (Merriam-Webster.com dictionary, n.d.). Ease is a state of calm and contentment (Kolcaba, 2003) and as calmness amid distress (Reven, 2022a). According to Story theory, ease is to experience smooth flowing harmonious moments in everyday life (Liehr & Smith, 2018). In this study, ease is conceptualized as calmness amid distress.

Stress

Those in recovery programs are in need of interventions to safely relieve and control stress (Cicero & Ellis, 2017; Lee et al., 2017; Moody et al., 2017; Paula et al., 2017; Reis & Jones, 2017). Stress was seen in SUD recovery in multiple ways and was equated with pain, turmoil, loss, and sadness that comes with facing life in recovery (Yang et al., 2020). Stress as a response was associated with many life situations such as illness and transitions. It is to be anticipated with treatment and recovery in substance use disorder. According to Cicero and Ellis (2017) stress manifests in those seeking recovery as fear of becoming “dope sick” or severely ill from withdrawal from substances. Additionally, stress is perceived as a reason to abuse drugs to escape psychological pain and trauma (Patterson, 2022; Volkow & Boyle, 2018). Finally, depression, boredom, and hopelessness, feelings reported as common in those in recovery, can lead to relapse (Cicero & Ellis, 2017). In this study, relief of stress is conceptualized as mediated needs and relief of suffering.

Stress and Aromatics

Stress reduction in relation to bergamot essential oil was explored. Bergamot essential oil can bind to GABAergic receptors and influence the HPA axis providing possible explanation for its anxiolytic properties (Morrone et al., 2007; Saiyudthong & Marsden, 2011). Over the decades, BEO has been successfully used among persons with mood alterations including anxiety, pain, and stress (Lizarraga-Valderrama, 2021; Mannucci et al., 2017; Perry & Perry, 2006; Scuteri et al., 2017). However, to date, there is no report of using BEO to reduce stress among adults in SUD recovery programs.

Aromatherapy in the management of stress has been explored. In those undergoing hemodialysis, it appears that aromatherapy can be used as an inexpensive, fast acting, and

effective treatment to reduce stress (Bouya et al., 2018). Reducing stress in ICU patients can support sleep and promote better outcomes (Cannard, 1996). Aromatherapy with massage and music significantly reduced anxiety and stress for emergency room nurses in one study (Cooke et al., 2007) though insufficient evidence was found for reduction of job-related stress in nurses using aromatherapy and massage (H. Li et al., 2019). Twenty-four hour diffusion of lavender essential oil in a designated area on a nursing unit lowered reported stress levels in nurses (Johnson et al., 2017). Aromatherapy compared to music in a pediatric emergency waiting area with a non-significant reduction in anxiety and stress on those days when aroma was diffused (Holm & Fitzmaurice, 2008). A forty to fifty percent decrease in stress, anxiety, feelings of fatigue and feeling overwhelmed was found with use of aromatherapy by aroma-patch in oncology nurses (Reven et al., 2020).

Summary

For those working hard to stay in treatment for SUD, the need to reduce stress and increase comfort and ease is apparent. There is a growing body of evidence suggesting a link between stress and drug addiction. Given the devastating impact of ongoing substance abuse, providing patients in treatment with this aroma-based intervention could potentially boost their comfort and ease, improve their chances for responsiveness to treatment, and decrease their chances of failure and relapse. The benefits and impact of this study using aromatherapy via an aroma inhaler were explored related to increased comfort and ease and decreased stress. Knowledge gained through this study is vital to the search for ways to promote health and wellbeing for those in treatment programs.

Chapter Three: Methods

The purpose of this study was two-fold. First to examine the effect of the aromatic intervention using bergamot essential oil on comfort, ease, and stress in adults in a SUD recovery program. Second, to examine feasibility and acceptability of this intervention in this population. The research design, human subject protection, sampling method, variables, instruments, procedures for data collection, and plan for data analysis are discussed in the chapter.

Research Design

The research question directed the methodology (Polit & Beck, 2017). For this study an experimental pretest posttest design was used to compare an intervention group with a control group. The research question was, “What are differences in comfort, ease, and stress for persons in treatment for substance use disorder who receive aromatic intervention and for those who do not?” The following aims stem from the research question:

Aim 1. Test the Effects of Bergamot Essential Oil

To test the effects of a bergamot essential oil intervention on comfort, ease, and stress in adults in a SUD recovery program

Hypothesis 1a: Comfort and Ease

Participants in the intervention group will report higher scores on comfort and ease than those in the control group at post-intervention stage. Assume no difference at pre-intervention stage.

Hypothesis 1b: Stress

Participants in the intervention group will report lower scores in stress than those in the control group at post-intervention stage. Assume no difference at pre-intervention stage.

Aim 2. Determine Feasibility

Evaluate the feasibility and acceptability of a bergamot essential oil intervention for persons in a SUD recovery program.

2a. Recruitment, Enrollment, and Retention

Determine feasibility and acceptability by assessing participant recruitment, enrollment, and retention rates to determine optimal recruitment strategies. Reasons for non-participation will be recorded and used to develop strategies for future studies.

2b. Assess Fidelity

Assess intervention fidelity (consistent implementation) of the aromatherapy intervention using daily checklists in logbooks.

2c. Calculate Cost

Calculate a traditional cost analysis for the aromatic intervention implementation.

Research Method

This study utilized an experimental pretest-posttest design to compare an intervention group with a control group. Participants were randomly assigned to groups.

Conceptual Framework

An integrated theoretical framework combining the theory of comfort (Kolcaba, 2003) and the concept of welcoming ease (Reven, 2022a) is used as theoretical guidance for this study. The concepts of comfort, ease, and stress reduction are described within the integrated framework. Comfort is defined as the experience of relief (Reven, 2022a). Ease is defined as calmness amid distress (Reven, 2022a). Relief of stress is defined as mediating needs and relieving suffering (Kolcaba, 2003). These concepts are foundational to a holistic view in which human beings are described as whole and

responsive within complex environments. M. C. Smith (2019) identifies health, healing, and wellbeing as essential to the knowledge base of nursing. In this study, it is assumed that adults engaged in treatment for SUD seek health, wellbeing, and quality of living.

A description of the theoretical foundation of the study made explicit the theoretical, conceptual, and empirical levels of abstraction. The concepts were described at three differing levels of abstraction. The first level described the theoretical definition of the concept extracted from the theory. The second level described the conceptual definition at the variable level derived from the way the author of the instrument described conceptually what was measured in the instrument. The third level described the operational definition at the empirical level.

Comfort

Comfort was described theoretically as the experience of relief and conceptually described at the variable level with the Generalized Comfort Questionnaire (GCQ) as relief, ease, and transcendence. Comfort was operationalized using the GCQ original version containing 24 positively worded and 24 negatively worded questions. The alpha coefficient of the GCQ is .88 (Kolcaba, 2003). For this study, after pilot testing, a reduced number (modified version) of questions was used. According to Kolcaba (2003), many nurse researchers begin with the full 48 questions and reduce and modify the GCQ to fit the study population and purpose. To date the GCQ has been used in a variety of settings. A common theme is that these settings are complex, very much like treatment for SUD, and comfort means more than simply an absence of pain (Kolcaba, 2003, p. 47). A visual analogue scale (VAS) was used daily to measure comfort.

Ease

Ease was described theoretically as calmness amid distress and conceptually described at the variable level with the Ease measure as the experience of smooth flowing harmonious

moments in everyday living. Ease was operationalized using the Ease measure with 20 questions, 15 assessing ease and 5 assessing unease. The alpha coefficient of the Ease measure is .86 (Adenmosun et al., 2021).

Stress

Stress was described theoretically as mediating needs and relief of suffering and was conceptually described at the variable level with the Depression, Anxiety, and Stress Scale (DASS). The scale is sensitive to levels of chronic non-specific arousal and assesses difficulty relaxing, nervous arousal, and being easily upset / agitated, irritable / over-reactive and impatient. The short form version of the DASS, with 21 items was used to measure stress. The alpha coefficient of the DASS is .88 (subscales range from .82 to .93) (Henry & Crawford, 2005). Depression and anxiety remain in the instrument to identify these commonly co-occurring confounding variables. Both the 48 question and 21 question versions have similar psychometric properties (Henry & Crawford, 2005).

Study Procedures

The GCQ, Ease measure, and DASS were administered pre and post intervention. A visual analogue scale (VAS) was used as a daily measure of comfort. It provided validation for the GCQ (Kolcaba, 2003). Total time to complete all surveys was approximately 5 to 10 minutes with an average of 6 minutes (Results from pilot testing, with reduced GCQ questions $n = 28$, Ease $n = 20$, and DASS $n = 21$) (Supplement: Protocol Manual/ surveys).

Fidelity was assessed with a logbook that was used by participants to record frequency of use in the intervention group and to record overall comfort (VAS) in the intervention and the control group (Supplement: Protocol Manual/ logbook).

All instruments and measures have established discriminant or construct validity, internal consistency reliability, and specificity. Each has been used with diverse populations including chronic illness patients (Pasick et al., 2001). These have published means scores/SDs identifying clinically significant differences (Ferrans et al., 2005) and are sensitive to change over time (Pasick et al., 2001; Wyrwich et al., 2003). See Appendix A for a list of information collected from participants.

Prior to trial entry participants were asked about their sense of smell. Each participant who met prescreening criteria was eligible and scheduled for consent. With the pivot to online recruitment and mailing of all study materials, olfactory testing was not possible though it was queried in each participant during prescreening.

Study Sample and Setting

Adults (>18 years) who were currently receiving treatment for SUD in the outpatient treatment program at West Virginia University Chestnut Ridge Center (WVUCRC) (n = 340 approx.) comprised the study population. Inclusion criteria were patients diagnosed with SUD and participating in treatment at all stages (one, two, three, and peer recovery), and who desire to pursue continuous recovery phases (per facility protocol) (Amendment to IRB protocol 09262022 opened enrollment to all levels of outpatient treatment). All participants were alert and oriented, provided written consent, and were able to read and write English. Exclusion criteria included those who had a medical history of asthma or other serious respiratory disease, pregnant or nursing, a strong dislike citrus, or a known allergy to citrus. Permission to review patients' medical records was obtained by voluntary informed consent of participants and with approval of the WVU Institutional Review Board (IRB).

Sample size

Sample size was calculated using G*Power v.3.1.9.7 on repeated measure ANOVA given $\alpha=0.05$, 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 was required. A total sample size of $n=49$ for intervention group and $n=49$ for control group was sought.

Randomization

Random assignment was done using computer-generated random numbers (random number table [RNT]) for group assignment. The group assignment was chosen using the RNT. Enrollers were blinded to group assignment until informed consents were signed. This randomized controlled trial (RCT) design was consistent with the CONSORT standards, and rigorous research procedures (Boutron et al., 2017). The RCT addresses threats to both internal and external validity and is robust for detecting differences between small groups (McCambridge et al., 2014).

Enrollment

Successful strategies for recruiting research participants in rural Appalachia were used (Carpenter & Theeke, 2018). Upon IRB approval, the Principal Investigator (PI) provided the enrollment fliers and explained the study to the staff at the Chestnut Ridge facility. The staff identified potential participants prospectively per our study eligibility criteria. Thus, personnel who already had clinic responsibilities and access to patient records, consistent with HIPAA requirements, supported recruitment contact. The PI or trained designee consented participants, collected baseline data, ensured random assignment for participants, and monitored all study protocols and procedures.

Aromatic Intervention Specific Considerations

This study was consistent with best practice standards outlined by the Aromatic Research Quality Appraisal Taskforce (ARQAT) and used the Transparent Reporting of Essential oil and Aroma Therapeutic Studies (TREATS) checklist (Reven, 2022b; Reven et al., 2022). A description of the aromatherapy intervention was provided that was clear enough to allow for replication. This included the rationale for use of bergamot, theoretical and conceptual framework, use of a professional aromatherapist, report of any allergic or adverse reactions, and safety consideration of essential oils during the trial. All information regarding bergamot essential oil (a natural botanical product) was included. The dose, frequency, and duration of exposure to the essential oil was discussed as well as control, carriers, and delivery system. Olfactory function questions such as presence of anosmia and previous use of essential oils were included. Finally, olfactory testing, odor recognition testing, odor bias, perceived intensity, and any adverse effects from olfactory testing were either performed or discussed in relation to the study (Bowles, 2020; Herz, 2009).

Each participant completed a brief prescreening survey administered by the person enrolling the participant. This survey was designed to query previous use of integrative modalities, use of essential oils, allergies, and participant report of their sense of smell (Supplement: Protocol Manual/ Prescreening survey).

Pre- and Post-surveys for GCQ, and Ease, and DASS were completed by participants along with a very brief post survey at the conclusion of the study asking about the aromatic intervention. The VAS was completed daily by all participants (Supplement: Protocol Manual/ surveys).

Standard Care

Standard care was the usual care received from the provider, including any routine follow up and contacts from the provider.

Control Group

The Enroller was blinded to group assignment until after enrollment was complete. Therefore, each person agreeing to participate in the study participated in a session that included prescreening for exclusion criteria and potential contraindications and instructions and demonstration for the aroma inhaler and the logbook in the same fashion as those randomized to the intervention group. Daily logbooks were used to record frequency of use in the intervention and the control group and to record overall comfort (VAS) in the intervention and the control group. Daily text message reminders for the first three days of study participation were provided to everyone who agreed to receive them. At the end of seven days, the PI or trained designee sent a text message to participants who agreed to receive text messages to remind them to complete their post survey and logbook. Participants sent back post surveys and logbook via the prepaid postage envelopes in their packets.

Intervention

The intervention group received the standard care plus the aromatic intervention. Each person agreeing to participate in the study participated in a session that included prescreening for exclusion criteria and potential contraindications, completion of consent and pre-survey, and demonstration of how to use an aroma stick properly. Daily logbooks were used to record frequency of use in the intervention group and to record overall comfort (VAS) in the intervention and the control group. Daily text message reminders

for the first three days of study participation were provided to everyone who agreed to receive them. At the end of seven days, the PI or trained designee sent a text message to participants who agreed to receive text messages to remind them to complete their post survey and logbook. Participants sent back post surveys and logbook via the prepaid postage envelopes in their packets.

Pretest and Posttest Study Design

For this intervention an experimental pretest posttest design was used. This design was chosen to increase internal validity. Seven days between tests was ample for several reasons. Within the population of adults in treatment for SUD, the risk that participants would learn something new from the presurveys that would influence post survey responses was considered minimal. There were two reasons for this. One, the population was already in a treatment program where questions such as those asked in the surveys were common. Two, lives of those in treatment for SUD are complex and the presurvey questions would fade into the background as participants face ongoing challenges of daily living.

It must be admitted that the increase in internal validity conversely affects external validity and the ability to generalize findings. However, in this pilot, internal validity was preferred to inform future design and testing where design could then be changed to enhance generalizability. Analysis of covariance with pretest scores as the covariate are usually preferable to simple gain-score comparisons (Campbell & Stanley, 1967).

Those in the control group received an aroma inhaler at the end of the study after completing and returning the post survey and logbook. Everyone who participated in the study, completed the post survey, and returned the logbook received a \$20 gift card.

Intervention Fidelity

Intervention design, training of providers, and intervention delivery were key elements to ensure the quality of the intervention (Murphy & Gutman, 2017). The PI, who was a Registered Aromatherapist, did all training for staff and designees. The PI and trained designees carried out recruitment for the study, obtained consent, and provided instruction on how to use the aroma inhalers (known as Aethereo®Sticks by Plant Extracts International Inc.). The PI checked with designees monthly and as needed to see that all processes were being done per the protocol. There was a copy of the study protocol available in a binder at Chestnut Ridge as well as electronically via email. To track all follow-up, contact and progress, an Excel Master Log Sheet (MLS) spreadsheet was utilized. Therapists and staff received information about the study and materials at the beginning of the study and as needed.

