

THE IMPACT OF THE BIOSOUND THERAPY SYSTEM ON POST ACUTE  
WITHDRAWAL SYNDROME

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the Faculty of Saybrook University in partial  
fulfillment of the requirements for the degree of  
Doctor of Philosophy (Ph.D.) in Mind-Body  
Medicine  
by  
Dixie Brown

San Francisco, California

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Approval of the Dissertation

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WITHDRAWAL SYNDROME

This dissertation by Dixie Brown has been approved by the committee members below,  
who recommend it be accepted by the faculty of Saybrook University in partial  
fulfillment of the requirements for the degree of

Doctor of Philosophy in Mind-Body Medicine

Dissertation Committee:

\_\_\_\_\_  
Robert Kallmeyer, PhD

\_\_\_\_\_  
Date

\_\_\_\_\_  
Eric Willmarth, PhD

\_\_\_\_\_  
Date

\_\_\_\_\_  
Kirwan Rockefeller, PhD

\_\_\_\_\_  
Date

## Abstract

### THE IMPACT OF THE BIOSOUND THERAPY SYSTEM ON POST ACUTE WITHDRAWAL SYNDROME

Dixie Brown

Saybrook University

Individuals in recovery from substance use disorders often experience Post Acute Withdrawal Syndrome (PAWS) during the 18-24 months post-abstinence. The greatest risk PAWS presents is the potential for relapse due to the detrimental effects on an individual's physical, emotional, spiritual and mental wellbeing. While much research has been done on the use of complementary and alternative medicine (CAM) practices for substance use disorders and other co-occurring disorders, there is little information on the use of these practices for PAWS. Furthermore, in general, there is very little information on the use of the BioSound Therapy System (BTS), a mind, body, and spirit approach that integrates biofeedback, music therapy, meditation, and guided imagery into one cohesive unit. In light of this gap in research literature, the primary research question of this study was: What is the impact of the BioSound Therapy System on Post Acute Withdrawal Syndrome? A total of 4 women in an outpatient substance use disorder treatment setting responded to this study. Over the course of a 4 week period, these women participated in 2 weekly sessions (8 total sessions) of the BTS. This mixed-methods, multi-case study examined what the impact of the BTS was on positive/negative affect, perceived stress, and overall wellbeing was for these participants. These 4 adult women completed pre- and posttest questionnaires after each session as well as a semi-structured interview upon completion of all 8 sessions. The quantitative results were graphed and analyzed, and the interviews were transcribed, and thematic analysis was used to analyze the data.

Common themes that emerged from the interviews included (a) increased ability to think clearly and focus (b) increased ability to handle physical symptoms (c) increased relaxation (d) increased positive emotions (e) increased ability to handle stress (f) decreased negative emotions and (g) decreased anxiety. The study results suggest that there was a positive impact in the use of the BTS for PAWS. This was evident in 4 of the 6 PAWS symptom clusters including difficulty thinking clearly, difficulty remembering things, difficulty managing feelings, and stress sensitivity. There was little evidence that the BTS was effective in improving sleep quality or physical coordination. This is the first study to look at the impact of the BTS on PAWS. The results of this study indicate a need for further research regarding the use of the BTS for PAWS in substance use disorder treatment settings.

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## Chapter 1: Introduction

Over the past decade, substance use disorders have been on the rise, declaring it a national epidemic. The number of individuals suffering from addiction have increased nationally by 1% in the past decade to an astounding 25 million people in the United States (Substance Abuse and Mental Health Service Administration (SAMHSA), 2016). In 2013, the National Institute on Drug Abuse reported that the substance use crisis is costing our nation over \$740 billion annually. As the number of people with addictions increases, the need for effective treatment increases; thereby, leading to a need for medical professionals to seek the most effective methods for treating the active addiction, while also addressing the individual's need for sustaining long term recovery.

Unfortunately, addiction doesn't end with abstinence from drugs or alcohol. Post Acute Withdrawal Syndrome (PAWS) is a phenomenon defined by Terence Gorski (1986) as bio-psychosocial syndrome as a result of central nervous system damage due to substance dependence and the psychosocial stress of dealing with life without the use of drugs and alcohol. The symptoms of PAWS are divided into six different symptom clusters: difficulty thinking clearly, difficulty remembering things, difficulty managing emotions, difficulty sleeping restfully, problems with physical coordination, and stress sensitivity. PAWS may last 18-24 months, and the greatest risk PAWS presents is the potential for relapse due to the detrimental effects on an individual's physical, emotional, spiritual and mental wellbeing.

Kelly (1997) reported that substance abuse treatment programs have focused on a Minnesota model of treatment which includes psychological counseling and group support, typically the attendance at meetings of Alcoholics Anonymous or other similar 12-step fellowships. SAMSHA (2016) still reports that the most common modalities for treatment include cognitive behavioral therapy, motivational enhancement, and 12 step fellowships. While

these are “tried and true” methods of treatment, in past 20 years there has been a slight shift in treatment modalities, numerous studies have shown that complementary and alternative medicine practices have been effective in the treatment of substance dependence and the symptoms of PAWS (Horowitz, 2002; Kelly, 2009; Lake et al. 2009; SAMSHA, 2016). SAMSHA (2016) also reports that while these methods are effective, therapy must be tailored to the individual patient and to focus on the individual’s wellness needs: physically, emotionally, spiritually, and mentally. The National Institute of Drug Abuse (NIDA) reported in 2018 that drug addiction relapse rates range from 40-60% for all individuals who seek treatment, suggesting there may be a need for alternative treatment options for those seeking addiction support.

Gorski (2013) describes the multidimensional nature of substance dependence and the effects of Post Acute Withdrawal Syndrome on the whole person. The one-dimensional medical approach to substance dependence lacks support for its efficacy, leading to a need for alternative approaches to treatment for substance use disorders and PAWS. The National Institute of Drug Abuse (2018) explains that effective treatment addresses all the person’s needs, not just their drug or alcohol use. Using a bio-psychosocial approach, focusing on wellness, to treat substance dependence is gaining support as a result of the research indicating the widespread benefits on the reduction of relapse potential, cravings, and in PAWS symptoms. Recently, SAMSHA (2016) published an article recognizing the importance of treating the eight dimensions of wellness including emotional, environmental, financial, intellectual, occupational, physical, social, and spiritual aspects of the person’s life. The support from SAMHSA indicates there has been a shift in the treatment model for substance dependence, addressing it from a holistic approach rather than the one-dimensional medical model of treatment. Substance dependence and PAWS affect all areas of the individual’s life, thereby affecting their ability to heal without them being addressed as part of a comprehensive treatment plan. The use of integrative practices

may directly support the individual's emotional, spiritual, environmental and physical wellness, which may positively affect the individual's wellbeing and recovery process.

In response to the increased need for effective treatment, the founder of BioSound Healing, Rick Gallant, created a mind, body, and spirit approach to contribute to the field of substance dependence treatment through the development of the BioSound Therapy System (BTS), which integrates biofeedback, music therapy, meditation, and guided imagery into one cohesive unit. While the research on the efficacy of this treatment modality is limited, the research suggests that the integration of these complementary and alternative medicine practices into substance dependence treatment is highly effective (Froilán-Dávila, 2014).

The goal of this current study was to understand the impact of the BioSound Therapy System (BTS) on Post Acute Withdrawal Syndrome (PAWS) for clients with substance use disorders and who present with symptoms of PAWS at a day treatment and intensive outpatient treatment center. This mixed-methods, multi-case study research studied how the use of these modalities in conjunction with one another impact the normal course of the treatment and enhance the recovery process for clients with substance use disorders.

This research is relevant for substance use treatment because it offers new insight into the impacts and possible benefits of these particular complementary and alternative medicine (CAM) practices for treatment of PAWS. There have been two completed quantitative pilot studies addressing the efficacy of the BioSound Therapy system for substance use treatment, however, these studies did not include a qualitative assessment of the impacts of the system nor did they offer any understanding specifically related to the impact of Post Acute Withdrawal Syndrome (Froilán-Dávila, 2014). This current study offers practitioners a greater understanding of the impacts and benefits of the BTS and how the system may be able to decrease symptoms of PAWS and promote wellbeing and recovery. For treatment centers, the BTS is a relatively

inexpensive way of integrating multiple CAM practices into their treatment program and to have a positive impact on their clients' recovery process.

## **Chapter 2: Literature Review**

### **Post Acute Withdrawal Syndrome (PAWS)**

Post Acute Withdrawal Syndrome (PAWS) is a phenomenon defined by Terence Gorski (1986) as a bio-psychosocial syndrome as a result of central nervous system damage due to substance dependence and the psychosocial stress of dealing with life without the use of drugs and alcohol. The symptoms of PAWS are divided into six different symptom clusters: difficulty thinking clearly, difficulty remembering things, difficulty emotions, difficulty sleeping restfully, problems with physical coordination, and stress sensitivity. PAWS may last 18-24 months, and the greatest risk PAWS presents is the potential for relapse due to the detrimental effects on an individual's physical, emotional, spiritual and mental wellbeing. According to Gorski (1986), 75-95% of all recovering persons who were tested have brain dysfunction present. According to NIDA (2014), drug use can lead to significant changes in neurons and brain circuits, which can severely compromise the health of the brain. Research also suggests that these symptoms of long-term withdrawal associated with the alcohol and drug related damage to the brain might contribute to many cases of relapse (Gorski, 1986). NIDA (2014), also states that because of the brain disruption as a result of drug and alcohol use, a person's self-control and ability to make sound decisions is greatly compromised. When the symptoms of PAWS are left unmanaged, they have the potential to negatively affect the patient's withdrawal process and lead to relapse.

Froilán-Dávila (2014) suggests that clients in early recovery may experience physical changes such as high blood pressure and tension, as well psychological symptoms such as depression, anxiety, irritation, fear, restlessness, and feeling discontent. The client may also continue to experience drug cravings and these symptoms may result in relapse. A study by Uva, Luminet, Cortesi, Constant, Derely, and Timary (2010) suggest that PAWS effects selective attention, flexibility, state affectivity, decision-making, craving, and inhibition. Another study

by Baker, Japuntich, Hogle, McCarthy, and Curtin (2006) reports that while recent studies may suggest that drug withdrawal does not motivate drug use and relapse, the evidence presented in their study does suggest that because withdrawal is multidimensional, the likelihood of return to drug use is likely during the withdrawal period.

PAWS impacts an individual's ability to focus, think clearly, manage stress and emotions, therefore negatively impacting the ability to make improvements in these areas without additional support. Gorski (2013) describes the multidimensional nature of substance dependence and the effects of Post Acute Withdrawal Syndrome on the whole person. The one-dimensional medical approach to substance dependence lacks support for its efficacy, leading to a need for alternative approaches to treatment for substance use disorders and PAWS.