For participants, the PI or designee provided a brief instructional session about how to use the aroma inhaler and logbook correctly. This occurred after consent was signed and presurveys (GCQ, Ease, and DASS) were completed. The intervention and control groups then received the packet that was randomly assigned. These packets included materials as outlined in the Protocol Manual (Supplement). Intervention folders included an aroma inhaler, a cover letter, a copy of the consent form, pre surveys, a logbook, a reminder paper, and a 6x9 postage paid envelope (contains post surveys—GCQ, Ease, DASS, and post survey for aroma). Control group folders were identical except for the logbook did not have the daily checklist.

Those randomized to the control group were able to see and receive instruction about the aroma inhaler. After this, the aroma inhaler was collected, labeled, and stored in

a secure location. The control group participant received their aroma inhaler at the completion of the study when they returned their study materials at the end of seven days. In addition to the aroma inhaler, all participants kept their study folders with the cover letter, copy of consent, aroma inhaler information sheet, and reminder paper.

To support study fidelity, a text communication reminder was offered to all participants. Texts were sent during the first three days of the study and at the end of the study. Participants were able to decline to share their cell phone numbers and not receive these reminders. The PI sent standard reminders to participants via text message. Incentive for participation consisted of a \$20 gift card that was provided at study completion after post surveys and logbook were collected. All participants retained their aroma inhaler. The control group received this incentive in the same fashion with the addition of their aroma inhaler.

Rationale for Method of Aromatic Intervention

In this intervention, participants were asked to use aroma inhalers three times daily for seven days in the settings where they live. They were asked to maintain a daily logbook noting use of the inhalers, any feelings or happenings occurring during the time of use and rating their comfort using a VAS for each day.

To determine a way to administer this aromatic intervention, a careful search of the literature was conducted. Short, intermittent inhalation of certain essential oils has been shown to be effective in reducing stress and anxiety and increasing perception of comfort and wellbeing (Armstrong et al., 2019, 2019; Blissett et al., 2018; Candy et al., 2020; Nesami et al., 2018; Reven et al., 2020). Participants use aroma inhalers as directed inhaling the pure essential oil for approximately three minutes per day for seven days for a total of 21 minutes. In almost all studies involving essential oils and palliative care, multiple administrations were utilized with

total timings between 15 to 30 minutes on average (Mannucci et al., 2017; Navarra et al., 2015; Perna et al., 2019).

Many studies of aromatics included multiple administrations of essential oils either via inhalation or inhalation plus massage including weekly full body massage using essential oils for three weeks (Wilkinson, 1995; Wilkinson et al., 1999), weekly for four weeks (Soden et al., 2004; Wilcock et al., 2004), daily 20-minute application for five days (Lai et al., 2011), and three times weekly for five weeks (Ovayolu et al., 2014). In the case of this study, a seven-day intervention was chosen after a small pilot where it was determined that interest in the intervention was high for about seven days. Use of reminder texts on days 1 through 3 was also determined as helpful during this pilot.

Other aspects of the intervention included keeping daily logbooks. Keeping daily logbooks helps to avoid recall bias and can also increase protocol adherence (Janssens et al., 2018). Home use of aroma inhalers was chosen because in one study positive effects of a center-based program were supported by use of the aromatic intervention outside of the center (Tang & Tse, 2014). Use of aroma inhalers was something participants would do in the privacy and comfort of their own living environments.

Ethical Principles

Three key ethical principles served to guide this human subject research including respect for persons, beneficence, and justice. The principle of respect for persons related to voluntary and informed consent, privacy and confidentiality, and the right to withdraw from participation without penalty. The principle of beneficence was satisfied in the context of research by refraining from intentionally causing injury and by assuring that risks were reasonable in relation to probable benefits. The principle of justice required fairness in the distribution of both the

burdens and the benefits of research (Beauchamp, 2008; Emanuel et al., 2008). This was seen in having all participants use a daily logbook and distributing the aroma inhaler to all participants either during the intervention or at the end of the participant's participation.

Institutional Review Board (IRB)

Participation in the study was completely voluntary. Prior to conducting the study, approval was obtained from the WVU Institutional Review Board (IRB), and informed consent and HIPAA authorization was obtained from participants. Participants had ample time to read consent forms entirely and ask questions about the study. The consent addressed the purpose of the study, confidentiality of information, potential benefits and risks, and the ability to withdraw from the study at any time without repercussions. Additionally, the researcher was available, either in person or by email to participants to answer any questions that arose or assist with any problems.

The involvement of human subjects included completion of a brief informational session, completion of survey questionnaires at regular intervals, and performance of the study intervention as agreed. If a participant experienced or expressed any psychological distress or disclosed information that indicated a need for urgent psychological or clinical care, the researcher connected the participant with on or off-site experts and appropriate social services to meet identified needs. The identity of study participants was kept confidential. As much as was possible, study activities were conducted to promote participant privacy. All data were stored on a password-encrypted device and kept in a secure location.

Data Collection

Data were collected at baseline and as possible, within three days of completion of the study. Also, a daily logbook with checklist was used to assess fidelity and feasibility of the

intervention and a daily assessment of comfort. A data management plan, secure data collection, and secure storage was maintained per IRB and university guidelines. Missing data was identified, and efforts were made to recollect promptly. Paper surveys were used to collect data. All data was de-identified. The biostatistician consultant provided quality assurance and data integrity techniques including data management protocols and an audit trail of the data management decisions.

Data Analysis

For Aim 1, descriptive (frequencies, means, ranges, standard deviations) and bivariate analysis was conducted on the demographics, GCQ, Ease measure, VAS, and DASS scales. Statistical assumptions (i.e., normal distribution and homogeneity of variances etc.) was tested. Sample demographics of patients were reported. Fisher's exact test was used for categorical variables; repeated measures ANOVA for VAS data and paired and independent samples *t*-tests were used for pre-post survey data. Pearson's and Spearman's correlation analyses was used to explore relationships among variables (Pallant, 2020). The statistical significance was set at a 5% ($\alpha = 5\%$). All analyses were completed using Statistical Package for the Social Sciences (IBM SPSS) version 28.

For Aim 2, descriptive statistics were used to analyze the data. Participant recruitment, enrollment, and retention rates were tabulated and reported. Reasons for non-participation and attrition were recorded and will be used to develop strategies to address these occurrences. Aim 2b, adherence to the intervention protocol, was calculated from responses in the logbooks (Piamjariyakul et al., 2019). For Aim 2c, to determine the cost of the intervention implementation, all charges related to implementation were

calculated. This included costs of personnel time for administering each session, the materials, and incentives.

Timeline

The study began when IRB approval was obtained (Supplement: Protocol Manual/timeline).

Conclusion

The novelty of this proposed study was the use of a small-randomized clinical trial with rigorous scientific procedures to test an aromatherapy intervention using bergamot essential oil to impact perception of comfort and reduce perceived stress for adults in recovery treatment for substance use disorder. The study addressed gaps in the literature about adding aromatics to complementary holistic nursing interventions in healthcare. This therapy is considered easy and less costly to implement in outpatient, patient's home settings. In addition, feasibility and acceptability data was gathered as this is essential for future research planning that aligns with the NCCIH and the latest strategic plan (NCCIH, 2021).

Chapter Four: Results

The purpose of the study was two-fold. First, to examine the effect of the aromatic intervention using bergamot essential oil on comfort, ease, and stress in adults in a SUD recovery program. Second, to examine feasibility and acceptability of this intervention in this population.

Research Question

The research question was, “What are differences in comfort, ease, and stress for persons in treatment for substance use disorder who receive aromatic intervention and for those who do not?” This study used an experimental pretest posttest design to compare an intervention group with a control group.

Primary Objectives & Aims

The innovation of this study was 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 at post-intervention stage.

Hypothesis 1b: Participants in the intervention group will report lower scores in stress than those in the control group at post-intervention stage.

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

2a. Determine feasibility and acceptability by assessing participant recruitment, enrollment, and retention rates to determine optimal recruitment strategies. Reasons for non-participation will be recorded and will be used to develop strategies to address this.

2b. Assess intervention fidelity (consistent implementation) of the aromatherapy intervention using daily checklists in logbooks.

2c. Calculate a traditional cost analysis for the aromatic intervention implementation.

Study Design & Methodology

The study used a basic randomized experimental intention to treat design comparing treatment group with the control group (Shadish et al., 2001). Data were collected from participants prior to study, daily, and post intervention. For Aim #1, descriptive and bivariate analysis were conducted. Statistical assumptions were tested. Sample demographics and prescreening data were reported.

Sample

This study drew from a sample comprised of volunteers of adults (>18 years) who were currently receiving treatment for SUD in the outpatient treatment program at West Virginia University Chestnut Ridge Center (WVUCRC) (n = 340 approx.). Sample size was calculated using G*Power v.3.1.9.7 on repeated measure ANOVA given $\alpha=0.05$, 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 was required. A total sample size of n=49 for intervention group and n=49 for control group was sought. Inclusion criteria were patients diagnosed with SUD who were enrolled in treatment, and who desired to pursue continuous recovery phases (per

facility protocol). All participants were alert and oriented, provided written consent, and were able to read and write English. Exclusion criteria included patients who had a medical history of asthma or other serious respiratory disease, were pregnant or nursing, had a strong dislike citrus, or a known allergy to citrus.

Random assignment was done using a computer generated random number table (RNT). The group assignment was chosen using the RNT. Enrollers were blinded to group assignment until informed consents were signed. This randomized controlled trial (RCT) design is consistent with the CONSORT standards, and rigorous research procedures (Boutron et al., 2017). The RCT addresses threats to both internal and external validity and is robust for detecting differences between small groups (McCambridge et al., 2014) (Appendix A).

Prescreening for Aromatic and Essential Oil Descriptive Statistics

Each participant completed a brief prescreening survey administered by the person enrolling the participant. This survey was designed to query previous use of integrative modalities, use of essential oils, allergies, and participant report of their sense of smell (Supplement: Protocol Manual/ prescreening survey). This study was consistent with best practice standards outlined by the ARQAT and the TREATS checklist was used (Reven, 2022b) (Appendix P). Participants were asked about familiarity with the intervention (had they previously used the essential oils), and hedonics (like or dislike of the essential oil or odor of bergamot) (Appendix C).

Because the study was conducted remotely, it was not possible to complete olfactory testing prior to participants receiving their aroma inhaler. Odor recognition was queried by asking each participant if they had ever smelled bergamot as a fruit or essential oil before, a few 7 (12.1%) had, most participants, 51 (87.9%) had not.

Bias was assessed by asking those who had smelled bergamot if they liked or disliked the smell. The majority said they did not dislike the smell. Two participants admitted they were not sure if they liked or disliked the smell and expressed that they wanted to be in the study. Without being able to do in person olfactory testing, these two participants were allowed to stay in the study. Participants were free to withdraw from the study at any time without repercussions.

Prescreening included questions about physical conditions and preferences of odors and allergies. If the participant answered yes to either question about strong dislike for or an allergy to citrus, they were excused from the study. Those who were pregnant, nursing, or had severe respiratory illness such as asthma, chronic bronchitis, or a chronic obstructive pulmonary disease (COPD) were excused.

Participant's expectations about a treatment's efficacy can influence their response (Eklund et al., 2019). To determine if there was a positive bias toward the use of integrative interventions such as aromatherapy, potential participants were asked a series of questions about use of integrative or complementary therapies such as massage, yoga, acupuncture, aromatherapy with essential oils, herbs, medications, mindfulness practices etc. They were given the opportunity to share why they used each therapy and queried on a scale of 0 to 10 with 0 being the least effective and 10 being most effective how effective the integrative therapy was for the symptom they used it for.

Next, to determine familiarity specifically with essential oils including expectations and preferences, participants were asked about previous use of essential oils and which essential oils they considered their most or least favorite. A strong preference for an essential oil or a specific expectation of how it will affect a person can affect a person's response (Bowles, 2020). For example, if a participant stated that bergamot essential oil is their favorite and that it has the

expected effect of relaxation, then using bergamot during this study would likely be influenced by their expectations. Eighteen (31%) admitted to previous use of essential oils for a variety of reasons. Only one of these said that citrus was their favorite while none said that bergamot specifically was (Appendix C).

Baseline Descriptive Statistics for Groups

Data analysis included descriptive data for frequencies, means, and standard deviations. Statistical assumptions related to normal distribution and homogeneity of variances were analyzed. An independent samples t-test was used for baseline data. There were no significant differences between the groups at baseline (Appendix E).

Demographic Variables

To describe the sample of adults in treatment for substance use disorder in north central Appalachia, descriptive statistics were run on the demographic variables. In this study the total sample size was 58 participants. Of the 58 participants, 18 (31%) were male and 40 (69%) were female. The majority were white (96.6%). Their ages ranged from 19 years to greater than 60 years with the majority between thirty-one to forty years of age (53.4%). Marital status was most often reported as single at 36 (62.1%) followed by married at 11 (19%) and divorced at 7 (12.1%). When data on children in the home were reported a small majority had 1 to 2 children (12.1%), no children at 6 (10.3%), and 3 to 4 children at 3 (5.2%). Children in the home had limited availability in the medical record with 42 (72.4%) unavailable. When level of education data were available from the medical record (87.9% unavailable), the most frequent was high school/GED (10.3%). Most participants reported their home was in Monongalia county 25 (43.1%), followed by Marion county 12 (20.7%). Data on employment were limited with 25 (43.1%) with no data available, otherwise the vast majority of those who reporting employment

were employed for wages at 28 (48.3%). Stage of treatment included being a peer recovery coach 2 (3.4%), stage 1 at 9 (15.5%), stage 2 at 27 (46.6%), and stage 3 at 20 (34.5%). The most frequent primary diagnosis was opioid use disorder (OUD) at 35 (60.3%) followed by multi substance use disorder at 21 (36.2%). The most common secondary diagnosis was having both anxiety and depression at 10 (17.2). There were no data available for 17 (29.3%). Data on income were not available as it was collected from the medical record of each participant and will not be discussed further (Appendix D).

Reliability of Scales

Three instruments used in this study have established discriminant or construct validity, internal consistency reliability, and specificity. The GCQ scale has good internal consistency, with a Cronbach alpha coefficient reported at .88 for the 48-question scale (Kolcaba, 2003). In the current study, after pilot testing, a reduced number of questions was used. This reduced scale of 28-questions had good internal consistency with a Cronbach alpha coefficient of .911.

According to Adenmosun and colleagues (2021) the Ease measure has good internal consistency with an alpha coefficient reported of .86. In the current study, the Cronbach alpha coefficient was .902. And for the DASS-21, The alpha coefficient of the DASS is .88 (subscales range from .82 to .93) (Henry & Crawford, 2005). In the current study the alpha coefficient was .922. The three-question post scale used to measure participant's scoring for the aromatic aspect of the intervention, created by the researcher and not subjected to pilot testing, had a Cronbach alpha coefficient of .563.

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 at post-intervention stage. Assume no difference at pre-intervention stage.

Hypothesis 1b: Participants in the intervention group will report lower scores in stress than those in the control group at post-intervention stage. Assume no difference at pre-intervention stage.

Paired Samples t-Test

To evaluate the impact of the intervention on participant's scores, a paired-samples t-test was conducted to compare the means before and after intervention for each outcome (Appendix F). For the GCQ, there was no statistically significant change in scores in either group. For the intervention group pre-test ($N = 17$, $M = 121.29$, $SD = 14.546$), $t(16) = -1.927$, $p = .072$ (two-sided) to post-test ($N = 17$, $M = 127.12$, $SD = 18.617$). The mean difference in GCQ scores was -5.824 with a 95% CI: -12.230 to $.583$. Mean increase from 121.29 to 127.12. In the control group pre-test ($N = 26$, $M = 117.88$, $SD = 23.538$), $t(25) = .226$, $p = .823$ (two-sided) to post-test ($N = 26$, $M = 116.96$, $SD = 23.172$). The mean difference in GCQ scores was $.923$ with a 95% CI: -7.427 to 9.318 .

For the Ease measure, there was no statistically significant change in the intervention group. However, in the control group there was a statistically significant drop in post scores. In the intervention group pre-test ($N = 17$, $M = 54.39$, $SD = 9.745$), $t(16) = -1.698$, $p = .108$ (two-sided) to post-test ($N = 17$, $M = 57.67$, $SD = 9.081$). The mean difference in Ease scores was -3.278 with a 95% CI: -7.349 to $.794$. In the control group pre-test ($N = 27$, $M = 55.11$, $SD =$

9.154), $t(26) = 11.176$, $p < .001$ (two-sided) to post-test ($N = 27$, $M = 39.67$, $SD = 8.983$). The mean difference in Ease scores was 15.444 with a 95% CI: 12.604 to 18.285.

For the DASS-21, in the intervention group there was no statistically significant change from pre-test ($N = 17$, $M = 17.41$, $SD = 11.479$), $t(16) = 1.364$, $p = .192$ (two-sided) to post-test ($N = 17$, $M = 14.12$, $SD = 11.112$). The mean difference in DASS-21 scores was 3.294 with a 95% CI: -1.827 to 8.416. In the control group there was no statistically significant change from pre-test ($N = 27$, $M = 20.44$, $SD = 11.683$), $t(26) = -.892$, $p = .380$ (two-sided) to post-test ($N = 27$, $M = 21.81$, $SD = 12.746$). The mean difference in DASS-21 scores was -1.370 with a 95% CI: -4.528 to 1.787 (Appendix F).

Independent Samples t-Test

An independent-samples t-test was conducted to compare the means between intervention and control groups for each outcome pre and posttest (Appendix G). For comfort using the GCQ, it did show greater increase in the intervention group mean score post intervention compared to the control group. The pretest intervention group ($M = 118.64$, $SD = 14.416$) and control group ($M = 117.00$, $SD = 22.417$; $t(53.238) = -.335$, $p = .370$, two-tailed) (equal variances not assumed) differences in baseline mean scores were very small. The magnitude of the differences in the means (mean difference = -1.640, 95% CI: -11.468 to 8.18) was moderate (eta squared = -.085). Posttest intervention group ($M = 127.12$, $SD = 18.617$) and control group ($M = 116.96$, $SD = 23.172$; $t(41) = -1.514$, $p = .069$). The magnitude of the differences in the means (mean differences = -10.156, 95% CI: -23.705 to 3.39) was very large (eta squared = -.472).

For ease using the Ease measure it did show greater increase in the intervention group mean score post intervention compared to the control group. The pretest intervention group ($M = 53.56$, $SD = 9.557$) and control group ($M = 54.56$, $SD = 9.041$; $t(55) = .405$, $p = .687$, two-tailed)

differences in baseline mean scores were very small. The magnitude of the differences in the means (mean difference = 1.002, 95% *CI*: -3.956 to 5.961) was moderate (eta squared = .108). Posttest intervention group ($M = 57.56$, $SD = 9.081$) and control group ($M = 55.56$, $SD = 9.130$; $t(42) = -.721$, $p = .475$, two-tailed). The magnitude of the differences in posttest mean (Mean differences = -2.013, 95% *CI*: -7.650 to 3.625) was very large (eta squared = .221).

For stress using the DASS-21. There was a statistically significant increase in stress in the control group. The pretest intervention group ($M = 18.76$, $SD = 10.948$) and control group ($M = 19.97$, $SD = 11.128$; $t(55) = .410$, $p = .684$, two-tailed). The magnitude of the differences in the means (mean difference = 1.209, 95% *CI*: -4.702 to 7.120) was moderate (eta squared = .109). Posttest intervention group ($M = 14.12$, $SD = 11.112$) and control group ($M = 21.81$, $SD = 12.746$; $t(42) = 2.046$, $p = .024$, two-tailed). The magnitude of the differences of posttest mean (Mean differences = 7.697, *CI*: .106 to 15.289) was very large (eta squared = .634).

Two-Way Repeated Measures ANOVA

An intention to treat design was used and all data analyzed. Overall, mean scores before and after in the intervention group moved in a positive direction showing some improvement in scores for comfort and ease. Scores for stress moved in a negative direction, indicating less stress (Appendix H).

For the GCQ scores there was no significant interaction between intervention and control group and time, Wilks' Lambda = .966, $F(1, 41) = 1.444$, $p = .236$, partial eta squared = .034 (Appendix I). There was no substantial main effect for time, Wilks' Lambda = .982, $F(1, 41) = .762$, $p = .388$, partial eta squared = .018. The main effect comparing the two types of intervention was not significant, $F = 1.312$, $p = .259$, partial eta squared = .031, suggesting a very small difference in the effectiveness of the intervention compared to the control group.

For the Ease measure scores there was no significant interaction between intervention and control group and time, Wilks' Lambda = .981, $F = .796$, $p = .377$, partial eta squared = .019.

There was a substantial main effect for time, Wilks' Lambda = .907, $F = 4.310$, $p = .044$, partial eta squared = .093. The main effect comparing the two types of intervention was not significant, $F = .152$, $p = .699$, partial eta squared = .004, suggesting no difference in the effectiveness of the intervention compared to the control group.

For the DASS-21 scores there was no significant interaction between intervention and control group and time, Wilks' Lambda = .935, $F = 2.939$, $p = .094$, partial eta squared = .065.

There was no substantial main effect for time, Wilks' Lambda = .988, $F = .5$, $p = .483$, partial eta squared = .012. The main effect comparing the two types of intervention was not significant, $F = 2.464$, $p = .124$, partial eta squared = .055, suggesting a very small difference in the effectiveness of the intervention compared to the control group.

Comfort Variable Correlation

To test for possible correlations between the comfort scale and the VAS a correlation analysis for the logbook data was run (Appendix J). In both groups there was a large positive correlation between increased perception of comfort and more days of participation in the study (day 1 to day 7). This correlates with the posttest results for comfort in the intervention group though the change is not as large.

Ease Variable Correlations

Two separate scales were used to measure ease, the Ease measure (Adenmosun et al., 2021) and the GCQ with subscale ease (Kolcaba, 2003). Correlation analysis shows that there is a significant correlation between the Ease measure and the subset ease in the GCQ (Appendix K, Table 10).

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

2a. Determine feasibility and acceptability by assessing participant recruitment, enrollment, and retention rates to determine optimal recruitment strategies.

Recruitment

Recruitment took place between August 2022 and January 2023. The recruitment flier was shared with the therapists and staff at the West Virginia University Department of Medicine and Psychiatry, Chestnut Ridge via email and hard copy.

Recruitment was done online because, since the COVID pandemic, all Comprehensive Opioid Addiction Treatment (COAT) recovery group sessions have been held online. During the first session a participant who lived several hours away expressed interest in participating but said that the travel to enroll and pick up study materials would be prohibitive. This led to a pivot to virtual recruitment and enrollment using Zoom sessions and mailing all study materials. The study team took on the added burden of mailing to reduce the burden of travel on participants.

Overall, the most successful recruitment strategy was through virtual visits by the PI to COAT clinic sessions online followed by recruitment from the online Adverse Childhood Experiences (ACES) groups. A phone number specific to the study was shared with participants along with the flier and those who did not wish to share contact information at the time of the meeting were encouraged to reach out later. Those recruited from the session were asked to share their contact information via private chat on the Zoom platform. When a participant did not know how to do this, the therapist facilitated.

Recruitment was initially focused on those in stages two and three of treatment, but therapists heard from their participants that those in stage one and in the peer recovery phase of

treatment were also interested in participating, so IRB approval was obtained (09262022), and recruitment expanded (Supplement: Protocol Manual).

Enrollment

Enrollment occurred in three steps including expression of interest, provision of contact information, and follow up and prescreening call. Once eligibility was established from prescreening, an enrollment session was scheduled with the PI. Use of private online interactive spreadsheets facilitated communication between the PI, extern, and administrative assistant.

The consent and pretests were all completed online through Qualtrics WVU. Most if not all participants completed enrollment using their cell phones. Qualtrics surveys can be completed on these devices, but in several cases reading the consent and the three surveys was reported to be challenging. Some participants could not manage to complete the documents and for them the PI either read the questions and marked answers. In one case the PI met the enrollee at the Chestnut Ridge clinic because the enrollee had neither a phone designed to interact in a survey format or a computer.

Retention

Retention was facilitated in several ways. The main method was through constant contact between the PI and study participants via texting and phone calls. This constant contact helped when study participants were confused. The main point of confusion was randomization. When participants received a study packet without an aroma inhaler some believed there had been a mistake. The PI mitigated this distress by being always available by text and by responding quickly with reassurance. To promote fairness in this study all participants received an aroma inhaler and all study materials. The aroma inhaler was sent to every participant either with the packet or with the thank you and gift card at completion of the study.

The population for this study was approximately 340. Out of 111 who expressed interest in the study, 73 were screened, 15 were excluded with 10 not meeting criteria and 5 who declined to participate with the most common reason being lack of time. Of the 58 allocated to the study arms, 25 were in the intervention group and 33 in the control group. One enrollee in the control group was unable to complete any part of the study due to mail not reaching them two times and inability to come to the clinic. This left 32 in the control group. Seven were lost to follow up in the intervention group. Lost to follow up in this case meant that participants reported that they had put their return packet in the mail, but these packets were never received by the PI. In the control group, four return study packets were never received. One control group participant discontinued the intervention due to illness. Per the intention to treat design, all data from the 25 participants in the intervention group were included in analysis. All data from the control group for the 32 participants were included in analysis (Appendix B).

2b. Assess intervention fidelity (consistent implementation) of the aromatherapy intervention using daily checklists in logbooks.

Intervention fidelity of the aromatherapy intervention was assessed using daily logbooks. Intervention fidelity was high as expressed in use of the logbook to record use of the aroma inhaler (Appendix L). Most, if not all of those in the intervention group used their aroma inhaler at least three times each day (Appendix M). The intervention group logbook contained a checklist for the participant to record their use of the aroma inhaler. In all, 19 logbooks were collected and data analyzed from those in the intervention group. All participants were asked to keep comments general and not share personal information that could identify them such as their name, address, or other identifying information. Comments from the logbook were very positive with reports of feeling less anxiety and stress and more relaxed and calmer (Appendix N).

Post intervention, three questions about the experience with the aroma inhaler were asked on a 0 to 10 scale with 0 being less positive and 10 being most positive (Appendix O). Only those participants randomized to the intervention group answered these questions. Perceived enjoyment of the aroma inhaler was assessed using the question “On a scale of 1 to 10 rate overall how enjoyable the aroma of the inhaler was.” All participants said the aroma inhaler was at least “slightly enjoyable” 2 (3.4%) with the majority reporting “very enjoyable” 7 (12.1%). Perceived intensity of the aroma inhaler was assessed post study with the question “On a scale of 1 to 10, rate the usual strength of the smell of the aroma inhaler”. All participants responded at 5 “neutral” or above and the majority 6 (10.3%) reported the smell as “fairly strong.” To see how likely those in the study thought they would be to continue using their aroma inhaler after the study ended, the question “How likely are you to continue to use this aroma inhaler” all participants responded at either 5 “neutral” or above with the majority 12 (20.7%) “very likely” to continue to use.

2c. Calculate a traditional cost analysis for the aromatic intervention implementation.

Implementing this intervention study cost a total of \$2350.89. This included creation of a total of 60 study packets, gift cards, and mailing costs. On average a study packet consisted of a two-pocket folder, paperwork (copy of consent, welcome letter, 2 study instruction half sheets to post in the home, 7-page half-page folded logbook, return self-addressed stamped envelope with paperwork, and an aroma inhaler [intervention group only]). Mailing costs varied between the groups with an average of \$7.20 for intervention group and \$8.16 for control group.

The most expensive part of this study was the gift cards at \$20 each. Every participant (n = 57), regardless of whether their posttest materials were received, was sent a thank you in the form of either a \$20 Walmart gift card and a handwritten note along with the aroma inhaler (for

the control group). One extra gift card was issued for a participant whose mail was reported as stolen, so 58 gift cards at \$20 each for a total of \$1,160.00 were distributed.

To confirm receipt of their gift card, participants were asked to answer a two question survey through Qualtrics (1. Yes, I received my \$20 gift card; 2. My study ID is ###). Receipt of 41 of the 58 gift cards was confirmed either by this survey or by text usually with a photo of the card. The PI made multiple attempts to reach the remaining 17 participants but was unsuccessful.

The aroma inhalers were provided by Plant Extracts international at a discount and represent about \$220.00 in actual cost. Participants who were interested reported that they went to the company website and ordered more. Retail, these inhalers cost \$7 each. Participants were not asked if they thought the cost outweighed benefits.

Time of the PI, extern, and administrative assistant were calculated. The PI spent an average of 10 hours per week for 20 weeks recruiting, enrolling, following up, and coordinating the study with all parties. The extern reported an average of 3 to 10 hours a week over the course of 20 weeks. The administrative assistant reported an average of 5 hours a week.

Report of Adverse Reactions

There were no reports of adverse reactions in this aromatherapy intervention. Participants in the intervention group were provided three follow up questions with extra space for comments. Those in the control group had their logbook for comments. There were no reports or comments indicating adverse reactions.

Conclusion

The results of this study show that the use of an aroma inhaler with bergamot essential oil three times daily for one week improved scores for comfort and ease and decreased perception of stress. Recruitment, enrollment, and retention rates were high. Out of a population of

approximately 340, one-hundred and eleven persons were interested in the study and 57 completed it. Participants used daily logbooks to track their use of the aroma inhaler and rate their comfort. Comments from those in the intervention group were very positive. Participants reported a reduction in stress and anxiety, and an increase in feeling calm and relaxed.

Chapter Five: Discussion

This study employed a quantitative pretest posttest experimental design to examine the effect of an aroma inhaler used three times daily for seven days. The benefits and impact were explored related to self-reports of comfort, ease, and stress in adults in treatment for SUD. The findings of the study offer potential in the search for ways to promote health and wellbeing for those in treatment programs.

To date, there is no reported use of bergamot EO to impact comfort and ease and reduce stress among adults in treatment for SUD. This completed study serves to fill a recognized gap in the literature of how those in treatment for SUD in north central Appalachia can be supported during treatment by using aromatherapy. The study further advances knowledge on the topic by exploring the feasibility of using aromatherapy by examining recruitment, enrollment, and retention rates.

Findings of Primary Variables

The first aim of this study was to discover if integrating aromatherapy could help improve the perception of comfort, ease, and stress and support recovery treatment program progression. In this sample population, improvement was reported in the areas of comfort, ease, and stress, that while not significant, still showed improvement and warrants further investigation. Findings were consistent with the literature. Studies in humans using *Citrus bergamia* (Bergamot [BEO]) show promise for anxiety reduction and improving wellbeing (Buckle, 2015a; Chang & Shen, 2011; Han et al., 2017; Kerkhof-Knapp Hayes, 2015; Price & Price, 2012; Reven et al., 2022). Increasing the level of comfort has been identified as vital to success by those in recovery treatment programs (Yang et al., 2020).

Descriptive Findings

Participants shared their thoughts about their daily experience of the aroma inhalers by commenting in the logbook. The intervention group expressed an enjoyment of the aroma inhaler and found the influence relaxing and calming (Appendix N). Participants described their experience of using the aroma inhaler as “relaxing”, “grounding”, and “calming”. This is coherent with the concept of comfort as defined as the experience of relief (Kolcaba, 2003). Further description included feelings of being more “focused” at work, and “us[ing] an extra time as was anxious in traffic” which is coherent with ease as defined as calmness amid distress (Reven, 2022a). Relief of stress was defined as mediating needs and relieving suffering (Kolcaba, 2003). Participants reported “still in pain but I find the scent really calms me down” and “used aroma inhaler extra time to remain focused at work”.