### **Complementary and Alternative Medicine Practices for Substance Use**

In 2002, Kelly reports that as a result of limited success with standard treatments for substance dependence, many treatment centers have begun using complementary and alternative medicine practices as a part of their program. This small shift in paradigm has led to numerous studies on CAM approaches that may be effective in the treatment of substance dependence. Some of the integrative approaches that may be beneficial include sound therapy, biofeedback, guided imagery and meditation. A study funded by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) suggests alternative methods of treatment may be beneficial to decreasing the risk of relapse, decreasing cravings and the symptoms of PAWS.

Lake and Spiegel (2006) indicate the use of these integrative approaches for substance dependence have been beneficial in reducing cravings, decreasing symptoms of withdrawal, and reducing the risk of relapse. Lake et al. (2006) addresses mindfulness meditation as an integrative approach to treatment for numerous psychiatric disorders. One study noted suggests that clients who experienced chronic anxiety had significant positive change in their lives

through the reduction of anxiety and panic as a result of participating in the study. The authors discuss the goal of meditation being to nurture and strengthen a person's ability to relax, become self-aware, gain insight and make positive behavioral changes. This study also reports that mindfulness meditation affects the sympathetic nervous system's fight-or-flight response and minimize the negative response. Lake et al. (2006) also explains that the use of meditation is beneficial for client with depression. The authors also describe the therapeutic benefits of meditation including the person's ability to change the affective and bodily experience during times of stress, shifting the person's ability to see feelings as interim rather than reality. This book also discusses the overall safety of nonbiological alternatives such as guided imagery, biofeedback, and massage. All these approaches are considered generally safe. This book is important to the topic of integrative approaches because it describes their benefit on symptoms often experienced with Post Acute Withdrawal Syndrome including anxiety, depression, difficulty managing emotions, increased fight-or-flight response, and the ability to relax and gain self-awareness and insight.

LaFave, L., Desportes, L., McBride, C. (2009) explain current trends in substance abuse treatment, as well as the use of evidence-based models and abstinence-based programs such as Alcoholics Anonymous. This article focuses on establishing coping strategies for women with substance abuse, the development of personal empowerment, and the ability to make life changes based on the development of effective coping and interpersonal skills. Ultimately, this is accomplished by improving life functioning through development of skills, insight, and self-efficacy. The qualitative results indicate the women in this strength-based program recognized they had choices, felt empowered, and learned how to have healthy relationships through healthy detachment, resolving ambivalence about using substances, accepting responsibility, expressing feeling, and placing higher value on themselves. It is suggested that through a strength-based

program, women are able increase self-esteem, make better choices and have the ability to develop healthy relationships. This study is important in addressing an alternative model of treatment, giving therapists responsibility for developing flexible treatment approaches to help engage and motivate clients for treatment and building their skill set to achieve recovery and increase likelihood for maintaining abstinence. According to LaFave, L., Desportes, L., McBride, C. (2009) research suggests the importance of alternative methods of treatment to focus on a flexible, integrative, strength-based approach to healing, facilitating growth and self-efficacy for clients.

### **Biofeedback**

To begin a BTS session, the participant uses Heart Rate Variability (HRV) biofeedback with the goal of improving coherence and learning self-regulation techniques through the use of breath. The Association of Applied Physiology and Biofeedback (2018) describes biofeedback as a process that allows an individual to learn how to change their physiological activity to improve their health and wellbeing. Specific instruments measure physiological activity such as brainwaves, heart function, breathing, muscle activity, and skin temperature. These instruments immediately "feedback" information to the user. This "feedback", usually in addition to therapeutic processes to change thinking, emotions, and behavior, support physiological changes. The goal of biofeedback is that through practice and over time, these changes may be maintained without the use of the specific instrument.

The first major biofeedback tool, the electroencephalograph, was developed in the 1920's and it was Dr. Kamiya's landmark study in 1969 that made biofeedback known in the United States as an effective tool for mental health treatment. Dr. Kamiya demonstrated the standard phases of the feedback loop: recording the physiological function with the EEG, providing positive reinforcement to clients by informing them each time the desired pattern was achieved

and ultimately, clients having the ability to achieve this desired pattern on their own (Horowitz, 2006). Research suggests that EEG patterns of clients with substance dependence differs widely from the non-addicted population (Sokhadze, Cannon, Trudeau, 2008). According to Sokhadze et al. (2008) the research suggests that EEG patterns may be able to predict clients with substance dependence that may be risk for relapse. The study indicated that relapse was predicted with 83-85% success. The results of this study suggest a greater sense of relaxation, an increase in personal insight, and a decrease of anxiety from the use of EEG biofeedback. The research also suggests the use of EEG biofeedback may increase cognitive functioning. According to Horowitz (2006), biofeedback is effective in treatment for substance dependence as a result of significant improvement on the Test of Variables of Attention and increased client retention rate following the use of biofeedback. Among the participants in this study, 77% maintained abstinence at 12 months compared to 44% with the control group. The results indicated an increase in operant conditioning, relaxation and self-regulation. These studies imply there may be a benefit to utilizing biofeedback techniques with clients suffering from substance dependence and may decrease symptoms of PAWS.

Khatami, M., Woody, G., O'Brien, C., & Mintz, J. (1982) performed a double-blind study on EMG biofeedback for 37 narcotic addicts in an outpatient methadone clinic. Patients were evaluated using the Beck Depression Inventory, anxiety checklist, withdrawal sickness rating, Hamilton Depression Scale, Hamilton Anxiety Scale, and BPRS. Each patient completed 15 biofeedback sessions, five sessions per week for thirty minutes. The results indicated that all psychiatric ratings of anxiety, depression, and psychopathology were significantly reduced. Self-reported craving for narcotics and self-rated anxiety were also reduced. Results also reported a decrease in drug seeking behaviors, physical symptoms, and sickness. One month follow ups

indicated that 75% of the experimental patients had reported remaining abstinent while 43% of the control group had reported abstinence.

Du, Fan, Jiang, Sun, Li, & Zhao (2014) tested 45 participants to determine if cue-exposure therapy (CET) combined with biofeedback therapy could decrease cravings and physiological reactivity to drug related cues. Craving was assessed using a 100-point visual analog scale and skin conductance (SC) and muscle electromyography (MEG) were recorded with a biofeedback device. Results indicated a reduction in cravings and lower SC and MEG following two months of treatment.

Scott, Kaiser, Othmer, & Sideroff (2005) examined whether EEG biofeedback may improve treatment outcomes for a mixed substance abusing inpatient population. Patients were evaluated using the Test of Variables of Attention (TOVA) and the MMPI. 121 volunteers in inpatient treatment were randomly assigned to EEG biofeedback or control groups. The participants received 40 to 50 biofeedback sessions training Beta and SMR to address attentional variables. Researchers compared treatment retention and abstinence rates as well as psychometric and cognitive measures for the test and control groups. Results reported an average of 138-day length of stay for experimental subjects and 101 days for the control group. Results also indicated 77% of experimental subjects were abstinent after 12 months, while only 44% of the control subjects were abstinent. Results also indicated an improvement in focus, attention, and impulsivity.

Research suggests that EEG patterns of clients with substance dependence differs widely from the non-addicted population (Sokhadze, Cannon, & Trudeau, 2008). According to Sokhadze et al. (2008) the research suggests that EEG patterns may be able to predict clients with substance dependence that may be at risk for relapse. The study indicated that relapse was predicted with 83-85% success. The results of this study suggest a greater sense of relaxation, an

increase in personal insight, and a decrease of anxiety from the use of EEG biofeedback. The research also suggests the use of EEG biofeedback may increase cognitive functioning.

Trudeau (2005) found that specific patterns of QEEG abnormality associated with substance use toxicity suggested underlying brain pathology that may be amended through the use of individualized brainwave biofeedback and could be used in conjunction with classic alpha-theta training. Trudeau (2005) reviewed literature that focused primarily on alpha-theta biofeedback that measures the occipital alpha (8-13 Hz) and theta (4-8 Hz) and feedback by separate auditory tones for each frequency representing amplitudes greater than pre-set thresholds. Research suggests that the use of this protocol may elicit a relaxation response. Other protocols reviewed used autogenic phrases to facilitate relaxation. While research was limited at the time of this review, Trudeau suggested the use of EEG biofeedback may improve substance use treatment outcomes (2005).

While there is limited research on the use of HRV biofeedback for substance use disorders, there is evidence to suggest that the use of biofeedback is effective in improving relaxation, self-regulation, and decreasing cravings, thereby improving symptoms of PAWS.

### **Sound Therapy**

The BTS integrates sound therapy through the use of Binaural Beats during the 30-minute sound massage portion of the session. The word binaural means “having or relating to two ears”. Binaural Beats is the process by which two different sound waves are sent to each ear through headphones. Brainwave entrainment happens inside the brain and is caused by a physiological response. Upon hearing two tones of different frequencies – sent simultaneously to the left and right ears – the brain perceives a third tone based on the mathematical difference between the two frequencies. The brain then follows along at the new frequency and produces brainwaves at the same rate of Hertz (Hz) for the purpose of creating an emotional or

physiological response such as increasing relaxation, increasing focus, or reducing stress (Binaural Beats Meditation, 2018).

According to Froilán-Dávila (2014), music therapy has been used a healing technique since biblical times in civilizations such as Egypt, China, India, Greece and Rome. Music therapy was introduced to the United States in the late 18<sup>th</sup> Century and was further developed during World War I and World War II, when music therapy was used in Veterans Administration Hospitals as a modality for the treatment of traumatic war injuries. According to Morse, Giordano, Perrine, Downs, Waite, Madigan, Bailey...Blum (2011) sound therapy strongly modulates activity in a network of mesolimbic structures involved in reward processing. This research found that clients who utilized sound therapy showed significant improvement in ten withdrawal symptoms including stress, depression, cravings, mood swings, anxiety, resentment, anger, fear, body aches, and headaches.

Other studies suggest that sound therapy has a positive effect on dopamine, eliciting a response on the pleasure center of the brain as well as minimizing the stress response and elicits an endorphinergic response (Morse et al. 2011). According to Morse et al. (2011), it is known that drug seeking behavior is related to low dopamine receptors and music therapy strongly modulates activity in the mesolimbic structures involved in reward processing as well as the hypothalamus and insula, which are thought to facilitate regulation of the autonomic and physiological responses to reward and emotional stimuli. This research indicates the use of music therapy will be beneficial in the treatment of PAWS symptoms and decrease drug-seeking behaviors. Music therapy may also reduce the risk for relapse through an improved emotional and physiological response to environmental and emotional stressors and triggers related to drug craving and drug seeking behaviors.

The following research explains the correlation between sound therapy, binaural beats, and meditation, which are key components of the BTS. A review of literature regarding meditation follows this section. In a study by Lavallee, C., Koren, S., and Persinger, M. (2011), the research assesses the quantitative electroencephalographic correlates of meditation and the effects of facilitative and hindering binaural beats on the meditative process. The results indicated that beginner meditators were not able to maintain certain levels of  $\theta$  power in occipital regions when hindering binaural beats were presented and when facilitative binaural beats were presented, the experienced meditators were able to display increased  $\theta$  power in the left temporal lobe. This research suggests that experienced meditators have developed ways to counter the hindering environmental stimuli when beginners have not yet developed this ability.