The integrated theoretical framework combining the theory of comfort (Kolcaba, 2003) and the concept of welcoming ease (Reven, 2022a) guided the study of this research question and problem. The concepts of this theory included comfort, ease, and stress reduction. The relationships and findings were coherent with concepts of this integrated theoretical framework.

Everyday Living

In this study, participants were challenged by work and family demands and at times would complete their enrollment calls on their lunch break. For mothers with young children, challenges were seen in illness, limited sleep, and juggling many demands. This is supported by the literature. It is not unusual for this population who must exert concerted effort and commitment to not only meet daily demands but also fulfill rigorous treatment program requirements. Those in treatment for SUD report high levels of stress and they are looking for ways to help them manage this stress and succeed (Carpenter et al., 2021).

Those in treatment for SUD struggle to handle everyday living and are often affected by anxiety and depression (Cicero & Ellis, 2017; Johannessen et al., 2019; Yang et al., 2020). The DASS-21 was used to measure stress. It also has components to measure anxiety and depression. It was not the aim of this study to examine these covariates though this could be the focus of future study.

Barriers to Success in SUD Treatment

There are barriers to success in treatment for this population. One significant barrier is travel (Clary et al., 2020). From the start of recruitment interested persons expressed that it was a financial burden to travel to pick up study materials. We overcame this barrier by pivoting to the online format and using the postal service. Mailing study materials to participants was largely successful, however, returning posttests and logbooks proved to be a challenge. Also, participant living conditions made for some difficulties with some participants having to get their mail from relative's houses and having mailboxes that were not secure in neighborhoods where theft was an issue. This is consistent with the literature (Carpenter & Theeke, 2018).

Use of Integrative Modalities

In this sample population many reported trying integrative modalities such as meditation, yoga, mindfulness, massage, and aromatherapy to help with relaxation and stress reduction (Appendix C, Tables 1 and 2). Several reported they had first used aromatherapy while in their first stage of treatment. This addition of integrative additions to care is supported in the literature. The SUD treatment field is evolving and becoming multi-modal, individualized, and person-centered in approach (SAMHSA, 2020b). In the general population, almost eighteen percent of adult Americans use natural products like essential oils (NCCIH, 2020). There is

growing interest in “whole person” health with support for modalities such as mindfulness (NCCIH, 2020; Zullig et al., 2018).

Aromatherapy and Controlling for Bias

This study incorporated best practice in aromatic research as set forth by the ARQAT (Reven et al., 2022). Prescreening for preferences for integrative modalities, particularly essential oils, and aromatherapy, supports transparency in the findings. Based on this screening it was determined there was no positive bias toward essential oils and bergamot. This is important for several reasons. Over the past two decades there is a greater increase in understanding and appreciation of olfaction making assessment of olfactory function important (Bowles, 2020; Herz, 2009). Also, overall use and popularity of essential oils has increased over the past 20 years making the chances for previous exposure to essential oils likely (Buckle, 2015a; Price & Price, 2012). If researchers do not determine baseline ability to perceive odors, preferences, expectations, and familiarity, potential sources of bias and information related to causality are missed (Bowles, 2020; Herz, 2009; Reven et al., 2022).

Discussion of Feasibility

No matter the intervention if it is not feasible then it is not worth pursuing. In this population, results from the study suggest that using an aroma inhaler three times daily is both feasible and acceptable. The use of the logbook showed that there was almost 100% compliance with use three times daily with some participants using it more as needed. Also, one hundred percent of participants indicated they would be interested in participating in future studies. Results of this type are reflective of findings from the literature. In Hong Kong, the positive effect of a program where aromatherapy was introduced at a center and then continued in the home by an aromatic spray showed participants were likely to use the aromatherapy in their daily

lives (Tang & Tse, 2014). In a recent study examining aromatherapy effects in chemotherapy-induced peripheral neuropathy (CIPN), very good participation was reported with no missed clinic visits (Langley-Brady et al., 2023).

Contribution to the Knowledge Base of Nursing

This study contributes to the knowledge base of nursing as it examines health, healing, and wellbeing as areas of study that contribute to the knowledge base of nursing (Smith, 2019). Core nursing concepts of health, healing, and wellbeing provided the lens through which the problem of SUD treatment and recovery care were viewed. In the literature, risk for SUD is linked to complex interactions between personal, biological, and environmental factors (SAMSHA, 2020). When individuals no longer have the drugs in their systems in sufficient amounts, loss of pleasure (anhedonia), and increased sensitivity to stress and anxiety result (Volkow & Boyle, 2018). Even though not statistically significant, mean scores for all variables showed improvement in perception of comfort, ease, and stress. Comments from the logbook revealed that having an aroma inhaler provided meaningful relief for participants in this study.

Implications

Future Research

A focus for this pilot study was to determine recruitment, enrollment, and retention rates in this population. Recruiting over half of the desired study number in just five months is a good results in this population. This is better than what is reflected in the literature with some studies recruiting 14 months to two years (Langley-Brady et al., 2023; Soden et al., 2004; Wilcock et al., 2004; Wilkinson et al., 2007). Another focus was the dose of the essential oil. Future research could center on this and determining if different frequencies of administration would be more

effective. The literature shows that there is an interest in determining dosage of essential oils and how certain dosages impact human beings at different levels (Bowles, 2020).

Since it proved challenging to collect post study materials through the postal service, future research could incorporate more online components such as an online logbook and post-surveys. Additionally, longer time for recruitment could help boost numbers. According to Carpenter and Theeke (2018) planning a longer recruitment timeline can help in the Appalachian population as there is often hesitation to participate due to mistrust of researchers. Also, the plan for enrollment can be refined. There were sometimes delays of days and weeks between when participants expressed interest and when they were enrolled. There were 111 who expressed interest with only 57 enrolling, this could mean that some of those lost between interest and follow up were simply not enrolled quickly enough. Finally, many reviews of aromatherapy studies note that most studies are of short duration and fail to show any long term benefits of interventions using essential oils. This study was designed to determine if using the aroma inhaler in a specific way was feasible and acceptable in this population. It appears that it was acceptable. Future studies could include now increasing the length of time and help determine more about long term benefits.

This study employed an attention control in the form of a logbook for those in the control group. A future study could explore bergamot EO compared to another EO where chemical constituents are similar. This is supported in the literature when examining effects of EO in relation to EOs chemical make-up (Fung et al., 2012; Fung et al., 2021). Of those who expressed a preference for essential oils, lavender was the most popular. This is supported in the literature where lavender essential oil is one of the most widely used and researched of all essential oils (Donelli et al., 2019; Jafari-Koulaee et al., 2020; Koulivand et al., 2013). Bergamot was chosen

for this study because it is less known though has similar properties to the lavender traditionally used for rest and stress relief, *Lavandula angustifolia*. It may prove beneficial to see if one or the other provides better benefits, at what dosage, and to which persons—those who prefer and expect effects or from everyone.

Literature is largely absent about dosage of inhaled aromatherapy in healthcare (Ball et al., 2020; Bouya et al., 2018; Cai et al., 2021; Her & Cho, 2021; Lari et al., 2018; Li et al., 2022; Tsai et al., 2020). This is one of the first studies focused on determining a baseline dosage with an eye toward building further. This baseline information is necessary if aromatic interventions are to be incorporated into treatment plans. The literature is mostly silent on this topic and where dosage is mentioned there is a lack of consistency in how aromatic interventions are applied. This limits generalizability.

Practice

Nurses are poised to lead by providing the perspective, the care, and the voice for those working hard to recover in all areas of healthcare. Implications of this research include acknowledging the complex lives of those in treatment for SUD and their need for thoughtful integration of modalities such as aromatherapy. Practicing nurses can take the following points from this study.

First, this study provides clear information about the dosage used. The literature supports the delivery method of intermittent inhalation though not enough research exists to support a protocol (Bouya et al., 2018; Owayolu et al., 2014). Second, evaluation of perceived enjoyment and aroma intensity were queried. Using these insights, nurses can determine if three inhalations three times daily is in line with results they wish to see. Third, this study introduces the TREATS checklist. This first of its kind checklist provides the foundation for essential oil and aromatic

interventions and research reporting (Reven et al., 2022). Findings from this study can support efforts to introduce aromatherapy into holistic patient care. For more information about creating aromatherapy and EO policy in the healthcare setting visit <https://www.alliance-aromatherapists.org/>.

When nurses are educated about ways to manage stress and improve wellbeing, they can make a difference in the lives of those they serve. Nurse-delivered aromatherapy has been established in some hospital systems in the US. Nurses are being trained to offer aromatherapy to their patients for support of symptoms such as pain, anxiety, and nausea (Johnson et al., 2017). Along with implementing the intervention, data should be collected and reported to strengthen the evidence-base for aromatic and EO interventions (Anton et al., 2022; Johnson et al., 2016; Reven et al., 2022).

Policy

This study adds to the body of research designed to support use of aromatherapy in healthcare. While there is limited clinical evidence, complementary and integrative medicine is widely used (NCCIH, 2020). Aromatic interventions such as this one are low-cost and readily available and could be used more often in healthcare (*Aromatherapy With Essential Oils (PDQ®)–Patient Version - National Cancer Institute*, 2007). Findings from this research will help inform stakeholders and policy makers at multiple levels.

Limitations

Recruitment

Recruitment took place over five months and did not realize numbers to achieve power. Sample size was determined at 98 with a little over half (57) of this obtained on repeated measure ANOVA given $\alpha=0.05$, moderate effect size (0.25), power of 80%, two groups with 2

measurements, correlation among repeated measures (0.50). Descriptively, the data is encouraging, though these findings cannot be generalized. In the literature, lack of power in aromatherapy studies is common. In a recent study of effects of essential oils on CIPN *a-priori* power analysis determined a population of 200 but this was not feasible due to funding and time constraints (Langley-Brady et al., 2023).

Multiple reviews of aromatherapy for outcomes of pain, anxiety, sleep, menopausal symptoms, and stress relief note that small samples sizes inhibit meta-analyses and drawing conclusions and recommend more studies that are fully funded and powered (Armstrong et al., 2019; Choi et al., 2018; Hines et al., 2018; Xiao et al., 2021). The literature supports this finding though the majority of summary research reports aromatherapy research is largely underpowered and underfunded (Ball et al., 2020; Cheng et al., 2022; Farahani et al., 2019; Freeman et al., 2019). There is a great need for studies that are well crafted and specifically designed to determine dosage (Schneider et al., 2019).

Challenges with SUD Population in Appalachia

In this study there were challenges recruiting from the population. This is also found in the literature. This study drew from a population of adults in treatment for SUD in Appalachia that included at least ten counties in the north central and northern and eastern panhandles of West Virginia. Challenges to recruitment in Appalachian culture are well documented including mistrust of outsiders, general lack of assertiveness, and fear of being taken advantage of. Additionally, the Appalachian population often have a distrust of the medical community, including researchers (Carpenter & Theeke, 2018). To successfully recruit, a culturally competent approach was used including developing and maintaining trust. This was accomplished through relationships made with key providers at the treatment center. This

included both administration and direct care providers, namely therapists who ran COAT clinic sessions.

Limitations Related to Enrollment

There were challenges related to the design of the study. Access to the study population was affected by the restrictions imposed after the COVID pandemic. When this study was conceived it was planned for face-to-face meetings in clinic group sessions. Since the pandemic all COAT sessions through WVUCRC remain online and participants met the researcher virtually without meeting in person. This made recruitment more difficult as this population is culturally more prone to distrust researchers (Carpenter & Theeke, 2018). According to a key contact at WVUCRC, this population is frequently asked to participate in research and this may also have caused some lack of enthusiasm for this study.

Second, because of the need to pivot to online enrollment, time from initial interest to consent lengthened. When participants were interested, they then provided contact information and set up a time to have a phone call for prescreening. Once this was completed and eligibility determined, an online zoom meeting was scheduled for consent, study instructions, and pre-surveys. Time from beginning to end of the study went from a matter of days to weeks and sometimes months. The complexity of the lives of those in treatment meant that participants were likely lost to follow up because the study team just could not connect. This is also found in the literature (Carpenter et al., 2021).

Third, because we could not simply hand materials to the participants and then collect them at their next session, a lot of time was spent trying to get the post surveys and logbooks back. Sixteen post survey packets were not received even though all participants said they were put in the mail. A lot of time was dedicated to reaching out to try to get these packets back. Face-

to-face interactions may have results in a higher post survey and logbook collection rate. This is supported in the literature with research focused on post-COVID pandemic and responses to face-to-face being more favorable when compared to remote interactions (Nelson et al., 2021).

Conclusion

In this pilot feasibility study, outcome measures of comfort, ease, and stress were examined. Findings from this study show that, while not statistically significant, improvement in self reports of perceived comfort, ease, and stress and acceptability of the intervention merits attention and further investigation. There is a need for further studies that are well crafted and specifically designed to determine dosage. Relieving the burden of stress has been identified as important for those in treatment for SUD to be successful. Aromatherapy is a safe and relatively low-cost intervention and results of this study show that it is acceptable to this population. Use of bergamot essential oil via an aroma inhaler (Aethereo®Stick) has been identified as an integrative modality that warrants further research in those in treatment for SUD in north central Appalachia, US.

References

- Adenmosun, E. O., Liehr, P., & Smith, M. J. (2021). Measuring ease: Content validity and early reliability of a newly developed measure. *Applied Nursing Research*, 61, 151459. <https://doi.org/10.1016/j.apnr.2021.151459>
- Anton, R., Boutefnouchet, S., Colls, P., Couic-Marinier, F., Kopferschmitt, J., & Morel, J.-M. (2022). *Need to improve the quality of clinical studies in aromatherapy* (p. 8) [White Paper]. The Gattefosse Foundation. <https://www.fondation-gattefosse.org/en/infotheque/white-paper-from-the-scientific-board/>
- 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>
- Aromatherapy With Essential Oils (PDQ®)—Patient Version—National Cancer Institute* (nciglobal,ncienterprise). (2007, March 9). [PdqCancerInfoSummary]. <https://www.cancer.gov/about-cancer/treatment/cam/patient/aromatherapy-pdq>
- Bagetta, G., Morrone, L. A., Rombolà, L., Amantea, D., Russo, R., Berliocchi, L., Sakurada, S., Sakurada, T., Rotiroti, D., & Corasaniti, M. T. (2010). Neuropharmacology of the essential oil of bergamot. *Fitoterapia*, 81(6), 453–461. <https://doi.org/10.1016/j.fitote.2010.01.013>
- Baird, C. (2014). Complementary and alternative therapies in addictions treatment. *Journal of Addictions Nursing*, 25(4), 214–216. <https://doi.org/10.1097/JAN.0000000000000053>

- Ball, E. L., Owen-Booth, B., Gray, A., Shenkin, S. D., Hewitt, J., & McCleery, J. (2020). Aromatherapy for dementia. *Cochrane Database of Systematic Reviews*, 2020(8). Embase. <https://doi.org/10.1002/14651858.CD003150.pub3>
- Battaglia, S. (2003). *The complete guide to aromatherapy*. International Centre of Holistic Aromatherapy.
- Beauchamp, T. L. (2008). The Belmont report. In E. J. Emanuel, C. Grady, R. A. Crouch, R. K. Lie, F. G. Miller, & D. Wendler (Eds.). In *The Oxford textbook of clinical research ethics* (pp. 149–155). Oxford University Press, Incorporated.
- Blissett, K.-A., Chima, V., & Lantz, M. S. (2018). From stress to serenity: The use of aromatherapy to engage patients in care. *The American Journal of Geriatric Psychiatry*, 26(3), S119. <https://doi.org/10.1016/j.jagp.2018.01.145>
- Bliuc, A.-M., Best, D., Iqbal, M., & Upton, K. (2017). Building addiction recovery capital through online participation in a recovery community. *Social Science & Medicine*, 193, 110–117. <https://doi.org/10.1016/j.socscimed.2017.09.050>
- Boutron, I., Altman, D. G., Moher, D., Schulz, K. F., Ravaud, P., & for the CONSORT NPT Group. (2017). CONSORT statement for randomized trials of nonpharmacologic treatments: A 2017 update and a CONSORT extension for nonpharmacologic trial abstracts. *Annals of Internal Medicine*, 167(1), 40. <https://doi.org/10.7326/M17-0046>
- Bouya, S., Ahmadidarehsima, S., Badakhsh, M., Balouchi, A., & Balouchi, M. (2018). Effect of aromatherapy interventions on hemodialysis complications: A systematic review. *Complementary Therapies in Clinical Practice*, 32(101225531), 130–138. <https://doi.org/10.1016/j.ctcp.2018.06.008>

- Bowles, E. J. (2020). *Dr Joy's aromatherapy: Use essential oils with confidence for psyche, skin, medicine and health*. <https://nla.gov.au/nla.obj-2918800428>
- Brookes, J. C. (2010). Science is perception: What can our sense of smell tell us about ourselves and the world around us? *Philosophical Transactions. Series A, Mathematical, Physical, and Engineering Sciences*, 368(1924), 3491–3502. <https://doi.org/10.1098/rsta.2010.0117>
- Buckle, J. (1998). Clinical aromatherapy and touch: Complementary therapies for nursing practice. *Critical Care Nurse*, 18(5), 54–61.
- Buckle, J. (2015a). *Clinical aromatherapy: Essential oils in healthcare* (3rd ed.). Elsevier.
- Buckle, J. (2015b). Aromatherapy for stress in patients and hospital staff. *Alternative and Complementary Therapies*, 21(5), 210–213. <https://doi.org/10.1089/act.2015.29016.jbu>
- Cai, H., Xi, P., Zhong, L., Chen, J., & Liang, X. (2021). Efficacy of aromatherapy on dental anxiety: A systematic review of randomised and quasi-randomised controlled trials. *Oral Diseases*, 27(4), 829–847. Embase. <https://doi.org/10.1111/odi.13346>
- Campbell, D. T., & Stanley, J. C. (1967). *Experimental and quasi-experimental designs for research* (2. print; Reprinted from "Handbook of research on teaching"). Houghton Mifflin Comp.
- Candy, B., Armstrong, M., Flemming, K., Kupeli, N., Stone, P., Vickerstaff, V., & Wilkinson, S. (2020). The effectiveness of aromatherapy, massage and reflexology in people with palliative care needs: A systematic review. *Palliative Medicine*, 34(2), 179–194. <https://doi.org/10.1177/0269216319884198>
- Cannard, G. (1996). The effect of aromatherapy in promoting relaxation and stress reduction in a general hospital. *Complementary Therapies in Nursing and Midwifery*, 2(2), 38–40. [https://doi.org/10.1016/S1353-6117\(96\)80062-X](https://doi.org/10.1016/S1353-6117(96)80062-X)

- Carpenter, R., Smith, M. J., & Newhouse, A. (2021). Mothering a child while participating in a substance use disorder program: A phenomenological study. *Archives of Psychiatric Nursing*, 35(6), 577–582. <https://doi.org/10.1016/j.apnu.2021.08.006>
- Carpenter, R., & Theeke, L. A. (2018). Strategies for recruiting a sample of adults with type 2 diabetes from primary care clinics in rural Appalachia: Incorporating cultural competence. *International Journal of Nursing Sciences*, 5(3), 230–237. <https://doi.org/10.1016/j.ijnss.2018.06.003>
- 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>
- Cheng, H., Lin, L., Wang, S., Zhang, Y., Liu, T., Yuan, Y., Chen, Q., & Tian, L. (2022). Aromatherapy with single essential oils can significantly improve the sleep quality of cancer patients: A meta-analysis. *BMC Complementary Medicine & Therapies*, 22(1), 1–12. ccm. <https://doi.org/10.1186/s12906-022-03668-0>
- Cho, E. H., Lee, M.-Y., & Hur, M.-H. (2017). The effects of aromatherapy on intensive care unit patients' stress and sleep quality: A nonrandomised controlled trial. *Evidence-Based Complementary and Alternative Medicine*, 2017, e2856592. <https://doi.org/10.1155/2017/2856592>
- Choi, J., Lee, J. A., Alimoradi, Z., & Lee, M. S. (2018). Aromatherapy for the relief of symptoms in burn patients: A systematic review of randomized controlled trials. *Burns*, 44(6), 1395–1402. Embase. <https://doi.org/10.1016/j.burns.2017.10.009>

- 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.
- Clary, E., Ribar, C., & Weigensberg, E. (2020). *Challenges in providing substance use disorder treatment to child welfare clients in rural communities* (p. 16). Office of the Assistant Secretary for Planning and Evaluation, US Department of Health and Human Services. aspe.hhs.gov
- Cooke, M., Holzhauser, K., Jones, M., Davis, C., & Finucane, J. (2007). The effect of aromatherapy massage with music on the stress and anxiety levels of emergency nurses: Comparison between summer and winter. *Journal of Clinical Nursing*, 16(9), 1695–1703. <https://doi.org/10.1111/j.1365-2702.2007.01709.x>
- D’Agostino, A. R., Optican, A. R., Sowles, S. J., Krauss, M. J., Escobar Lee, K., & Cavazos-Rehg, P. A. (2017). Social networking online to recover from opioid use disorder: A study of community interactions. *Drug and Alcohol Dependence*, 181, 5–10. <https://doi.org/10.1016/j.drugalcdep.2017.09.010>
- Donelli, D., Antonelli, M., Bellinazzi, C., Gensini, G. F., & Firenzuoli, F. (2019). Effects of lavender on anxiety: A systematic review and meta-analysis. *Phytomedicine*, 65, 153099. <https://doi.org/10.1016/j.phymed.2019.153099>
- Eklund, A., De Carvalho, D., Pagé, I., Wong, A., Johansson, M. S., Pohlman, K. A., Hartvigsen, J., & Swain, M. (2019). Expectations influence treatment outcomes in patients with low back pain. A secondary analysis of data from a randomized clinical trial. *European Journal of Pain (London, England)*, 23(7), 1378–1389. <https://doi.org/10.1002/ejp.1407>

- Emanuel, E. J., Wendler, D., & Grady, C. (2008). An ethical framework for biomedical research. In E. J. Emanuel, C. Grady, R. A. Crouch, R. K. Lie, F. G. Miller, & D. Wendler (Eds.). *In The Oxford textbook of clinical research ethics* (pp. 123–135). Oxford University Press, Incorporated.
- Farahani, M. A., Afsargharehbagh, R., Marandi, F., Moradi, M., Hashemi, S.-M., Moghadam, M. P., & Balouchi, A. (2019). Effect of aromatherapy on cancer complications: A systematic review. *Complementary Therapies in Medicine*, 47((Farahani M.A.) Nursing Care Research Center (NCRC), School of Nursing and Midwifery, Iran University of Medical Sciences, Tehran, Iran). Embase. <https://doi.org/10.1016/j.ctim.2019.08.003>
- Farrar, A. J., & Farrar, F. C. (2020). Clinical aromatherapy. *The Nursing Clinics of North America*, 55(4), 489–504. <https://doi.org/10.1016/j.cnur.2020.06.015>
- FDA Drug Glossary of Terms. (2017). Drugs@FDA Glossary of Terms. FDA. <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms>
- Ferrans, C. E., Zerwic, J. J., Wilbur, J. E., & Larson, J. L. (2005). Conceptual model of health-related quality of life. *Journal of Nursing Scholarship: An Official Publication of Sigma Theta Tau International Honor Society of Nursing*, 37(4), 336–342. <https://doi.org/10.1111/j.1547-5069.2005.00058.x>
- Freeman, M., Ayers, C., Peterson, C., & Kansagara, D. (2019). *Aromatherapy and essential oils: A map of the evidence* (p. 64) [Essential oil evidence summary]. Department of Veterans Affairs. <https://www.hsrd.research.va.gov/publications/esp/aromatherapy.pdf>
- Fung, J. K. K., Tsang, H. W., & Chung, R. C. (2012). A systematic review of the use of aromatherapy in treatment of behavioral problems in dementia. *Geriatrics & Gerontology International*, 12(3), 372–382. <https://doi.org/10.1111/j.1447-0594.2012.00849.x>

- Fung, T. K. H., Lau, B. W. M., Ngai, S. P. C., & Tsang, H. W. H. (2021). Therapeutic Effect and Mechanisms of Essential Oils in Mood Disorders: Interaction between the Nervous and Respiratory Systems. *International Journal of Molecular Sciences*, 22(9), 4844. <https://doi.org/10.3390/ijms22094844>
- Gnatta, J. R., Kurebayashi, L. F. S., Turrini, R. N. T., & Silva, M. J. P. da. (2016). Aromatherapy and nursing: Historical and theoretical conception. *Revista Da Escola de Enfermagem Da USP*, 50(1), 127–133. <https://doi.org/10.1590/S0080-623420160000100017>
- Goeders, N. E. (2003). The impact of stress on addiction. *European Neuropsychopharmacology*, 13(6), 435–441. <https://doi.org/10.1016/j.euroneuro.2003.08.004>
- 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>
- Harada, H., Kashiwadani, H., Kanmura, Y., & Kuwaki, T. (2018). Linalool odor-induced anxiolytic effects in mice. *Frontiers in Behavioral Neuroscience*, 12. <https://www.frontiersin.org/article/10.3389/fnbeh.2018.00241>
- Hawkins, J. (2018). *The effect of bergmot essential oil on anxiety among children with autism*. <https://jewlscholar.mtsu.edu/handle/mtsu/5640>
- Henry, J. D., & Crawford, J. R. (2005). The short-form version of the Depression Anxiety Stress Scales (DASS-21): Construct validity and normative data in a large non-clinical sample. *British Journal of Clinical Psychology*, 44(2), 227–239. <https://doi.org/10.1348/014466505X29657>

- Her, J., & Cho, M.-K. (2021). Effect of aromatherapy on sleep quality of adults and elderly people: A systematic literature review and meta-analysis. *Complementary Therapies in Medicine*, 60((Her J., 12746@snubh.org) Seoul National University Bundang Hospital, 82, Gumi-ro, 173 beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do, South Korea). Embase. <https://doi.org/10.1016/j.ctim.2021.102739>
- 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>
- Herz, R. S. (2016). The role of odor-evoked memory in psychological and physiological health. *Brain Sciences*, 6(3). <https://doi.org/10.3390/brainsci6030022>
- Hines, S., Steels, E., Chang, A., & Gibbons, K. (2018). Aromatherapy for treatment of postoperative nausea and vomiting. *Cochrane Database of Systematic Reviews*, 3. <https://doi.org/10.1002/14651858.CD007598.pub3>
- Holm, L., & Fitzmaurice, L. (2008). Emergency department waiting room stress: Can music or aromatherapy improve anxiety scores? *Pediatric Emergency Care*, 24(12), 836–838. <https://doi.org/10.1097/PEC.0b013e31818ea04c>
- Hur, M.-H., Song, J.-A., Lee, J., & Lee, M. S. (2014). Aromatherapy for stress reduction in healthy adults: A systematic review and meta-analysis of randomized clinical trials. *Maturitas*, 79(4), 362–369. <https://doi.org/10.1016/j.maturitas.2014.08.006>
- 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>

IHI. (2018). *The IHI triple aim / IHI - Institute for Healthcare Improvement* [Government].

Institute for Healthcare Improvement Web Site.

<http://www.ihl.org:80/Engage/Initiatives/TripleAim/Pages/default.aspx>

IntNSA. (2011, May 20). *IntNSA / International Nurses Society on Addictions*.

<https://www.intnsa.org/>

Jafari-Koulaee, A., Elyasi, F., Taraghi, Z., Ilali, E. S., & Moosazadeh, M. (2020). A Systematic review of the effects of aromatherapy with lavender essential oil on depression. *Central Asian Journal of Global Health*, 9(1), Article 1. <https://doi.org/10.5195/cajgh.2020.442>

Janssens, K. A. M., Bos, E. H., Rosmalen, J. G. M., Wichers, M. C., & Riese, H. (2018). A qualitative approach to guide choices for designing a diary study. *BMC Medical Research Methodology*, 18(1), 140. <https://doi.org/10.1186/s12874-018-0579-6>

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>

Johansson, L., & Wiklund-Gustin, L. (2016). The multifaceted vigilance—Nurses' experiences of caring encounters with patients suffering from substance use disorder. *Scandinavian Journal of Caring Sciences*, 30(2), 303–311. <https://doi.org/10.1111/scs.12244>

Johnson, J. R., Rivard, R. L., Griffin, K. H., Kolste, A. K., Joswiak, D., Kinney, M. E., & Dusek, J. A. (2016). The effectiveness of nurse-delivered aromatherapy in an acute care setting. *Complementary Therapies in Medicine*, 25, 164–169. <https://doi.org/10.1016/j.ctim.2016.03.006>

- Johnson, K., West, T., Shelly, D., Todd, J., Haynes, B., Bernhardt, J., & Johnson, R. (2017). Use of aromatherapy to promote a therapeutic nurse environment. *Intensive & Critical Care Nursing*, 40, 18–25. <http://dx.doi.org.wvu.idm.oclc.org/10.1016/j.iccn.2017.01.006>
- Kasar, K. S., Yildirim, Y., Senuzun Aykar, F., Uyar, M., Sagin, F. G., & Atay, S. (2020). Effect of inhalation aromatherapy on pain, anxiety, comfort, and cortisol levels during trigger point injection. *Holistic Nursing Practice*, 34(1), 57–64. <https://doi.org/10.1097/HNP.0000000000000350>
- Kerkhof-Knapp Hayes, M. (2015). *Complementary nursing in end of life care: Integrative care in palliative care : Handbook for nurses and health care professionals : Aromacare, massage, aquacare, relaxation*. Kicozo - Knowledge Institute for Complementary Nursing.
- Kolcaba. (2001). Evolution of the mid range theory of comfort for outcomes research. *Nursing Outlook*, 49(2), 86–92. <https://doi.org/10.1067/mno.2001.110268>
- Kolcaba. (2003). *Comfort theory and practice*. Springer Publishing Company.
- Kolcaba, K. Y., & Kolcaba, R. J. (1991). An analysis of the concept of comfort. *Journal of Advanced Nursing*, 16(11), 1301–1310. <https://doi.org/10.1111/j.1365-2648.1991.tb01558.x>
- Koulivand, P. H., Khaleghi Ghadiri, M., & Gorji, A. (2013). Lavender and the nervous system. *Evidence-Based Complementary and Alternative Medicine : ECAM*, 2013, 681304. <https://doi.org/10.1155/2013/681304>
- Kyle, G. (2006). Evaluating the effectiveness of aromatherapy in reducing levels of anxiety in palliative care patients: Results of a pilot study. *Complementary Therapies in Clinical Practice*, 12(2), 148–155. <https://doi.org/10.1016/j.ctcp.2005.11.003>

Lai, T. K. T., Cheung, M. C., Lo, C. K., Ng, K. L., Fung, Y. H., Tong, M., & Yau, C. C. (2011).

Effectiveness of aroma massage on advanced cancer patients with constipation: A pilot study. *Complementary Therapies in Clinical Practice*, 17(1), 37–43.

<https://doi.org/10.1016/j.ctcp.2010.02.004>

Langley-Brady, D. L., Campbell, R. T., Maihle, N. J., Barnes, V. A., Bratton, A. R., & Zadinsky,

J. K. (2023). A pilot randomized controlled trial evaluating essential oils for chemotherapy-induced peripheral neuropathy. *Pain Management Nursing*,

S1524904222002260. <https://doi.org/10.1016/j.pmn.2022.12.008>

Lari, Z. N., Atarzadeh, F., Ghoreishi, P. S., Hosseinkhani, A., & Jaldat, A. M. (2018). Effects of

aromatherapy on sexual dysfunction: A review of Persian traditional medicine. *Iranian Journal of Obstetrics, Gynecology and Infertility*, 21(4), 79–86.