The article by Lavallee et al. (2011) suggests that continued meditation practice with the use of binaural beats allows clients to reach deeper meditative states and helps them to block out external stimuli; these external stimuli can often be the cause of triggers for drug or alcohol use (Froilán-Dávila, 2014). This implies that a regular meditative practice may benefit the clients' recovery process and decrease the symptoms of PAWS.

## **Meditation**

The goal of the sound therapy and massage portion of the BTS is to induce a meditative state to facilitate the healing process. The following section describes how meditation is effective for substance use recovery and improving overall wellbeing. Meditation has a long recorded history in many Eastern cultures including Hindu and Buddhist and gained popularity in the United States in the mid-20<sup>th</sup> century (Froilán-Dávila, 2014). Horowitz (2010) suggests that there are numerous health benefits to meditation including improved cardiovascular health, chronic pain, menopausal symptoms, HIV/AIDS, cancer, substance abuse and psychological trauma. In 1979, Jon Kabat-Zinn, PhD., developed the Mindfulness Based Stress Reduction

(MBSR) program that has been shown to assist in overcoming negative thought patterns that effect emotions and pain perception (Horowitz, 2010). MBSR has also been shown to reduce anxiety, ruminative thoughts, and increase self-compassion. A study by Temme, Fenster, and Ream (2012) reports that meditation is highly effective in decreasing negative mood states as well as decreasing the risk of relapse in chemically dependent clients. According to Horowitz (2010), practicing meditation helps induce relaxation states that produce changes in the autonomous nervous system as well as effect cognitive restructuring, learning, and changes in the structure of the brain. This research suggests that meditation will be highly effective in treatment for PAWS symptoms as a result of the impact on the client's physical and emotional state. The effect that meditation has on the nervous system is beneficial in treating each of six clusters of symptoms associated with PAWS including difficulty thinking clearly, difficulty remembering things, difficulty managing emotions, difficulty sleeping restfully, problems with physical coordination, and stress sensitivity.

Temme, L. J., Fenster, J., & Ream, G. L. (2012) focus on the effects of meditation in substance abuse treatment. The results indicate clients who were utilizing meditation practices had a decrease in negative mood and a decrease in relapse warning signs. This research also indicates a correlation between negative mood and the increased risk of relapse. Temme et al. (2012) suggest that meditation facilitates the client's ability to self-regulate behavior and emotions. Social pressure, cravings, and negative mood are all factors that lead to relapse and the research suggests meditation could have a positive impact on these factors, therefore decreasing the risk of relapse.

## **Massage**

The BTS integrates sound therapy with a vibrational massage for a 30-minute session following the use of biofeedback. According to Gorski (1986), deep relaxation may be helpful in

reducing the stress often related to early sobriety. Deep relaxation is a way to relax the mind and the body to reduce stress and develop a sense of wellbeing (p. 63). This deep relaxation helps facilitate rebalancing the body and minimizing the production of stress hormones; deep relaxation also relieves thought-process impairments, emotional-process impairments, memory impairments, and stress sensitivity. These studies have indicated that the use of complementary and alternative medicine practices such as massage therapy have been effective in the treatment of substance use disorders and PAWS symptoms.

According to Knaster (1996), massage has been used by massage professionals, medical professionals, midwives, sports trainers, shamans, and teachers of dance and martial arts during pregnancy, healing ceremonies and in the treatment of psychological disorders (p. 143). While the relationship between massage and psychology has not always been clear, many of the pioneers of psychotherapy advocated for the use of massage as a treatment for psychological disorders at one point in their careers (Rich, 2010). Research has suggested that the use of massage therapy has been associated with positive effects on the reduction of pain, anxiety, and depression (Rich, 2010).

Although there has been limited research on massage therapy and its benefits on substance use disorders, much of the work has focused on the benefits of massage relating to stress, anxiety, depression, immune function, pain and neuromuscular conditions, attention and cognitive factors, and lifespan developmental factors (Rich, 2010). Research suggests that therapeutic massage induces a relaxation response, increases blood and lymphatic circulation, increases endogenous endorphin release, potentiation of analgesic effects, decreases edema, and releases muscle spasms (Rich, 2010). The work that has been done has focused on the symptoms of PAWS and has been helpful in bringing massage therapy to treatment centers as an integrative approach to substance use disorder treatment. The Homewood Health Center in Guelph, Ontario

has utilized massage therapy in its addiction recovery program since 1994. A registered massage therapist, Chris O'Connor states the following;

This is a nice way for them to nurture themselves and focus more on their body, many people addicted to substances aren't paying attention to that, so it lets them reconnect...massage gets people back in touch with their bodies and helps them understand why certain things might be going on with their bodies that they don't have a grasp on (Loria, 2013).

A Meta-analysis of 37 studies of massage therapy by Moyer, Rounds and Hannum (2004) found that therapeutic massage might alter autonomic nervous system activity, decreasing sympathetic activity and increasing parasympathetic activity which suggests a relaxation response and decreased stress. This meta-analysis also found that single applications of massage therapy reduced state anxiety as well as trait anxiety, pain, and depression with multiple treatments. The authors also found a reduction in heart rate and blood pressure for a single session of massage therapy. Sixty-four percent of the participants receiving massage found a reduction in state anxiety over those receiving the comparison treatment. Seventy-three percent of the participants experienced a reduction of depression following the massage treatment. Moyer et al. (2004) concluded that reductions of trait anxiety and depression were massage therapy's largest effects, with a course of treatment providing benefits similar in magnitude to those of psychotherapy.

As cited in Rich (2010), another review of 25 studies of massage therapy by Moraska, Pollini, Boulanger, Brooks, and Teitlebaum (2008) found that single treatments reduced salivary cortisol and heart rate. Some of the evidence in these studies pointed to a positive impact on diastolic blood pressure. Rich (2010) also cites several studies that explored the effects of chair massage on stress and anxiety reduction. The authors found significant reductions in both state

and trait anxiety levels in those who received massage therapy. They also discovered that those who received massage had greater decreases in blood pressure.

A pilot study by Black, Jacques, Webber, Spurr, Carey, Hebb, & Gilbert (2010) aimed to investigate the effectiveness of chair massage for reducing anxiety in individuals participating in an inpatient withdrawal management program for psychoactive drugs. This was the first study focused on the effects of chair massage for patients withdrawing from psychoactive drugs. This randomized, controlled clinical trial studied 82 adult patients withdrawing from alcohol, cocaine and opioid painkillers. Forty of the patients received a 20-minute back, shoulder, neck and head massage from the same massage therapist. The control group participated in a 20-minute relaxation session in the same room with the same lighting and music. The results of this study found that the chair massage was far superior to the relaxation control treatment in reducing anxiety for patients during drug withdrawal. The effects were immediate and state anxiety was sustained, at least partially, for 24 hours. There was no sustained decrease in anxiety among subjects in the relaxation control group. Black et al. (2010) states,

By improving the experience of the withdrawal process and providing patients a wider range of approaches to manage the way that they feel...chair massage may help retain patient within service areas and improve overall wellness.

Reader, Young & Connor (2005) studied the use of massage therapy as an adjunct to standard alcohol detoxification procedures in 50 adult patients with alcohol dependence. Twenty-five patients received a fully clothed, seated 15-minute back, shoulder, neck and head massage at bedside for four consecutive days. The experimental group rested on their bed or at bedside for 15-minute intervals. This study used the Alcohol Withdrawal Scale (AWS) and a free response questionnaire to assess the advantages and disadvantages of the patient's detoxification experience. The results suggested a decrease in systolic and diastolic blood

pressure, heart rate and increase in skin temperature. The results also indicated a reduction in pulse rate on three of the four days of the massage treatment. Massage also significantly contributed to changes in the AWS score early in the detoxification admission and to respiratory function at the end of detoxification. The results suggested that the strongest impact of massage on AWS scores and pulse rate was post massage on day one. The participants reported feeling more engaged in the treatment process as a result of feeling supported and safe. The participants also reported an increased appetite.

Rich (2010) cites a study by Field, Grizzle, Scafidi & Schanberg (1996) that investigated the effects of massage on depression. The study participants received a 30-minute massage on two consecutive days per week for five weeks. The comparison group received relaxation therapy including yoga and progressive muscle relaxation. The results suggested that massage therapy group were less depressed based on self-reports and behavioral observations than those in the comparison group. The results also reported that massage therapy recipients had lowered urinary cortisol levels and higher serotonin levels, suggesting a reduction in stress as well as depression. Another study by Fields (2006) found massage therapy participants had reduced urinary cortisol and norepinephrine levels.

Based on the meta-analysis by Moyer et al. (2004), while massage therapy did not reduce pain immediately after one treatment, there was noted reduction in pain levels following multiple massage therapy sessions. The multiple massage treatments were also associated with a reduction of delayed assessment of pain. Research found significant support for the analgesic effects of massage therapy for low back pain and moderate support for analgesic effects on shoulder and headache pain. Research also suggests that massage therapy may have an effect on pain as a result of improvement in sleep patterns as sleep deprivation is linked to an increase in pain. Rich (2010) also notes that another study by Preyde (2000) found that participants who

received massage treatment had a reduction in pain. The study found that after a one month follow up, 63% of participants in massage therapy group reported no pain. The research findings suggest that massage therapy is effective in reducing pain, anxiety, and depression and that the use of massage therapy in treatment programs may enhance the patient's health and wellbeing (Rich, 2010). Black et al. (2010) found that the use of chair massage may be especially beneficial for this particular patient population, through the reduction of anxiety, improving the patients' feelings of wellbeing and also helping to improve their physical health. According to Black et al. (2010) the findings in this study were independent of age, gender, education, or primary presenting problem, which suggests that the results of this study can be generalized to the population who utilizes withdrawal management services.

Research by Reader et al. (2005) also suggests that the use of massage therapy for the addicted population would be beneficial. The chair massage lowered heart rate and blood pressure and positively impacted the patient's Alcohol Withdrawal Scale scores. The Alcohol Withdrawal Scale assesses anxiety, agitation, and tactile, auditory, and visual disturbances. This suggests that massage treatment may be helpful in minimizing the symptoms of PAWS, if used on a regular basis.

Based on the research findings from Moyer et al. (2004) state anxiety, trait anxiety, pain and depression may be reduced through massage therapy. These findings suggest that massage therapy may alter the autonomous system, which is responsible for assisting in the function of all internal organs. If massage therapy can decrease sympathetic nervous system activity and increase parasympathetic activity, then it could be suggested that the use of massage may be beneficial in minimizing the symptoms of PAWS by regulating the body to function more effectively.