<https://doi.org/10.22038/ijogi.2018.11230>

Lee, M., Lim, S., Song, J.-A., Kim, M.-E., & Hur, M.-H. (2017). The effects of aromatherapy

essential oil inhalation on stress, sleep quality and immunity in healthy adults:

Randomized controlled trial. *European Journal of Integrative Medicine*, 12, 79–86.

<https://doi.org/10.1016/j.eujim.2017.04.009>

Lehrner, J., Eckersberger, C., Walla, P., Potsch, G., & Deecke, L. (2000). Ambient odor of

orange in a dental office reduces anxiety and improves mood in female patients.

Psychology & Behavior, 71, 83–86. [https://doi.org/10.1016/S0031-9384\(00\)00308-5](https://doi.org/10.1016/S0031-9384(00)00308-5)

Li, B. S. Y., Chan, C. W. H., Wong, I. K. Y., Yu, Y. H. U., & Li, M. (2022). Effectiveness of

aromatherapy in managing behavioural and psychological symptoms of dementia: A

mixed methods: systematic review. *British Geriatrics Society Abstracts from the Autumn*

- Meeting (Virtual), November 24-26, 2021. *Age & Ageing*, 51, 1–1.
<https://doi.org/10.1093/ageing/afac035.765>
- Li, H., Zhao, M., Shi, Y., Xing, Z., Li, Y., Wang, S., Ying, J., Zhang, M., & Sun, J. (2019). The effectiveness of aromatherapy and massage on stress management in nurses: A systematic review. *Journal of Clinical Nursing*, 28(3–4), 372–385.
<https://doi.org/10.1111/jocn.14596>
- Liehr, P., & Smith, M. J. (2018). Story theory. In M. J. Smith & P. R. Liehr (Eds.). In *Middle range theory for nursing* (4th ed., pp. 241–263). Springer.
- Linck, V. M., da Silva, A. L., Figueiró, M., Caramão, E. B., Moreno, P. R. H., & Elisabetsky, E. (2010). Effects of inhaled linalool in anxiety, social interaction and aggressive behavior in mice. *Phytomedicine*, 17(8), 679–683. <https://doi.org/10.1016/j.phymed.2009.10.002>
- Liu, S.-H., Lin, T.-H., & Chang, K.-M. (2013). The physical effects of aromatherapy in alleviating work-related stress on elementary school teachers in Taiwan. *Evidence-Based Complementary and Alternative Medicine*, 2013, 1–8.
<https://doi.org/10.1155/2013/853809>
- 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>
- Louis, M., & Kowalski, S. D. (2002). Use of aromatherapy with hospice patients to decrease pain, anxiety, and depression and to promote an increased sense of well-being. *American Journal of Hospice and Palliative Medicine*, 19(6), 381–386.
<https://doi.org/10.1177/104990910201900607>
- 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>
- McCambridge, J., Kypri, K., & Elbourne, D. (2014). In randomization we trust? There are overlooked problems in experimenting with people in behavioral intervention trials. *Journal of Clinical Epidemiology*, 67(3), 247–253.
<https://doi.org/10.1016/j.jclinepi.2013.09.004>
- Merriam-Webster.com dictionary. (n.d.). *Definition of disease*. Retrieved February 14, 2022, from <https://www.merriam-webster.com/dictionary/disease>
- Miller, W. R., & Walker, D. D. (1997). Should there be aromatherapy for addiction? *Addiction*, 92(4), 486–487. <https://doi.org/10.1111/j.1360-0443.1997.tb03384.x>
- Moody, L., Satterwhite, E., & Bickel, W. K. (2017). Substance use in rural central Appalachia: Current status and treatment considerations. *Rural Mental Health*, 41(2), 123–135.
<https://doi.org/10.1037/rmh0000064>
- 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>
- Murphy, S. L., & Gutman, S. A. (2017). Intervention fidelity: A necessary aspect of intervention effectiveness studies. *The American Journal of Occupational Therapy*, 66(4), 387–388.
- 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. (2020). *Aromatherapy*. <https://www.nccih.nih.gov/health/aromatherapy>

NCCIH. (2021). *NCCIH strategic plan fiscal year 2021–2025*.

<https://www.nccih.nih.gov/about/nccih-strategic-plan-2021-2025>

Nelson, P. M., Scheiber, F., Laughlin, H. M., & Demir-Lira, Ö. E. (2021). Comparing face-to-face and online data collection methods in preterm and full-term children: An exploratory study. *Frontiers in Psychology, 12*.

<https://www.frontiersin.org/articles/10.3389/fpsyg.2021.733192>

Nesami, M. B., Shorofi, S. A., Nikkhah, A., Moghaddam, H. R., & Mahdavi, A. (2018). Effect of lavender aromatherapy on well-being among hemodialysis patients: A randomized clinical trial. *Pharmaceutical and Biomedical Research*.

<https://doi.org/10.18502/pbr.v4i2.215>

Newman, M. A., Sime, A. M., & Corcoran-Perry, S. A. (1991). The focus of the discipline of nursing. *Advances in Nursing Science, 14*, 1–6.

NIDA. (2020, February 25). *Understanding drug abuse and addiction: What science says*.

National Institute on Drug Abuse. <https://nida.nih.gov/publications/teaching-addiction-science/understanding-drug-abuse-addiction-what-science-says>

Nightingale, F. (1969). *Notes on nursing: What it is and what it is not*. Dover Press.

Nord, D., & Belew, J. (2009). Effectiveness of the essential oils lavender and ginger in promoting children's comfort in a perianesthesia setting. *Journal of PeriAnesthesia Nursing, 24*(5), 307–312. <https://doi.org/10.1016/j.jopan.2009.07.001>

Oberleitner, L. M., Beitel, M., Schottenfeld, R. S., Kerns, R. D., Doucette, C., Napoleone, R.,

Liong, C., & Barry, D. T. (2016). Drug counselors' attitudes toward non-pharmacologic treatments for chronic pain. *Journal of Addiction Medicine, 10*(1), 34–39.

<https://doi.org/10.1097/ADM.0000000000000177>

- Ovayolu, Ö., Seviğ, Ü., Ovayolu, N., & Sevinç, A. (2014a). The effect of aromatherapy and massage administered in different ways to women with breast cancer on their symptoms and quality of life: Effectiveness of aromatherapy in breast cancer. *International Journal of Nursing Practice*, 20(4), 408–417. <https://doi.org/10.1111/ijn.12128>
- Ovayolu, Ö., Seviğ, Ü., Ovayolu, N., & Sevinç, A. (2014b). The effect of aromatherapy and massage administered in different ways to women with breast cancer on their symptoms and quality of life: Effectiveness of aromatherapy in breast cancer. *International Journal of Nursing Practice*, 20(4), 408–417. <https://doi.org/10.1111/ijn.12128>
- Pallant, J. (2020). *SPSS survival manual: A step by step guide to data analysis using IBM SPSS*. <https://www.taylorfrancis.com/books/9781003117407>
- Pasick, R. J., Stewart, S. L., Bird, J. A., & D'Onofrio, C. N. (2001). Quality of data in multiethnic health surveys. *Public Health Reports*, 116(1_suppl), 223–243. <https://doi.org/10.1093/phr/116.S1.223>
- Patterson, E. (2022). *The history of drug abuse and addiction rehabilitation*. DrugAbuse.Com. <https://drugabuse.com/addiction/history-drug-abuse/>
- Paula, D., Luis, P., Pereira, O. R., & Maria Joao, S. (2017). Aromatherapy in the control of stress and anxiety. *Alternative & Integrative Medicine*, 06(04), 1–5. <https://doi.org/10.4172/2327-5162.1000248>
- Perna, S., Spadaccini, D., Botteri, L., Girometta, C., Riva, A., Allegrini, P., Petrangolini, G., Infantino, V., & Rondanelli, M. (2019). Efficacy of bergamot: From anti-inflammatory and anti-oxidative mechanisms to clinical applications as preventive agent for cardiovascular morbidity, skin diseases, and mood alterations. *Food Science & Nutrition*, 7(2), 369–384. <https://doi.org/10.1002/fsn3.903>

- Pernicious Definition & Meaning—Merriam-Webster.* (n.d.). Retrieved January 17, 2022, from <https://www.merriam-webster.com/dictionary/ Pernicious>
- 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>
- Piamjariyakul, U., Petite, T., Smothers, A., Wen, S., Morrissey, E., Young, S., Sokos, G., Moss, A. H., & Smith, C. E. (2019). Study protocol of coaching end-of-life palliative care for advanced heart failure patients and their family caregivers in rural Appalachia: A randomized controlled trial. *BMC Palliative Care*, 18, 119. <https://doi.org/10.1186/s12904-019-0500-z>
- Pinto, J. M. (2011). Olfaction. *Proceedings of the American Thoracic Society*, 8(1), 46–52. <https://doi.org/10.1513/pats.201005-035RN>
- Polit, D. F., & Beck, C. T. (2017). *Nursing research: Generating and assessing evidence for nursing practice* (Tenth edition). Wolters Kluwer Health.
- Price, S., & Price, L. (Eds.). (2012). *Aromatherapy for health professionals* (4th ed). Churchill Livingstone/Elsevier.
- Prochaska, J. O., & Velicer, W. F. (1997). The transtheoretical model of health behavior change. *American Journal of Health Promotion: AJHP*, 12(1), 38–48. <https://doi.org/10.4278/0890-1171-12.1.38>
- Reis, D., & Jones, T. (2017). Aromatherapy: Using essential oils as a supportive therapy. *Clinical Journal of Oncology Nursing*, 21(1), 16–19. <https://doi.org/10.1188/17.CJON.16-19>
- Reven, M. E. (2022a). Welcoming ease: Building a concept from nursing practice. *Applied Nursing Research*, Volume 64.

- Reven, M. E. (2022b, September 18). *The power of disillusionment: Creating the aromatic research quality appraisal taskforce*. The Alliance of International Aromatherapists (AIA) 2021 International Aromatherapy Conference and Wellness Expo. Aromatherapy Hot Topics: From Self-Care to Clinical Trials. Wheeling IL, USA.
- Reven, M. E., Bowles, E. J., Peppers-Citizen, M., May-Fitzgerald, A. C., Audia, D. D., Cohen, M. M., Joswiak, D. J., Kurkas Lee, B. A., Resnick, J. A., Tomaino, J. M., & Unger, B. J. (2022). *A quest for quality reporting in aromatic research: 2022 white paper* (p. 54) [White Paper]. Aromatic Research Quality Appraisal Taskforce ARQAT.
<https://www.arqat.org/the-white-paper>
- Reven, M. E., Humphrey-Rowan, J., & Moore, N. (2020). West Virginia University oncology nurses don aromatherapy patches: A pilot feasibility study. *The International Journal of Professional Holistic Aromatherapy*, 8(4), 7–15.
- Rombolà, L., Corasaniti, M. T., Rotiroti, D., Tassorelli, C., Sakurada, S., Bagetta, G., & Morrone, L. A. (2009). Effects of systemic administration of the essential oil of bergamot (BEO) on gross behaviour and EEG power spectra recorded from the rat hippocampus and cerebral cortex. *Functional Neurology*, 24(2), 107–112.
- Rombolà, L., Tridico, L., Scuteri, D., Sakurada, T., Sakurada, S., Mizoguchi, H., Avato, P., Corasaniti, M., Bagetta, G., & Morrone, L. (2017). Bergamot essential oil attenuates anxiety-like behaviour in rats. *Molecules*, 22(4), 1–11.
<https://doi.org/10.3390/molecules22040614>
- 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., & Karthikeyan, S. (2015). Changes in substance abuse treatment use among individuals with opioid use disorders in the United States, 2004-2013. *JAMA*, 314(14), 1515. <https://doi.org/10.1001/jama.2015.10345>

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. (2020a). *Enhancing motivation for change in substance use disorder treatment* (p. 212) [Treatment Improvement Protocol No. 35]. U.S. Department of Health and Human Resources.

https://store.samhsa.gov/sites/default/files/d7/priv/tip35_final_508_compliant_-_02252020_0.pdf

SAMHSA. (2020b). *Mental health and substance use disorders*. <https://www.samhsa.gov/find-help/disorders>

SAMHSA. (n.d.). *Medication-Assisted Treatment (MAT)* [Government]. Substance Abuse and Mental Health Services Administration. <https://www.samhsa.gov/medication-assisted-treatment>

- Schneider, R., Singer, N., & Singer, T. (2019). Medical aromatherapy revisited—Basic mechanisms, critique, and a new development. *Human Psychopharmacology*, 34(1). Embase. <https://doi.org/10.1002/hup.2683>
- 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>
- Serfaty, M., Wilkinson, S., Freeman, C., Mannix, K., & King, M. (2012). The ToT Study: Helping with touch or talk, a pilot randomised controlled trial to examine the clinical effectiveness of aromatherapy massage versus cognitive behaviour therapy for emotional distress in patients in cancer/palliative care: The ToT Study. *Psycho-Oncology*, 21(5), 563–569. <https://doi.org/10.1002/pon.1921>
- Shadish, W. R., Cook, T. D., & Campbell, D. T. (2001). *Experimental and quasi-experimental designs for generalized causal inference*. Houghton Mifflin.
- Smith, M. C. (2019). Regenerating nursing's disciplinary perspective. *Advances in Nursing Science*, 42, 3–16.
- Smith, M. C., & Kyle, L. (2008). Holistic foundations of aromatherapy for nursing. *Holistic Nursing Practice*, 22(1), 3–9. <https://doi.org/10.1097/01.HNP.0000306321.03590.32>
- Soden, K., Vincent, K., Craske, S., Lucas, C., & Ashley, S. (2004). A randomized controlled trial of aromatherapy massage in a hospice setting. *Palliative Medicine*, 18(2), 87–92. <https://doi.org/10.1191/0269216304pm874oa>

- Tang, S. K., & Tse, M. Y. M. (2014a). Aromatherapy: Does it help to relieve pain, depression, anxiety, and stress in community-dwelling older persons? *BioMed Research International*, 2014. <https://doi.org/10.1155/2014/430195>
- Tang, S. K., & Tse, M. Y. M. (2014b). Aromatherapy: Does It help to relieve pain, depression, anxiety, and stress in community-dwelling older persons? *BioMed Research International*, 2014, 1–13. <https://doi.org/10.1155/2014/430195>
- Tillett, J., & Ames, D. (2010). The uses of aromatherapy in women's health. *The Journal of Perinatal & Neonatal Nursing*, 24(3), 238–245.
<https://doi.org/10.1097/JPN.0b013e3181ece75d>
- Tisserand Institute. (n.d.). *Safety guidelines: Intermittent inhalation of essential oils* [Educational]. Tisserand Institute. <https://tisserandinstitute.org/safety-guidelines/>
- Tisserand, R., & Young, R. (2014). *Essential oil safety: A guide for health care professionals* (2nd ed.). Elsevier Ltd.
- TJC. (2018). *Non-pharmacologic and non-opioid solutions for pain management* (The Joint Commission No. 44; Quick Safety). Division of Healthcare Improvement.
https://www.jointcommission.org/-/media/tjc/newsletters/qs_nonopioid_pain_mgmt_8_15_18_final1pdf.pdf
- Tsai, S.-S., Wang, H.-H., & Chou, F.-H. (2020). The effects of aromatherapy on postpartum women: A systematic review. *J Nurs Res*, 28(3), e96.
<https://doi.org/10.1097/jnr.0000000000000331>
- UNODC. (2019). *World Drug Report 2019: 35 million people worldwide suffer from drug use disorders while only 1 in 7 people receive treatment*. United Nations: Office on Drugs and Crime. [//www.unodc.org/unodc/en/frontpage/2019/June/world-drug-report-2019_-](https://www.unodc.org/unodc/en/frontpage/2019/June/world-drug-report-2019_-)

35-million-people-worldwide-suffer-from-drug-use-disorders-while-only-1-in-7-people-receive-treatment.html

Valussi, M., Donelli, D., Firenzuoli, F., & Antonelli, M. (2021). Bergamot oil: Botany, production, pharmacology. *Encyclopedia*, 1(1), 152–176.