## Imagery

While the BTS participant is in a meditative state following the sound massage portion of the session, imagery is used to instill positive affirmations and promote improved overall wellbeing. Visualization was developed from hypnosis and does not assumed an altered state, which has been shown useful for those resistant to hypnosis (Kominars, 1997). According to Kominars (1997), visualization is learning to think with a guide. Visualization has been used in many treatment programs as part of a multimodal approach with varying results. The work of Kominars (1997) was to demonstrate the benefits of using visualization in substance dependence treatment. While the results of this study suggest further research was needed to demonstrate the effectiveness of visualization, Froilán-Dávila (2014) found that guided imagery was beneficial in helping client's focus, be in the present moment, and improve their overall sense of wellbeing. Qualitative research indicates that guided imagery facilitates calming of the mind, focus, decreasing negative emotions and thoughts, decreases anxiety and increases relaxation. The research implies that symptoms of PAWS may be decreased through the use of guided imagery.

Studies have implied a clear connection between guided imagery, the functioning of the immune system, and stress and relaxation. Trakhtenberg (2008) suggests that stress and relaxation may account for the changes in white blood cell counts, leading to changes in the immune functioning. As individuals experience more stress related events or have heightened awareness of stress, due to the absence of drugs or alcohol, their immune system functioning decreases. This immune suppression leads to the physiological symptoms experienced during Post Acute Withdrawal. A study by Johnsen and Lutgendorf (2001) investigated whether imagery was related to psychological and physiological responses to stress and relaxation. This study assessed the stress and relaxation responses of 176 participants following two sessions of imagery. The research suggested that individuals who used imagery were experiencing

decreased levels of stress and increased relaxation as well as physiological changes. While chronic stressful events negatively impact the immune system, the use of guided imagery has been shown to increase relaxation, reduce stress, reduce emotional suppression, decrease mood disturbances, and increase the quality of life (Eremin, Walker, Simpson, Heys, Ah-See...Walker, 2008). Eremin et al. (2008) studied 80 women undergoing multimodality treatment breast cancer that utilized relaxation training and guided imagery during their treatments. The research found that the relaxation training and guided imagery beneficially altered putative anti-cancer host defenses during and after their therapy. Another study performed by Eremin et al. (2008) assessed the psychosocial effects of relaxation and guided imagery in 96 women with advanced breast cancer. The results indicated that those using relaxation and guided imagery were more relaxed, easy going, experienced a greater quality of life and reduced emotional suppression than those who did not receive this therapy.

As these studies have suggested, the use of imagery plays an important role in decreasing stress and increasing relaxation, which facilitates the regulation of the immune system to support improved physical wellbeing for individuals with PAWS. In response to these results, many programs use imagery as part of a multimodal approach to substance use treatment. The increased physical wellbeing improves quality of life and allows for individuals recovering from addiction to focus their energy on psychological wellbeing to increase their likelihood of maintaining abstinence.

## **Chapter 3: Methods**

### **Introduction**

This mixed-methods, multi-case study research studied how the use of the BTS impacted PAWS for participants in a substance use day treatment and intensive outpatient program. This study used the Positive and Negative Affect Scale (PANAS), Perceived Stress Scale (PSS-10), and the BioSound Technologies Pre/Post Test, as well as a semi-structured interview to understand the participant's experience with the BTS, whether there were any changes in positive and negative affect, perceived stress, and overall wellbeing.

### **Background**

Post Acute Withdrawal Syndrome (PAWS) is a phenomenon defined by Terence Gorski (1986) as a bio-psychosocial syndrome as a result of central nervous system damage due to substance dependence and the psychosocial stress of dealing with life without the use of drugs and alcohol. The symptoms of PAWS are divided into six symptom clusters: difficulty with thinking clearly, difficulty remembering things, difficulty managing emotions, difficulty sleeping restfully, problems with physical coordination, and stress sensitivity. PAWS may last 18-24 months, and the greatest risk PAWS presents is a potential for relapse due to the detrimental effects on an individual's physical, emotional, spiritual and mental wellbeing.

Froilán-Dávila (2014) suggests that clients in early recovery may experience physical changes such as high blood pressure and tension, as well psychological symptoms such as depression, anxiety, irritation, fear, restlessness, and feeling discontent. The client may also continue to experience drug cravings and these symptoms may result in relapse. When these symptoms are left unmanaged, they have the potential to negatively affect the patient's withdrawal process and potentially lead to relapse.

## **Rationale**

The goal of this research was to study the impact of the BioSound Therapy System (BTS) on Post Acute Withdrawal Syndrome (PAWS) for clients with substance use disorders and who present with symptoms of PAWS at a day treatment and intensive outpatient treatment center. This research looked to understand participants experiences with the BTS and how it impacted PAWS as well as study how the use of biofeedback, sound therapy, massage, meditation, and imagery in conjunction with one another impact the normal course of the treatment and enhance the recovery process for clients with substance use disorders.

PAWS impacts an individual's ability to focus, think clearly, manage stress and emotions, therefore negatively impacting the ability to make improvements in these areas without additional support. Numerous studies have indicated the use of complementary and alternative medicine practices such as guided imagery, meditation, sound therapy, and biofeedback have been effective in the treatment of PAWS symptoms and substance dependence (Lake, 2009; Horowitz, 2002; Kelly, 1997). Support from SAMHSA indicates there has been a shift in the treatment model for substance dependence, looking at the whole person, rather than just the disease or symptoms. As a result of this evidence, BioSound Technologies has developed a system utilizing these complementary and alternative medicine practices simultaneously, which may prove even greater efficacy than utilizing these approaches independently.

In 2010, the founder of BioSound Technologies, Rick Gallant, created a mind, body, and spirit approach to contribute to the field of substance dependence treatment through the development of the BioSound Therapy System (BTS), which integrates biofeedback, music therapy, meditation, and guided imagery into one cohesive unit. The BTS is a vibrational platform constructed with memory foam and integrated with an audio/visual delivery system.

The BTS utilizes choreographed music that is synchronized with low frequency sine tones and binaural beats to induce a meditative state. There are many benefits the participant may receive from using the BTS. One of the major benefits is the calming effect the system has on the participants. The concept of the system is to help the participant with the racing thoughts, anxiety, or Post Acute Withdrawal Syndrome symptoms they may be experiencing by utilizing music therapy and massage to bring them into a meditative state. The guided imagery selections on the BTS are designed to address the guilt, fear, shame, and trauma associated as underlying issues many individuals with substance use disorders experience. The BTS offers guided imagery that focuses on addressing these underlying issues by guiding the individual to viewing themselves in a positive and healing light, rather than from a place of fear, guilt, shame, or trauma. Following the guided imagery session, an inspirational video offering positive affirmations will be played for the participant to complete the session. A heart-rate variability (HRV) biofeedback program (HeartMath) is also utilized at the beginning and end of the session, with the goal of teaching the participant self-regulation and breathing techniques they can utilize to help them manage their emotions (Froilán-Dávila, 2014).

This research is relevant for substance use treatment because it provides new data and provides a model for furthering research that focuses on the benefits of the BTS as a holistic approach to treatment for substance use disorders and the associated PAWS. The BTS has been used for several years as a part of holistic treatment centers around the country and has been shown to be a relatively inexpensive way of integrating multiple CAM practices into their treatment program as well as have a positive impact on their clients' recovery process (Froilán-Dávila, 2014).

## Study Design

The goal of this research was to study the impact of the BTS on PAWS as no other BTS study has addressed PAWS. Four individuals participated in the study by completing the BTS intervention with this researcher, a Licensed Clinical Addiction Specialist and Certified Addiction Professional, in addition to their usual treatment under the supervision of the program's Clinical Director, a Licensed Professional Counselor, as well as the program's Medical Doctor. The participants completed a series of pretests prior to each session (the Positive and Negative Affect Scale (PANAS), Perceived Stress Scale (PSS-10), and the BioSound Technologies Pre/Post Test), assessing positive and negative affect, perceived stress, and overall wellbeing. Participants then completed 8 sessions (over 4 weeks) using the BTS. Typically, insurance providers limit the length of stay at partial hospitalization to 4 weeks as the long as the client is making progress based on the American Society of Addiction Medicine (ASAM) standards of care. Since the average length of stay in a partial hospitalization program is about 4 weeks, this study was limited by the duration of treatment at this level of care. Each participant also completed posttest assessments (the Positive and Negative Affect Scale (PANAS), Perceived Stress Scale (PSS-10), and the BioSound Technologies Pre/Post Test) and subjective questionnaires following each session. Following the completion of the 8 sessions, each participant completed a semi-structured interview. Due to the depth of analysis, this study limited the number of participants to 4, thus ensuring ample time with each participant to gather a thorough understanding of their individual experience with the BTS. Many of the other studies reviewed for this research that used these CAM methods have been quantitative in nature and have included 25 or more participants (Froilán-Dávila, 2014; Reader, Young & Connor, 2005; Scott, Kaiser, Othmer, & Sideroff, 2005), however, those studies that were qualitative in nature only included 8 or less participants (LaFave, L., Desportes, L., McBride, C., 2009). Because this

study was also exploratory in nature, it was suitable to limit the number of participants to ensure this study design was appropriate and could be easily duplicated in further studies.

BTS uses an electronic data collection system using a tablet to collect pre- and post- data, however, for the purpose of this study the data was collected in paper format because the facility used to conduct the study did not have the electronic version of the BTS pre/posttest, therefore it was most appropriate for the ease of data collection to complete all pre and posttests on paper. The data was collected using a Likert scale assessing the symptoms of PAWS (overall wellbeing questionnaire) and had the option to add subjective comments for qualitative data as well. The data was stored in a locked room. Upon completion, the data was exported to Excel; averages, and improvements were noted during the data analysis.

An interview at the end of the 8 sessions assessed, from the participants' perspective, the impact of the BTS. These interviews looked at the pre and post symptomology such as perceived stress, anger, fear, anxious or depressed mood, body aches, muscle tension and headaches, as well as which components (biofeedback, sound massage, guided imagery) were most effective for them over the course of the 4-week treatment.

### **Specific Aims**

Specific Aim 1: To perform an 8-session multiple case study series with 4 adult women diagnosed with substance use disorders and experiencing symptoms of PAWS using the BioSound Therapy System (BTS) for positive and negative affect with a pre/posttest using the Positive and Negative Affect Schedule (PANAS).

Hypothesis 1: 8 sessions with the BTS will improve positive and negative affect.

Specific Aim 2: To perform an 8-session single case study series with 4 adult women diagnosed with substance use disorders and experiencing symptoms of PAWS using the BTS for perceived stress with a pre/posttest using the Perceived Stress Scale (PSS-10).

Hypothesis 2: 8 sessions with the BTS will decrease perceived stress.

Specific Aim 3: To perform an 8-session single case study series with 4 adult women diagnosed with substance use disorders and experiencing symptoms of PAWS using the BioSound Therapy System for overall wellbeing (mood, sleep, daily activities, physical and overall health) with a pre/posttest using the BioSound Technologies Pre/Post Test.