<https://doi.org/10.3390/encyclopedia1010016>

Van Der Watt, G., & Janca, A. (2008). Aromatherapy in nursing and mental health care.

Contemporary Nurse : A Journal for the Australian Nursing Profession, 30(1), 69–75.

Volkow, N. D., & Boyle, M. (2018). Neuroscience of addiction: Relevance to prevention and treatment. *American Journal of Psychiatry*, 175(8), 729–740.

<https://doi.org/10.1176/appi.ajp.2018.17101174>

West Virginia 2020-2022 council substance use plan. (n.d.). Retrieved June 4, 2021, from

[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](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)

Wilcock, A., Manderson, C., Weller, R., Walker, G., Carr, D., Carey, A.-M., Broadhurst, D.,

Mew, J., & Ernst, E. (2004). Does aromatherapy massage benefit patients with cancer attending a specialist palliative care day centre? *Palliative Medicine*, 18(4), 287–290.

<https://doi.org/10.1191/0269216304pm895oa>

Wilkinson, S. (1995). Aromatherapy and massage in palliative care. *International Journal of*

Palliative Nursing, 1(1), 21–30.

Wilkinson, S., Aldridge, J., Salmon, I., Cain, E., & Wilson, B. (1999). An evaluation of

aromatherapy massage in palliative care. *Palliative Medicine*, 13(5), 409–417.

<https://doi.org/10.1191/026921699678148345>

- Wilkinson, S. M., Love, S. B., Westcombe, A. M., Gambles, M. A., Burgess, C. C., Cargill, A., Young, T., Maher, E. J., & Ramirez, A. J. (2007). Effectiveness of aromatherapy massage in the management of anxiety and depression in patients with cancer: A multicenter randomized controlled trial. *Journal of Clinical Oncology*, 25(5), 532–539.
<https://doi.org/10.1200/JCO.2006.08.9987>
- WVU Today / WVU addresses addiction crisis with novel ultrasound treatment. (n.d.). Retrieved January 17, 2022, from <https://wvutoday.wvu.edu/stories/2021/03/17/wvu-addresses-addiction-crisis-with-novel-ultrasound-treatment>
- Wyrwich, K. W., Fihn, S. D., Tierney, W. M., Kroenke, K., Babu, A. N., & Wolinsky, F. D. (2003). Clinically important changes in health-related quality of life for patients with chronic obstructive pulmonary disease: An expert consensus panel report. *Journal of General Internal Medicine*, 18(3), 196–202. <https://doi.org/10.1046/j.1525-1497.2003.20203.x>
- Xiao, S., Wang, Y., Duan, S., & Li, B. (2021). Effects of aromatherapy on agitation and aggression in cognitive impairment: A meta-analysis. *Journal of Clinical Nursing*, (Xiao S.; Wang Y.; Li B.) *School of Nursing and Health, Henan University, Kaifeng, China*. Medline. <https://doi.org/10.1111/jocn.15984>
- 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>
- Yıldırım, D., Kocatepe, V., Can, G., Sulu, E., Akış, H., Şahin, G., & Aktay, E. (2020). The effect of lavender oil on sleep quality and vital signs in palliative care: A randomized clinical

trial. *Complementary Medicine Research*, 27(5), 328–335.

<https://doi.org/10.1159/000507319>

Zullig, K. J., Lander, L. R., Tuscano, M., Hobbs, G. R., & Faulkenberry, L. (2018).

Incorporating mindfulness-based relapse prevention into outpatient therapy for treatment of opioid use disorder with medication-assisted treatment. *Annals of Community Medicine and Practice*, 4(1), 1032.

Appendices

Appendix A: Information Collected from Study Participants

1. Variables of Comfort, Ease, and Stress (Self-report)
2. Stage of treatment in the SUD treatment program (Chart) (Updated to include all stages [1,2,3, and peer recovery] IRB approval date 09262022)
3. Presence of anxiety and/or depression (Chart)
4. Presence of severe mental illness Dx (Chart) (Removed, IRB approval date 09262022)
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)
12. Gender
13. Ethnicity
14. Age
15. Marital status

16. Children in the home

17. Level of education

18. Location

19. Employment

Appendix B

Diagram 1: CONSORT Flow Diagram

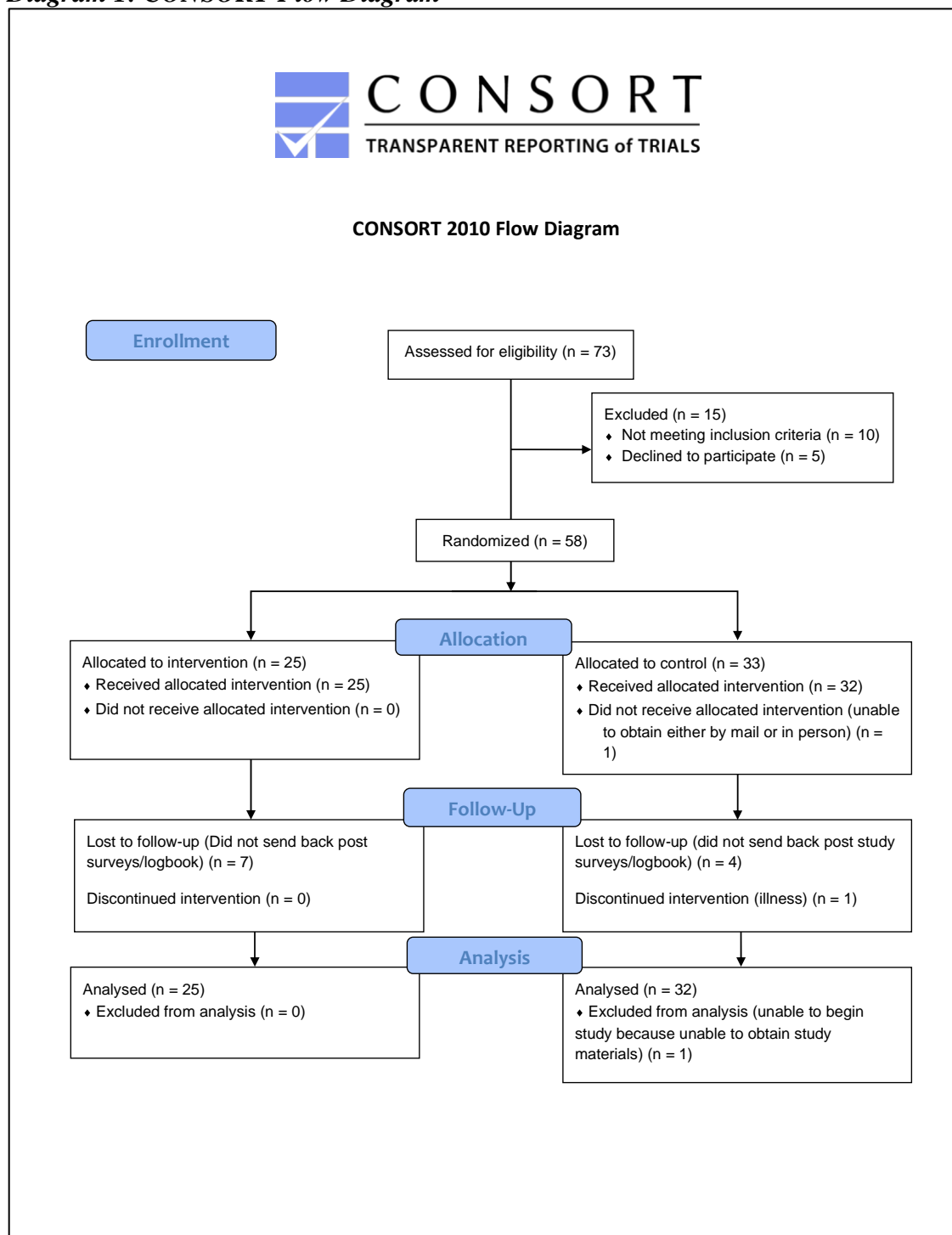


Diagram 1. Shows the progression from enrollment to analysis. A total of 57 participants completed the study and their data were analyzed.

Appendix C: Tables 1 and 2 Prescreen Questions

Prescreen Question Responses (Yes/No)

Question (Abbreviated)	Intervention group		Control group		Full sample	
	n	%	n	%	n	%
Dislike of citrus?						
Yes	0	0	2*	6.1	2	3.4
No	na		na		56	96.6
Ever smelled bergamot?						
Yes	3	12	4	12.1	7	12.1
No	22	88	29	87.9	51	87.9
Smelled & disliked bergamot?						
Yes	0		2*		2*	3.4
No	na		na		na	na
Ever tried integrative therapies?						
Yes	15	60	22	66.7	37	63.8
No	10	40	11	33.3	21	36.2
Have you tried essential oils (EO)?						
Yes	10	40	8	24.2	18	31
No	14	56	23	69.7	37	63.8
Ever tried bergamot EO?						
Yes	2	8	3	9.1	5	8.6
No	9	36	7	21.2	16	27.6
Difficulty recognizing odors?						

Yes	1	4	1	3	2**	3.4
No	24	96	32	97	56	96.6

*Note. *Two participants admitted they were not sure if they liked or disliked the smell and expressed that they wanted to be in the study. Without being able to do in person olfactory testing, these two participants were allowed to stay in the study.*

***Of the 2 participants reporting problems recognizing odors, none (0) had been told by a doctor that they had problems with their sense of smell. Both participants denied having a diagnosis of anosmia.*

Table 2

Prescreen Question Responses (Short answer responses) from those who had tried integrative therapies (Both Intervention and Control Groups)

Question	Responses
Have you ever tried any integrative or complementary therapies (examples include massage, yoga, acupuncture, aromatherapy with essential oils, herbs, meditation, mindfulness practices etc.)	17 meditation 15 yoga 11 mindfulness 10 massage 10 aromatherapy 7 acupuncture 4 essential oils 1 each chiropractor, herbals, hot rock therapy, hyperbaric chamber, and incense
The integrative therapy was used for a specific condition If yes, what was your main reason for using complementary therapies? Choose all that apply: Pain, anxiety, relaxation, stress relief, or other	13 anxiety 12 stress relief 12 relaxation 7 pain 3 exercise 1 each depression, detox, health, helps keep me sober, PTSD, sleep, trauma therapy

If there is a specific therapy used for a specific symptom	<p>Most said that all therapies worked together to help with symptoms as listed above</p> <p>Yoga was mentioned 11 times related to pain relief, stress relief, relaxation, and exercise</p> <p>Massage was mentioned 7 times related to anxiety, stress, relaxation, and pain</p> <p>Aromatherapy was mentioned 4 times with essential oils mentioned 2 times for a total of 6 times related to relaxation, sleep, stress and anxiety relief, support with mindfulness and medication, and PTSD</p> <p>Meditation was mentioned 5 times with relaxation and pain relief</p> <p>Acupuncture was mentioned 4 times related to stress, anxiety, pain, and cold sweats</p> <p>Mindfulness was mentioned 2 times related to pain and relaxation</p> <p>Bath products were mentioned once related to aches and pains</p> <p>Chiropractor was mentioned related to pain</p>
List essential oils you have tried	<p>13 lavender</p> <p>5 eucalyptus</p> <p>3 peppermint</p> <p>3 lemon</p> <p>2 spearmint</p> <p>1 each bergamot, CBD, chamomile, cinnamon, citrus, frankincense, lemon grass, linen, oasis, persimmon, pumpkin, rosemary, strawberry, tea tree, vanilla</p>
Favorite essential oil(s)	<p>6 lavender</p> <p>2 citrus</p> <p>2 eucalyptus</p> <p>1 each frankincense, Hawaiian, lemon grass, mint, oasis, tea tree</p>

Least favorite essential oil(s)	Six responses, 1 each CBD, citronella, clove, lavender, lemon, patchouli, peppermint
Tried bergamot essential oil for what reason	Four responses, “just tried it randomly”, “scent”, “to make the house smell better”, “used for sinuses as breathing mask”
What effect do you think bergamot had?	Three responses, “breath better and recover quicker”, “felt like on a beach with a cocktail, relaxed”, and “helped calm down”

Appendix D: Table 3***Descriptive Statistics: Categorical Demographic Variables***

Variable	N (%)
Gender	
Male	18 (31)
Female	40 (69)
Ethnicity	
White, Non-Hispanic	56 (96.6)
Latino or Hispanic	1 (1.7)
African American	1 (1.7)
Age	
19-30 years	10 (17.2)
31-40 years	31 (53.4)
41-50 years	10 (17.2)
51-60 years	5 (8.6)
> 60 years	2 (3.4)
Marital status	
Single	36 (62.1)
Married	11 (19)
Divorced	7 (12.1)
Widowed	1 (1.7)
Significant other	3 (5.2)

Variable	N (%)
Children in the home	
No children	6 (10.3)
1-2 children	7 (12.1)
3-4 children	3 (5.2)
No data	42 (72.4)
Education	
High school/ GED	6 (10.3)
Some college	1 (1.7)
No data	51 (87.9)
Location	
Barbour	1 (1.7)
Brooke	2 (3.4)
Harrison	3 (5.2)
Lewis	2 (3.4)
Marion	12 (20.7)
Monongalia	25 (43.1)
Ohio	1 (1.7)
Other	4 (6.9)
Preston	5 (8.6)
Taylor	1 (1.7)
Wetzel	2 (3.4)

Variable	N (%)
Employment	
Homemaker	2 (3.4)
Student	1 (1.7)
Employed for wages	28 (48.3)
Out of work, not looking for work	1 (1.7)
Unable to work	1 (1.7)
No data	25 (43.1)
Stage of treatment	
Peer recovery coach	2 (3.4)
Stage 1	9 (15.5)
Stage 2	27 (46.6)
Stage 3	20 (34.5)
Primary diagnosis	
Multi substance use disorder	21 (36.2)
Opioid use disorder	35 (60.3)
Other	2 (3.4)
Secondary diagnosis	
Anxiety	4 (6.9)
Anxiety, Depression, Other	2 (3.4)
Anxiety, Other	4 (6.9)

Variable	N (%)
Both (Anxiety/Depression)	10 (17.2)
Both, Other	3 (5.2)
Depression	6 (10.3)
Depression, Other	6 (10.3)
No data	17 (29.3)
Other (combined)	6 (10.3)

Appendix E: Table 4***Group Equivalents at Baseline for Study Variables***

Variable	Intervention group		Control group		t	p
	M	SD	M	SD		
Comfort	118.64	14.416	117.00	22.417	-.335*	.739
Ease	53.56	9.557	54.56	9.041	.405	.687
Stress	18.76	10.948	19.97	11.128	.410	.684

Note. Equal variance not assumed

Appendix F: Table 5***Paired Samples t-Test: Pre/Post Variables of Comfort, Ease, and Stress***

Intervention Group (n = 17)						
	Pretest		Posttest			
Variable	Mean	SD	Mean	SD	t	p
Comfort	121.29	14.546	127.12	18.617	-1.927	.072
Ease	54.39	9.745	57.67	9.081	-1.698	.108
Stress	17.41	11.479	14.12	11.112	1.364	.192
Control Group (n = 27)						
	Pretest		Posttest			
Variable	Mean	SD	Mean	SD	t	p
Comfort	117.88	23.538	116.96	23.172	.226	.823
Ease	55.11	9.154	39.67	8.983	11.176	< .001*
Stress	20.44	11.683	21.81	12.746	-.892	.380