Hypothesis 3: 8 sessions with the BTS will improve overall wellbeing.

### **Inclusion/Exclusion Criteria**

- The study population consisted of women from the sample population who agreed to participate and met eligibility criteria, including: primary diagnosis of Substance Use Disorder, currently and willing to continue receiving psychotherapy services, age 18-65, and co-occurring self-reported mental disorders including PTSD, depression, bipolar disorder (without psychotic features), and anxiety were included.
- Additional exclusion criteria included active suicidal ideation, active psychosis, current or history of seizure disorder, pregnant, and history of moderate to severe brain injury.

### **Enrollment/Randomization**

Willow Place for Women, Asheville, North Carolina gave this researcher permission to utilize its facility and client base for research purposes. Five participants were chosen from the center's client base, only 4 participants completed the study. Women were offered the opportunity to volunteer for participation; they were asked to complete an informed consent and HIPAA form, basic demographic form, and answer pre-screening questions. Based on their

qualifying information, they were selected to participate and enrolled with this researcher using paper forms that were stored in a private office with a locked door.

The informed consent and HIPAA were obtained prior to screening. Demographics and screening information were also obtained. Demographic, screening, Informed Consent, and HIPAA forms are included in the appendices.

### **Summary of Study Procedures**

This summary provides an overview of the study procedures in chronological order. After this summary, a detailed explanation of the study procedure follows.

1. Complete Informed Consent and HIPAA Authorization with Potential Participants
2. Complete screening assessment for each potential participant
3. Select participants based on screening assessment
  1. Assign Study number for each participant
  2. Schedule participants for 2 (1.75 hour) sessions weekly for 4 weeks and for one 1.5-hour long Interview
4. All Participants complete pre-test PAWS symptom scales – PANAS, Perceived Stress Scale, and BTS pre/posttest – 2x weekly
5. Perform 1.25-hour long session with each BTS participant 2x/weekly for 4 weeks
  1. Complete a 5-minute HRV biofeedback session using HeartMath to measure heart rate variability coherence which can indicate levels of stress and participants ability to regulate their breath and heart rate (as a measure of stress management)
  2. Complete an hour-long playlist on BTS including 30 min sound massage and 30-minute guided imagery and affirmations
  3. Complete 5 min HRV biofeedback session using HeartMath

6. Complete posttest assessments after each BTS session, reviewing symptoms and any subjective comments (comments section of the BTS pre/posttest) regarding the session and the symptoms
7. Upon completion of the 8 sessions, a qualitative assessment was completed to gather participants subjective experience on the BTS and impact on symptoms of PAWS. (See Attached Questions)
8. Using the collected data, analyze each participants' results of the study (Further described in Section 10.0)

1. Quantitative Data

- Descriptive Statistics of total scores for each survey- PANAS, PSS-10, and BTS Pre/Posttest

2. Qualitative Data

- Framework Thematic Analysis – method of analysis used to develop a thematic framework, develop textual codes to identify specific information that corresponds to the different themes identified, chart each theme and then map and interpret the patterns, associations, and explanations found within the themes.
- Themes such as thoughts, processes, or behaviors will be used to understand the impact of the BTS
- Report using Analytical Approach – explaining and describing results based on aforementioned thematic framework

## **Outcome Variables**

This study used the Positive and Negative Affect Scale (PANAS), Perceived Stress Scale (PSS-10), and the BioSound Technologies Pre/Posttest, to assess the participant's experience

with the BTS, whether there were any changes in positive and negative affect, perceived stress, and over wellbeing.

**Positive and Negative Affect Scale.** According to Watson (1988) reliability and validity was moderately good for the Positive and Negative Affect Scale. Over an 8-week time period, the test-retest correlations were 0.47-0.68 for the PA and 0.39-0.71 for the NA. The PANAS has strong reported validity with measures such as general distress and dysfunction, depression, and state anxiety.

**Perceived Stress Scale.** According to Cohen et al. (1983), the internal consistency reliability of the PSS-10 has been established. The PSS measures general stress and is not specific to any particular population; however, the PSS has been used in the substance use population (Tavolacci, 2013). According to Gorski (1986), stress sensitivity is increased during Post Acute Withdrawal and can increase the individual's likelihood of returning to substance use.

**BioSound Technologies Pre/Posttest.** While the BioSound Technologies Pre/Posttest has not been validated, it has been used with the substance use population to assess changes in PAWS symptoms including perceived stress, anxious or depressed mood, fear, anger, and self-reported physical symptoms including body aches, muscle tension, and headaches (Froilán-Dávila, R., 2014). This researcher is assessing the aforementioned because Post Acute Withdrawal Syndrome affects each of these areas for 18-24 months post abstinence (Gorski, 1986). Once collected and analyzed, this information will help to determine the potential uses for the BTS in substance use treatment centers.

### **Data Analysis Procedures**

This mixed methods study used descriptive statistics to analyze the quantitative data collected from the PANAS, PSS-10, and the BTS Pre/Posttest as well as a Framework Thematic

Analysis to analyze the qualitative data collected from the semi-structured interview questions after the completion of the 8 BTS sessions.

After the completion of each session, participants completed the PANAS, PSS-10, and the BTS Pre/Posttest. At the end of the 8 sessions, each participant's scores were graphed to determine any changes in Positive/Negative Affect, Perceived Stress, and Overall Wellbeing. Because the BTS Pre/Posttest measures 8 different variables, each variable was graphed to provide a greater understanding of the impact on each symptom noted in this survey. After each score was noted and graphed, mean, median, standard deviation, and range was calculated. These scores are reported in a chart to identify any changes in symptoms from before and after the intervention.

After the completion of the 8 BTS sessions, a semi-structured interview was conducted to gather subjective experience from the participants. The qualitative questions are included in the appendices. Each participant was asked about their overall experience with the BTS as well as any changes they may have noted throughout the process. Each survey was reviewed to discuss the noted changes in scores over the course of the 8 sessions. This researcher identified themes or patterns in thoughts, processes, and behaviors that the participants may have experienced during the study. Patterns and themes were determined initially by whether there are any commonalities in the responses to each of the interview questions for each participant. Then, this researcher identified whether there are commonalities among the participants, for example, if all the participants noticed changes in their mood or their energy levels or if they all felt more relaxed after the sound massage session. After reviewing for answers that were common throughout the interview, this researcher looked for similarities in responses that may be noteworthy as another possible theme. Using as much detail as possible from the participant, this researcher summarized these patterns and themes that were identified in the responses and

present the information as an explanation in text with examples from the participants. This researcher used the patterns, trends, and descriptive statistics to draw conclusions on the impact of the BTS on PAWS through textual explanation as well as a summary graph.

### **Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others**

The sample included a vulnerable population, those with substance use disorders; however, this researcher excluded anyone with psychotic disorders, potential risk for suicide, history of seizures or brain injuries, and pregnant women through self-report and clinical information collected prior to commencement of the study. This researcher did, however, assess participants with co-occurring mental health disorders such as PTSD, depression, and anxiety. The participants were assessed at every visit for any possible triggers associated with the use of the BTS, as well as using the pre- and posttest will help determine if there are any negative side effects as a result of the BTS. Following the completion of each session, participants completed a posttest to assess for any symptom changes, including adverse effects. Participants had the opportunity to leave comments as well as answer a few brief interview questions to ensure the safety of the participant throughout the process. While there was minimal risk, there is always a possibility of a participant being triggered by the BTS intervention. To decrease the impact of these risks, the participants were able to skip any item in the survey, stop participation in the BTS at any time, refuse to answer any interview question, and follow up with their primary therapist in the treatment program. No participants indicated being triggered during the course of this study.

### **Study Withdrawal/Discontinuation**

Participants were able to, at any point, notify this researcher of their withdrawal or discontinuation in person and if possible, the participant may complete written notice for study records. No participants withdrew from the study for any reason.

### **Statistical Considerations**

The biggest threat to the validity of the study was sampling and researcher bias. This researcher utilized participants from her own treatment center, which have developed rapport with her and may struggle with providing negative feedback or criticism, if it exists. To minimize the likelihood of this, the program's clinical director recruited the participants and assured them she would be supervising this researcher. In addition, this researcher reviewed, in detail, the informed consent regarding withdrawal from the study or reporting negative feedback or criticism would not have any impact on the course of their treatment.

To ensure reliability, this researcher defined each element of the study so that it may be duplicated. This researcher will also be using collection instruments that have been developed to specifically by BioSound Technologies to assess PAWS symptoms and any changes that may occur as a result of the intervention. This researcher also used the Positive and Negative Affect Scale (PANAS) as well as the Perceived Stress Scale (PSS-10) which both have good reliability and validity.

### **Privacy/Confidentiality Issues**

To protect the participant's confidentiality, all paper forms used for data collection were labeled with a Study Number assigned by this researcher, rather than using names. As treatment centers follow HIPAA compliance, this researcher had informed consents and HIPAA forms signed by each participant prior to the commencement of the research. No additional staff or interns were used for this study; therefore, no confidentiality agreements were needed.

**Follow-up and Record Retention**

The study consisted of 4 weeks of sessions. Records will be kept for 7 years post completion of the study. Participants were removed from active clients in the BTS electronic medical records systems upon completion of the study.

## Chapter 4: Results

This study examined the following research question: What is the impact of the BioSound Therapy System for Post Acute Withdrawal Syndrome? In this chapter, the results of the study are presented. First, the demographic information of the participants is presented. Following this, the substance use history and history of PAWS symptoms are presented. Quantitative results of the three pre- and posttest questionnaires, Positive and Negative Affect Schedule, Perceived Stress Scale, and the BioSound Therapy System Pre/Posttest, are presented. Finally, after the quantitative results are presented, the results and themes of the interviews are summarized.

### Overview of Participants

There were four participants in this study. The women ranged in age from 22 to 37 years old. The participants had between 2 months and 7 months of recovery.

**Participant 1 (P1)** was 22 years old, single, and had no children. Her drugs of choice included heroin, cocaine, and benzodiazepines. Her last use was December 21, 2017. She identified with substance use disorder criteria including: increased tolerance, history of withdrawal, using more than intended, unsuccessful attempts to stop, spending a great deal of time using, and continued use despite knowledge of exacerbation. She reported having been treated for substance use disorders numerous times. Participant 1 reported a history of withdrawal symptoms including: tremors, agitation, fatigue, and low motivation. She was experiencing insomnia, mood swings, irritability, and poor concentration during the completion of this study. This participant was also diagnosed with post-traumatic stress disorder, obsessive compulsive disorder, panic disorder, and major depressive disorder and was medicated for the aforementioned mental health diagnoses. She did not report a history of psychosis or suicide attempts.

**Participant 2 (P2)** was 37 years old, single, and had no children. Her drugs of choice included cocaine, opioids, and benzodiazepines. Her last use was April 11, 2018. She identified with substance use disorder criteria including: increased tolerance, history of withdrawal, using more than intended, unsuccessful attempts to stop, spending a great deal of time using, and continued use despite knowledge of exacerbation. She reported having been treated for substance use disorders approximately ten times in the past. Participant 2 reported a history of withdrawal symptoms including: tremors, insomnia, fatigue, and seizures. She was experiencing agitation, mood swings, irritability, fatigue, low motivation, and poor concentration during the completion of this study. This participant was also diagnosed with bipolar I disorder and generalized anxiety disorder and was medicated for the aforementioned mental health diagnoses. She did not report a history of psychosis, however, has had suicide attempts in the past.

**Participant 3 (P3)** was 27 years old, in a relationship, and had no children. Her drugs of choice included alcohol, cocaine, and marijuana. Her last use was January 19, 2018. She identified with substance use disorder criteria including: increased tolerance, history of withdrawal, using more than intended, unsuccessful attempts to stop, spending a great deal of time using, and continued use despite knowledge of exacerbation. She reported having been treated for substance use disorders only for the 3 months prior to admit at this treatment facility which was a continuation of residential treatment. Participant 3 reported a history of withdrawal symptoms including: mood swings and poor concentration. She was experiencing insomnia, agitation, irritability, fatigue, and low motivation during the completion of this study. This participant was also diagnosed with generalized anxiety disorder and major depressive disorder and was medicated for the aforementioned mental health diagnoses. She did not report a history of psychosis or suicide attempts.

**Participant 4 (P4)** was 25 years old, single, and had no children. Her drugs of choice included alcohol, cocaine, methamphetamines, and marijuana. Her last use was March 2, 2018. She identified with substance use disorder criteria including: increased tolerance, history of withdrawal, using more than intended, unsuccessful attempts to stop, spending a great deal of time using, and continued use despite knowledge of exacerbation. She reported having been treated for substance use disorders one time prior to this treatment stay. Participant 4 reported a history of withdrawal symptoms including: tremors, irritability, fatigue, agitation, and low motivation. She was experiencing mood swings, insomnia, and poor concentration during the completion of this study. This participant was also diagnosed with post-traumatic stress disorder, generalized anxiety disorder, panic disorder, and major depressive disorder and was medicated for the aforementioned mental health diagnoses. She did not report a history of psychosis or suicide attempts.

### **Positive and Negative Affect Schedule (PANAS) Results**

In this section, the results of the PANAS for each participant are displayed. The PANAS scale questions may be found in the appendices. Each participant completed a pre- and posttest PANAS during each of the 8 sessions.

Table 1 reports the average Negative Affect results for each participant during the pre- and posttest evaluation over the course of 8 sessions. Pre-test result averages ranged from 19.63 to 27.63 over all Negative Affect measures ( $M = 23.16$   $SD = 3.38$ ). Posttest averages ranged from 13.38 to 18.25 over all Negative Affect measures ( $M = 14.88$   $SD = 2.27$ ). Table 1 also displays the percent change of Negative Affect per participant. Percent change over 8 session ranged from -29% to -41% ( $M = -36$   $SD = 5$ ). All four participants reported a decrease in negative affect over the course of this study. These results indicate study participants

reported a decrease of negative affect over the course of this study. Figure 1 displays these results graphically.

**Table 1**

*Negative Affect: Pre- and Posttest Scores*

	Negative Affect	Pre	Post	% Change
P1		27.63	18.25	-34
P2		23.50	13.88	-41
P3		21.88	13.38	-39
P4		19.63	14.00	-29
Mean		23.16	14.88	-36
SD		3.38	2.27	5

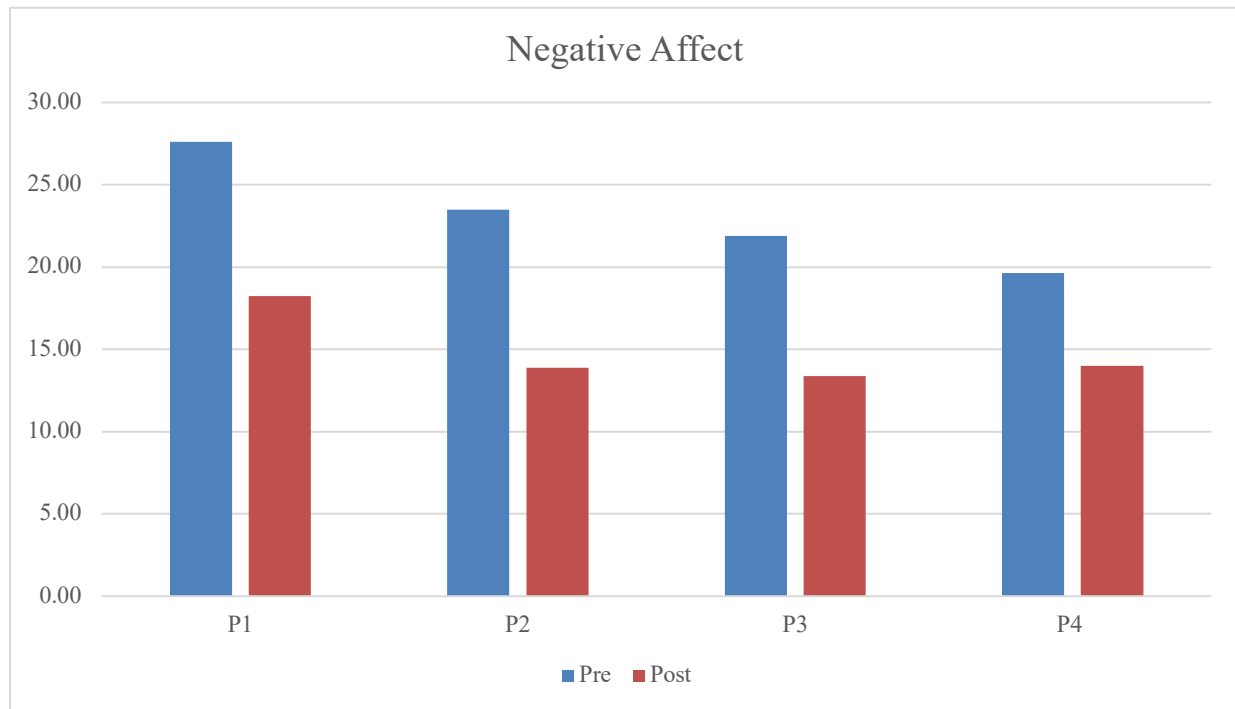
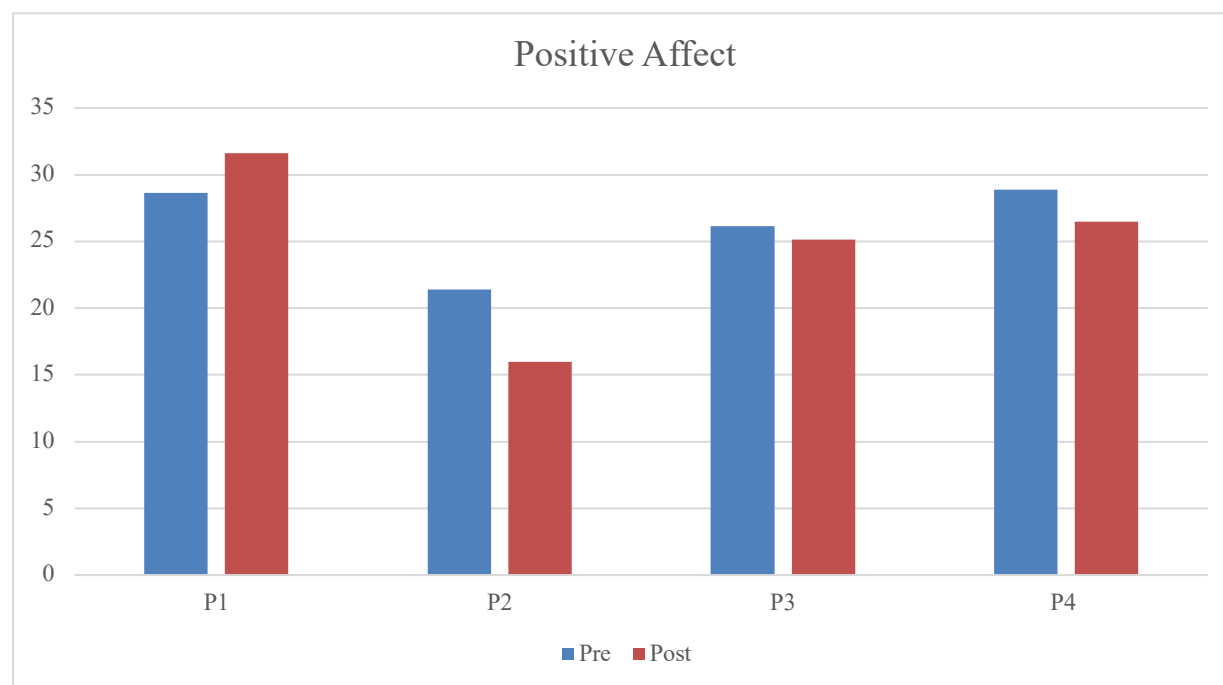
**Figure 1***Negative Affect Change*

Table 3 reports the average Positive Affect results for each participant during the pre- and posttest evaluation over the course of 8 sessions. Pre-test result averages ranged from 21.38 to 28.88 over all Positive Affect measures ( $M=26.26$   $SD=3.01$ ). Posttest averages ranged from 16 to 31.63 over all Positive Affect measures ( $M= 24.81$   $SD=6.51$ ). Table 3 also displays the percent change of Positive Affect per participant. Percent change over 8 session ranged from -34% to 9%. These results indicate study participants reported a decrease in positive affect for P2, P3, and P4. Only P1 reported an increase of positive affect over the course of this study. Figure 2 displays these results graphically.

**Table 3***Positive Affect: Pre- and Posttest Scores*

Positive Affect	Pre	Post	% Change
P1	28.63	31.63	9
P2	21.38	16.00	-34
P3	26.13	25.13	-4
P4	28.88	26.50	-9
Mean	26.26	24.81	-9.5
SD	3.01	6.51	18.01

**Figure 2***Positive Affect Change*

### Perceived Stress Scale (PSS) Results

In this section, results of the PSS for each participant are displayed. PSS survey questions may be found in the appendices. Each participant completed a pre- and posttest PSS during each of the 8 sessions.

Table 5 reports the average Perceived Stress results for each participant during the pre- and posttest evaluation over the course of 8 sessions. Pre-test result averages ranged from 16.5 to 25.5 over all Perceived Stress measures ( $M=22.25$   $SD=3.99$ ). Posttest averages ranged from .625 to 3.625 over all Perceived Stress measures ( $M=17.44$   $SD=6.69$ ). Figure 3 displays these results graphically. Table 6 displays the percent change of perceived stress per participant. Percent change over 8 session ranged from -42%- 0%. Average percent change demonstrates that study participants reported a decrease in perceived stress for P1, P3, and P4. P1 reported no change in perceived stressed over the course of the study.