Note. * indicates statistical significance at .05 or less

Appendix G: Table 6

Independent Samples t-Test, Pre/Post Table: Variables of Comfort, Ease, and Stress

Pre-intervention stage						
Variable	Intervention Group		Control Group		t	p
	Mean	SD	Mean	SD		
Pretest						
Comfort	118.64	14.416	117.64	22.417	-.335**	.739
Ease	53.56	9.557	54.56	9.041	.402	.687
Stress	18.76	10.948	19.97	11.128	.410	.684
Post-intervention stage						
Variable	Intervention Group		Control Group		t	p
	Mean	SD	Mean	SD		
Posttest						
Comfort	127.12	18.617	116.96	23.172	-1.585**	.121
Ease	57.67	9.081	55.65	9.130	-.721	.475
Stress	14.12	11.112	21.81	12.746	.479	.047*

*Significance < .05

**Equal variances not assumed using Levene's test for equality of variances

Appendix H: Table 7***Two-Way Analyses of Variance***

Variable	Intervention		Control		<i>F</i>	η^2
	M	SD	M	SD		
Pre Comfort	121.29	14.546	117.88	23.538	<i>F</i> (1, 41)	.018
Post Comfort	127.12	18.617	116.96	23.172		
Pre Ease	54.39	9.745	54.35	9.419	<i>F</i> (1, 42)	.093
Post Ease	57.67	9.081	55.65	9.130		
Pre Stress	17.41	11.479	20.44	11.683	<i>F</i> (1, 42)	.012
Post Stress	14.12	11.112	21.81	12.746		

Appendix I: Table 8***Multivariate Tests/ Wilks' Lambda***

Variable	Value	F	df	Error df	Sig.	Partial Eta Squared
<hr/> Comfort <hr/>						
time*Group	.966	1.444	1.000	41.000	.236	.034
time	.982	.762	1.000	41.000	.388	.018
<hr/> Ease <hr/>						
time*Group	.981	.796	1.000	42.000	.377	.019
time	.907	4.310	1.000	42.000	.044*	.093
<hr/> Stress <hr/>						
time*Group	.935	2.939	1.000	42.000	.094	.065
time	.988	.500	1.000	42.000	.483	.012

*Note. * Significant at the .05 level (two-tailed)*

Appendix J: Table 9***Correlation Analysis of Day 1 and Day 7 VAS from Logbooks***

Comfort	Intervention		Control		<i>r</i>	p
	M	SD	M	SD		
Day 1	59.79	17.558	49.15	17.558	.540*	.017
Day 7	77.21	12.934	58.74	28.995	.681**	<.001

Note. *. Correlation is significant at the .05 level (2-tailed). **. Correlation is significant at the 0.01 level (2-tailed)

Appendix K: Table 10***Comparison of Ease Measure and Subset Ease from GCQ***

Variable	Intervention		Control		F	p
	M	SD	M	SD		
Pre ease	53.56	9.557	54.56	9.041	.000	.687
Post ease	57.67	9.081	55.65	9.130	.174	.475
Pre subset ease	42.56	7.773	40.44	7.539	.098	.303
Post subset ease	42.25	8.729	41.79	9.297	.200	.868

Correlation of Ease Measure and Subset Ease from GCQ

	Correlation	Statistic Confidence Interval	
		Lower	Upper
Ease measure + Subset ease in GCQ	.678	.507	.798

Note. Ease measure has 20 questions. The Ease subscale of the GCQ has 10 questions.

Correlation of Ease Measure and Subset Ease from GCQ

	r	p
Pre ease + Pre subset ease	.678**	<.001
Post ease + Post subset ease	.780**	<.001

*Note. **Correlation is significant at the 0.01 level (2-tailed)*

Appendix L: Table 11

Intervention Fidelity: Daily Use of Aroma Inhaler by Those in the Intervention Group as Recorded in the Logbook

	Intervention group (n = 19)	
	M	SD
Day 1	3.26	.562
Day 2	3.32	.582
Day 3	3.32	.671
Day 4	3.16	.765
Day 5	3.26	.562
Day 6	3.16	.501
Day 7	3.32	.582

Appendix M: Table 12***Daily Use of Aroma Inhaler as Recorded by Intervention Group in the Daily Logbook***

	Number of uses of aroma inhaler by Intervention group (n = 19)					
	1 time	2 times	3 times	4 times	5 times	6 or more
Day 1	-	-	15	3	1	-
Day 2	-	-	14	4	1	-
Day 3	-	-	15	2	2	-
Day 4	-	1	16	1	-	1
Day 5	-	1	12	6	-	-
Day 6	-	1	14	4	-	-
Day 7	-	-	14	4	1	-

Note. - in cells to indicate no data were reported. One participant said that they used their aroma inhaler extra without indicating how many times including, “Used aroma inhaler extra to remain focused while at work” on day 3 and “Used aroma inhaler extra today because of the kids and their homework” on day 7.

Appendix N***Comments from Daily Logbook for Intervention Group***

“Continues to help relax/ ground me when stressed”

“I used right before bed, was very relaxing and calming”

“Used an extra time as was anxious with traffic”

“Used an extra time before group therapy feeling a little anxious”

“I used an additional time at around 9:30p. I feel that it helps me to calm down before bed”

“I woke up abruptly around 10:30 and used it again to calm and relax myself. I was able to fall right back to sleep”

“Used inhaler around 6pm, baby was crying and throwing a tantrum. I’m really starting to like it. I went to the company’s website today to see how to order more scents”

“Used aroma inhaler extra to remain focused at work”

“Used aroma inhaler at break times for work like a quick jumpstart”

“Nice quiet day without much stress. Inhaler is very calming and works rather quickly”

“I used it...because I was stressed and it calmed me down”

“Still in pain but I find the scent really calms me”

“I’m very happy with this study and glad to be a part of it. It works well for me”

“Just 3 times today not sure if even works or if just like the smell”

“Used a lot extra today. I used it every time I felt uneasy and it helped calm my nerves”

Appendix O: Post Aroma Questions

Diagram 2: Question one: On a scale of 0 to 10 rate overall how enjoyable the aroma of the inhaler was

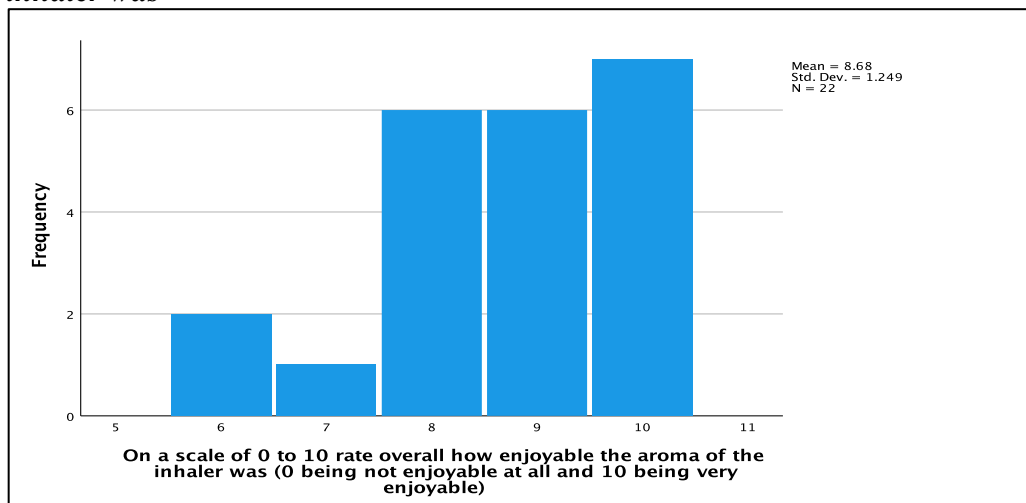


Diagram 3: Question Two: On a scale of 0 to 10 rate the usual strength smell of the aroma inhaler

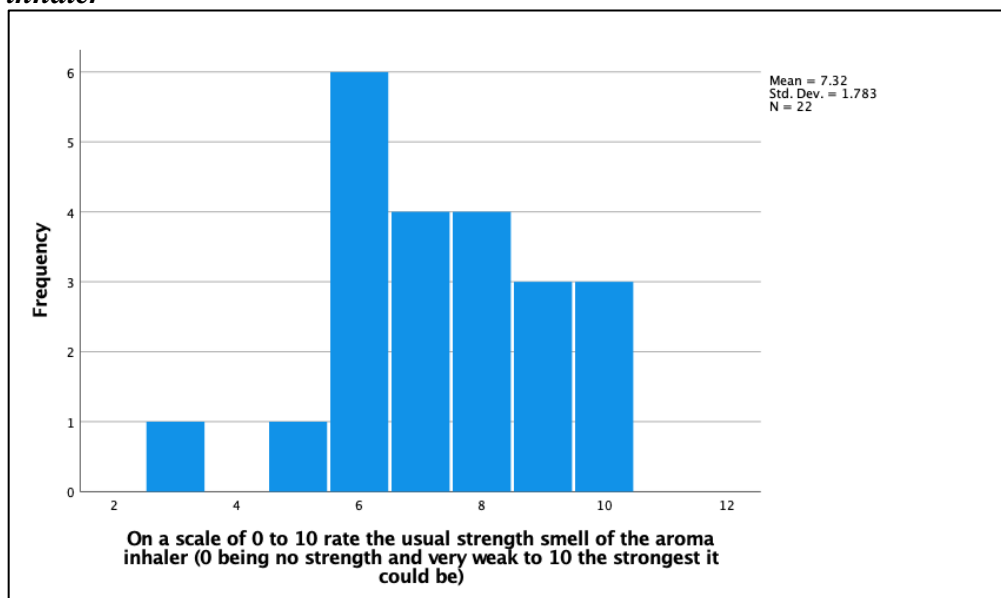
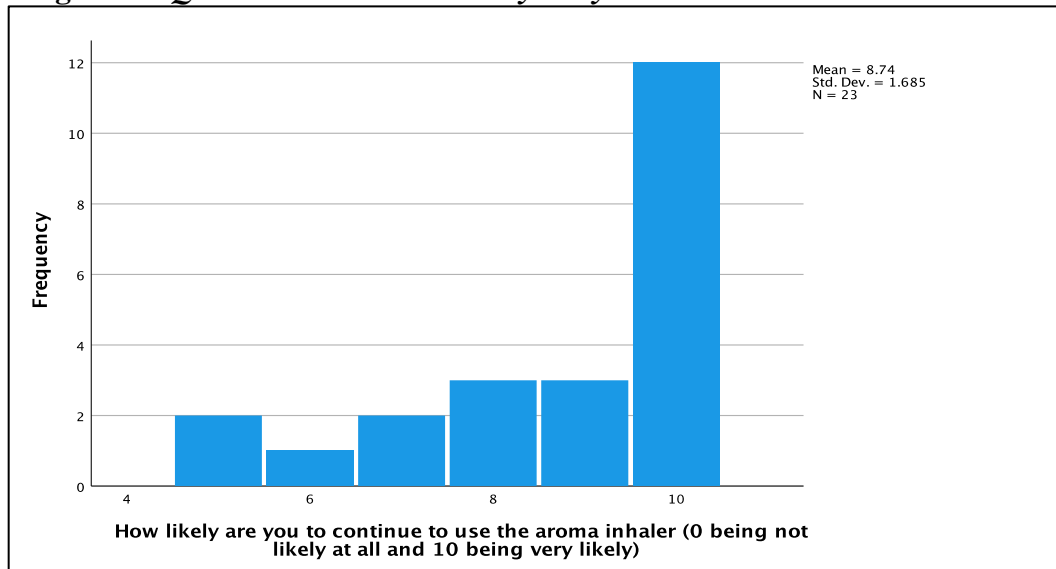


Diagram 4: Question Three: How likely are you to continue to use the aroma inhaler



Appendix P: TREATS

TREATS *Original critique, prior to pivot to online recruitment and mailing of study materials

Category (see Explanatory document for more details of each item)		Met =1 or *N/A	Partially met = 0.5 (Explain)	Not Met = 0	Explanations/ Comments/ Questions
Section 1: Essential oils (EO)					
1	Essential oil (EO) binomial (botanical) name (<i>Genus species</i>)	x			Provided by Plant Extracts Intl.
2	Extraction method	x			Provided by Plant Extracts Intl.
3	Plant part	x			Provided by Plant Extracts Intl.
4	Cultivation Method			x	
5	Country of Origin			x	
6	Source	x			Provided by Plant Extracts Intl.
7	Batch number of the EO	x			Provided by Plant Extracts Intl.
8	Identification of plant constituents	x			Table included
Total Section 1 (possible points = 8)					
Section 2A: Topical Application- Complete ONLY if topical delivery method used					
1	Dilution of EO (if applicable)	na			
2	Dose of EO	na			
3	Body surface area EO contacts	na			
4	Frequency of EO	na			
5	Duration of EO	na			
6	Description of control or placebo	na			
7	Carrier(s) name, including full binomial	na			
8	Source of carrier or delivery system	na			
Total Section 2A (possible points = 8)					
Section 2B: Inhalation (Complete ONLY if inhalation delivery method used)					
1	Mode of inhalation	x			Aethereo@Sticks
2	Dose of EO	x			Set by manufacturer, Plant Extracts International
3	Frequency of EO	x			3 x daily and prn (noted in diary) for 7 days
4	Duration of EO	x			Inhale for 3 seconds x 3 with each administration
5	Description of control or placebo	x			Standard care
6	Carrier(s) name, including full binomial *Mark N/A if no carrier used	NA			Using no carriers
7	Source of carrier or delivery system	x			Delivery system is a known product called an Aethereo@Sticks
Total Section 2B (possible points = 7)		6/6			

Category (see Explanatory document for more details of each item)		Met =1 or *N/A	Partially met = 0.5 (Explain)	Not Met = 0	Explanations/ Comments/ Questions
Section 3: Aromatherapy Intervention					
1	Clear description of aromatherapy interventions, outcome measures, and adherence to the researcher’s protocol Give partial credit if description of intervention & outcome measures is cited but not clear enough to replicate, or the research protocols were not followed	x			Dissertation work
2	Rationale for EO(s)	x			See background
3	Theoretical or conceptual framework	x			Integrated theoretical framework including Kolcaba’s Comfort theory and Reven’s Welcoming Ease Concept
4	Professional aromatherapist consulted	x			PI is a Registered Aromatherapist
5	Safety considerations	x			Addressed by using factory sealed inhalers, no oil on skin. Warning to keep out of reach of children and pets. Bergamot is bergapten-free)
6	Report of allergic and adverse reactions	x			Presurvey and postsurvey questions
7	Safety consideration of EO storage during trial	x			Provided with Aethereo®Sticks and education provided during orientation to study
	Total Section 3 (possible points = 7)	7/7			
Section 4: Olfactory function questions (Asked prior to trial)					
1	Anosmia	x			Plan to screen for this. Participants reporting altered sense of smell will receive the modified AROMA point of care test. Those with altered sense of smell will be included in the study
2	Previous use of EOs	x			Presurvey questions
	Total Section 4 (possible points = 2)	2/2			
Section 5: Olfactory bias questions if practical in experimental setting (Asked as part of trial. If not asked, the researcher may give explanation for excluding these steps. Give partial credit if mentioned in the limitations section)					

Category (see Explanatory document for more details of each item)		Met =1 or *N/A	Partially met = 0.5 (Explain)	Not Met = 0	Explanations/ Comments/ Questions
1	Olfactory testing	x			Modified AROMA test
2	Odor recognition testing	x			Modified AROMA test
3	Participants' expectation stated	x			Presurvey
4	Odor preference bias	x			Presurvey
5	Perceived aroma intensity	x			Modified AROMA test
6	Adverse effect from olfaction testing	x			Each AROMA test participant will be specifically assessed for adverse effects
Total Section 5 (possible points = 6)		6/6			
Version 9 