**Table 5**

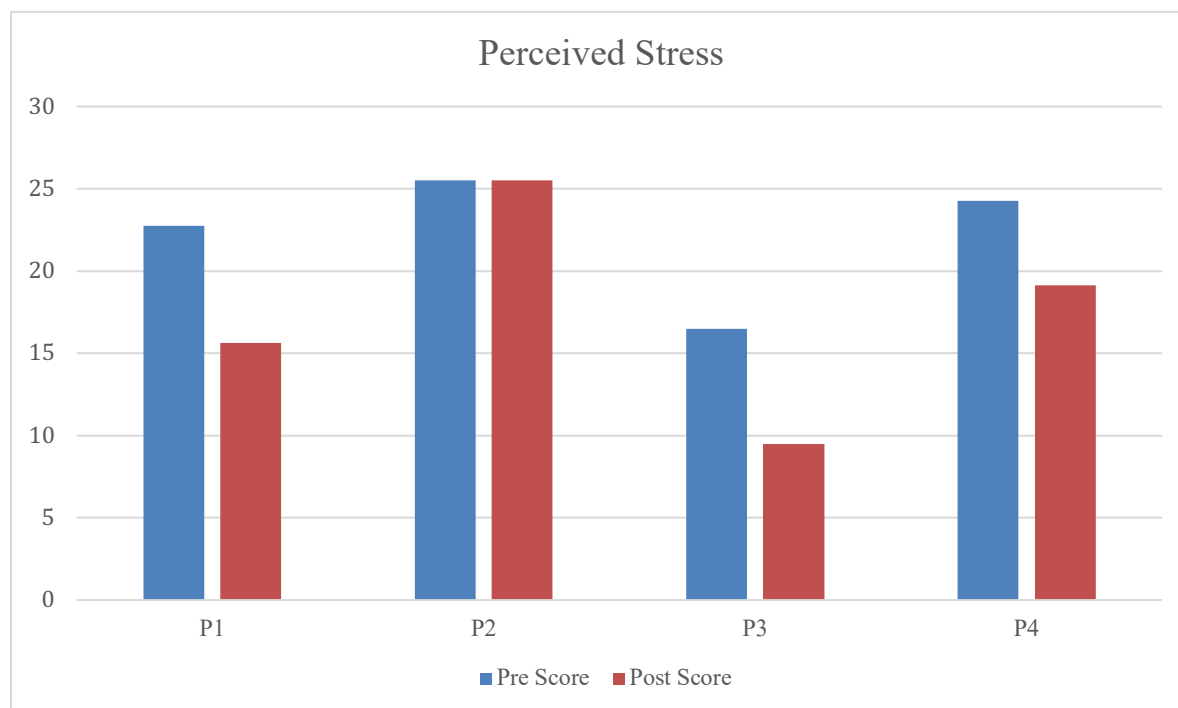
*Perceived Stress: Pre- and Posttest Scores*

Participant	Pre-test	Health Concern Category	Posttest	Health Concern Category
P1	22.75	Very High	15.625	Average
P2	25.5	Very High	25.5	Very High
P3	16.5	High	9.5	Low
P4	24.25	Very High	19.125	High
Mean	22.25		17.4375	
SD	3.99		6.69	

Scale: 0-7—very low, 8-11—low, 12-15—average, 16-20—high, and 21 or more—very high

**Figure 3**

*Perceived Stress Change*



**Table 6**

*Perceived Stress Percent Change*

Participant	% Change
P1	-31
P2	0
P3	-42
P4	-21

### **BioSound Therapy System Pre/Post Test (BTS) Results**

In this section of the results, results of the BTS for each participant are displayed. The BTS survey questions may be found in the appendices. Each participant completed a pre- and posttest BTS during each of the eight sessions.

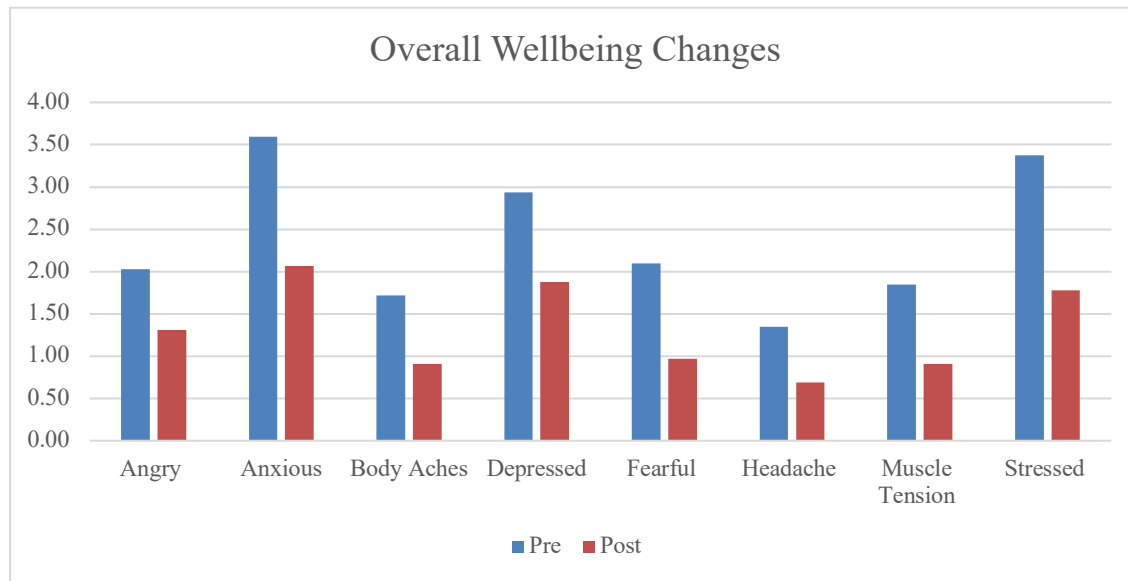
Table 7 reports the average BTS results for each participant during the pre- and posttest evaluation over the course of 8 sessions. Pre-test result averages ranged from 0.75 to 4.25 over all BTS measures. Posttest averages ranged from 0.125 to 3.25 over all BTS measures. Table 11 reports the overall average BTS results for all participants during the pre- and posttest evaluation over the course of 8 sessions. Pre-test result averages ranged from 1.34 to 3.59 over all BTS measures. Posttest result averages ranged from 0.69 to 2.06 over all BTS measures. Figure 4 displays these results graphically. Table 8 displays the percent change of BTS per participant. Percent change over 8 session ranged from -12% to -89%. Average percent change demonstrates study participants reported decrease in all overall wellbeing scores for all participants.

**Table 7***BTS: Pre- and Posttest Scores*

BTS Pre/Post Test	Pre P1	Post P1	Pre P2	Post P2	Pre P3	Post P3	Pre P4	Post P4
<i>Angry</i>	2.50	1.63	2.00	0.88	2.13	1.88	1.50	0.88
<i>Anxious</i>	3.88	2.38	3.50	1.75	3.88	2.63	3.13	1.50
<i>Body Aches</i>	2.50	1.50	0.75	0.13	1.50	1.00	2.13	1.00
<i>Depressed</i>	3.13	2.25	1.25	0.50	4.25	3.25	3.13	1.50
<i>Fearful</i>	3.13	1.75	1.13	0.38	1.88	0.88	2.25	0.88
<i>Headache</i>	1.88	1.25	1.13	0.13	1.25	1.00	1.13	0.38
<i>Muscle Tension</i>	2.25	1.50	0.75	0.13	2.88	1.25	1.50	0.75
<i>Stressed</i>	3.50	2.00	3.25	1.25	3.63	2.25	3.13	1.63

**Table 8***BTS Pre/Post Test Mean Scores*

BTS Pre/Post Test Mean Scores	Pre	Post
<i>Angry</i>	2.03	1.31
<i>Anxious</i>	3.59	2.06
<i>Body Aches</i>	1.72	0.91
<i>Depressed</i>	2.94	1.88
<i>Fearful</i>	2.09	0.97
<i>Headache</i>	1.34	0.69
<i>Muscle Tension</i>	1.84	0.91
<i>Stressed</i>	3.38	1.78

**Figure 4***Overall Wellbeing Changes***Table 9***BTS Pre/Post Test Percent Change*

Emotion/Physiological Response	P1	P2	P3	P4	Mean % Change
<i>Angry</i>	-35	-56	-12	-42	-36.00
<i>Anxious</i>	-39	-50	-32	-52	-43.25
<i>Body Aches</i>	-40	-83	-33	-53	-52.25
<i>Depressed</i>	-28	-60	-24	-52	-41.00
<i>Fearful</i>	-44	-67	-53	-61	-56.25
<i>Headache</i>	-33	-89	-20	-67	-52.25
<i>Muscle Tension</i>	-33	-83	-57	-50	-55.75
<i>Stressed</i>	-43	-62	-38	-48	-47.75

## **Results of Qualitative Responses**

Participant responses to their overall experience with the BTS were examined. Participants were interviewed briefly following each session, were able to add subjective responses to the BTS pre/posttest, and each participant also completed a semi-structured interview at the completion of all 8 sessions. Analysis of the participant data indicated that they experienced beneficial emotional and physiological shifts as a result of the BTS. Upon completion of the interviews, the themes were identified by reviewing the transcripts and identifying anything that the participant identified as an emotional or physiological shift during the course of the study. As each participant's transcript was reviewed, anything that stood out in more than one participant's experience as a shift was noted as a potential theme. Eleven themes emerged during this process. Upon completion of this analysis, these 11 themes were reviewed. It was determined that these themes also corresponded with the 6 PAWS symptom clusters. For the purpose of this research, to answer the question of whether the BTS had an impact on PAWS symptoms, these 6 symptom clusters were used as themes due to their direct correlation to the 11 identified themes from the qualitative responses. These themes were identified and described in the following sections.

### **Identified Themes**

Table 10 reports the participant responses within the eleven defined themes. These themes included:

- Better able to handle physical symptoms
- Better able to manage life stressors
- Decrease in anger
- Decrease in anxiety

- Decrease in depression
- Decrease in stress
- Increased ability to focus on breathing
- Increased positive emotions
- Increased ability to think clearly and focus
- Soothing and calming
- Overall reset

P3 affirmed all of these responses. P1 affirmed each of these responses with the exception of a decrease in anger. P2 affirmed each of these responses with the exception of better able to handle physical symptoms and increased ability to focus on breathing. P4 also affirmed each of these responses except for better able to handle physical symptoms and a decrease in anger. Upon further analysis of the aforementioned themes, each of these themes directly related to a PAWS symptom. The themes were narrowed down to the six PAWS symptom clusters including thinking clearly, remembering things, managing emotions, sleeping restfully, physical coordination, and stress sensitivity. Table 11 reports the participant responses to these PAWS symptoms. Each participant affirmed an improvement in thinking clearly, remembering things, managing emotions, and stress sensitivity. Only P1 identified with an improvement in sleep patterns and no participants affirmed a change in physical coordination.

**Table 10***Identified Themes*

<b>Theme</b>	<b>P1</b>	<b>P2</b>	<b>P3</b>	<b>P4</b>
<i>Better Able to Handle Physical Symptoms</i>	<b>X</b>		<b>X</b>	
<i>Better Able to Manage Life Stressors</i>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
<i>Decrease in Anger</i>		<b>X</b>	<b>X</b>	
<i>Decrease in Anxiety</i>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
<i>Decrease in Depression</i>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
<i>Decrease in Stress</i>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
<i>Increase Ability to Focus on Breathing</i>	<b>X</b>		<b>X</b>	<b>X</b>
<i>Increase in Positive Emotions</i>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
<i>More Focused/Ability to Think Clearly/More Mindful</i>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
<i>Overall Reset</i>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
<i>Soothing/Calming</i>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>

**Table 11***PAWS Symptom Clusters*

<b>PAWS Symptom Clusters</b>	<b>P1</b>	<b>P2</b>	<b>P3</b>	<b>P4</b>
<i>Thinking Clearly</i>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
<i>Remembering Things</i>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
<i>Managing Emotions</i>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
<i>Sleeping Restfully</i>			<b>X</b>	
<i>Physical Coordination</i>				
<i>Stress Sensitivity</i>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>

**Thinking Clearly**

Participants indicated that the BTS improved their ability to think clearly following the completion of each session. P1 spoke about how the bed was a nice refresher, allowing her the opportunity to take a break from her thoughts and re-evaluate her life circumstances. She went on to state:

Overall, it was just a very calming exercise for me and I felt like just taking a break was enough to, you know, like when I was having a difficult time, like I was looking at a puzzle or something, I could take a break from it, go back to it and I was able to put it together and I felt like that's how it worked for me to be able to shift my perspective and see things more clearly.

P3 explained that her experience with the BTS also helped her think more clearly. She stated:

It's easier to shove it [difficult situations] away and not notice it. So, when I would have to complete the questionnaires and think about it, taking that time helped me to think more clearly about it and notice a difference in how I could handle it.

P4 expressed how helpful the BTS was because she did not take medication for attention issues.

She stated:

I was overwhelmed because I'm ADHD really bad. It's overwhelming because I don't take medicine for it. This helped with that, to make me less hyper. So much less hyper. So, I could think clearly, and it really helped me concentrate. I would think a lot of random things and I am never fully about to concentrate without medication, so the bed helped me to have more awareness.

### **Remembering Things**

Participants indicated that the BTS improved their ability to remember things following the completion of each session. P1 explained that the BTS was helpful in allowing her the ability to focus and concentrate so that she was better able to remember things. P1 stated:

Being on the bed and just kind of letting my thoughts come freely and instances before I would think, I had this great thought or I want to write that down then I just can't remember it. But on the bed, I can reflect on it a little bit better and having that moment afterwards where I am able to think about it and actually remember my thoughts. I have also noticed this being applicable outside of the sessions. When I think, I have to do this today and I actually remember it and don't forget it. I am better able to maintain a schedule.

P4 also expressed that the BTS was helpful in allowing her to remember things, however, her experience was related to remembering experiences in the past that had been difficult for her to process. P4 stated:

The music part of the session made me think of all these random things, like flashbacks, but in a good way. Reminded me of the things when I was little and when I was at the beach and my beach house. It took me to times like that and it was really soothing, allowing me to process better, and I really enjoyed that. That's what stood out the most to me and helped ground me because it took me back to good childhood memories.

### **Managing Emotions**

Each of the participants acknowledged that the BTS impacted their ability to manage their emotions more effectively.

P1 described her experience as something "I was looking forward to, got me in a rhythm and I felt like that was pretty significant". It was something that she felt she could apply to other areas of her life and have greater tolerance to any changes that happened in her life. P1 also explained how the BTS helped her learn to persevere through things, "At first the meditation was really irritating, but to see how sticking it out and persevering through it, I could get a better result and apply that to my outside life which was really the point of it all, wasn't it?" In addition to allowing her to persevere, the BTS gave her the opportunity to have a break from her thoughts and in those situations, "Maybe the thing that I was freaking out about is going to be okay, I am still breathing, and it was, overall, a very calming exercise for me and I felt like taking a break was enough to reset". She also noted that:

I have noticed that taking that break and being able to re-evaluate has always given me a shift in perspective, even just listening to the mediation and what the audio is saying, just let it happen and relax. I always found that it's nice to just press that reset button and that it's not a bad thing to say I need break for a second, finding out that it's healthy to do that. I felt like knowing what your body needs and responding to that has been something I have learned from these last few weeks.

P2 also expressed that the BTS was helpful in managing her emotions. She acknowledged how anxious she was going into each session and how much better she felt afterwards, that what stood out the most for her was the calm that she felt afterwards. P2 explained that each session allowed her the opportunity to breathe and to debrief which gave her a chance to “handle life way better”. P2 stated:

I want to continue to use the bed. I don't know if it's because I feel relaxed in that moment or maybe I know if I am going through something, I could bring it [the relaxed feeling] home with me, if I used it. I go through life and don't pay attention to how I feel, I don't connect to my head and my heart, I feel disjointed and like I am going in all these different directions, but when I use the bed I can really tap into my physical sensations, what it feels like, and tap into my emotional state throughout the day. It's just taking that moment to pause and debrief. I am a little more connected to my body and my emotions.

P3 acknowledged that she was better able to cope with things after the BTS sessions. She stated:

I am coping with things better. If I am upset about something unexpected that happens and I am able to take that hour [on the BTS], I have noticed that I am better by the end of the session, I realize it's something that I could not control but not worth the energy.

In addition to being able to cope with emotions more effectively, P3 also acknowledged that she was better able to identify her emotions. She explained:

I also really liked the questionnaires, having to identify the emotions has really helped me. Because the first couple of times I really had to think about it because I had numbed out emotions for so long and then having to distinguish between different ones has really

helped me. Early in recovery we lump everything into mad, sad, glad, we don't know.

And for the first time I was able to see different ones.

P4 explained how the BTS impacted her emotions, specifically her anxiety. She stated:

It helps with my anxiety. So that's a big part of it, it's been a real struggle for me. That was the reason that I always did drugs and drank was because of my anxiety. It is really bad, and I overthink a lot of stuff and so using that, like I was saying with the awareness and makes me just calm down and forget all this random stuff that I am thinking about.

### **Sleeping Restfully**

Only P3 acknowledged a change in sleep patterns over the course of treatment. She explained that "The biggest things would be that I am handling stress better and I am actually able to sleep better, I feel like I am getting deeper sleep and I have better alertness when I sleep more".

### **Stress Sensitivity**

Each of the participants expressed a change in their sensitivity to stress over the course of the study. All participants identified the way they experience and handle stress to be the greatest impact of the BTS. P1 explained how the BTS helped her ability to handle her anxiety and feel less on edge than usual. She stated:

I really think that my anxiety is my biggest issue. It's something that I have dealt with for a long time, but I have noticed gradual changes over the few weeks and I have been more calm and able to handle more of the physical symptoms and there are times at night where I am like, I feel great and that's what happened. I don't think it can be faked, I just think if you want it to work for you, it can. It's been super beneficial, and I really enjoyed being a participant, I like knowing it had lasting effects on how I feel.

In addition to the ability to handle anxiety better, P1 also acknowledged how the BTS was helpful in alleviating pressure to accomplish things and nervousness. She explained:

I liked having the break to recharge and not feeling pressure around having to do things, but more so what can I do? What do I get to do? It's helped change my mindset and instead of the nervousness I was able to just mediate on things.

P2 acknowledged how the BTS impacted her stress sensitivity as well. She reported that what stood out the most for her was how calm she felt after each session. She stated:

Fairly often or very often I found myself upset about something unexpectedly or I felt nervous or stressed. I am lacking competence in handling my personal problems. I am feeling like I am not on top of things. So afterwards, I would feel a little bit of an increase in how I could things better because the bed was so soothing, when I get up, I feel way more relaxed and I had time to breathe and debrief. I could handle life way better.

P3 also recognized that she was managing stress more effectively. She explained how the BTS impacted her ability to destress when she was experiencing situations that created more tension in her life. She explained:

I definitely think I am managing stress better just in general, it's easier for me to destress. There have been a lot of triggers or situations that have created more tensions, but I think if this many things were going on a month ago, I would not be responding the same way. I realize that the stress definitely decreased after each session. The biggest thing would be that I am handling stress much better.

P4 described how soothing and calming the BTS was and how it impacted her ability to manage stress. She explained:

It made me less stressed out, because it was so calming, like I said before. It was especially helpful when I was really stressed out. I have been happier and feel like a lot of good things are happening.

### **Quantitative Summary**

Results from the surveys indicated that study participants reported a decrease in negative affect, positive affect, and perceived stress and an increase in overall wellbeing over the course of 8 sessions of the BTS.

### **Qualitative Summary**

Results from the interview responses indicated a positive impact in PAWS symptoms and that participants experienced beneficial emotional and behavioral shifts over the course of the study. All participants indicated an improvement in remembering things, thinking clearly, managing emotions, and stress sensitivity.

### **Overall Summary**

Results indicated that the BTS did have a positive impact on PAWS symptoms with the exception on sleeping restfully and physical coordination. Overall, participants reported a decrease in negative affect, positive affect, and perceived stress. Participants also reported an increase in overall wellbeing over the course of 8 sessions of the BTS.

## **Chapter 5: Discussion**

This mixed-methods, multi-case study research investigated how the use of the BTS impacted PAWS for participants in a substance use day treatment and intensive outpatient program. This study used the Positive and Negative Affect Scale (PANAS), Perceived Stress Scale (PSS-10), and the BioSound Technologies Pre/Posttest, as well as a semi-structured interview to understand the participant's experience with the BTS, whether there were any changes in positive and negative affect, perceived stress, and overall wellbeing. This chapter presents a discussion of the study results. Conclusions are presented first, then the delimitations and limitations, followed by suggestions for further research, and a summary.

### **Conclusions**

#### **Changes in Positive and Negative Affect**

All study participants reported that negative affect decreased. Mean negative affect scores decreased from 23.16 to 14.88. These reports are consistent with past research. Froilán-Dávila (2014) found that guided imagery facilitates calming of the mind, focus, decreasing negative emotions and thoughts, decreases anxiety, and increases relaxation. Temme, L. J., Fenster, J., & Ream, G. L. (2012) also found that clients who were utilizing meditation practices had a decrease in negative mood and a decrease in relapse warning signs. Another study by Temme, Fenster, and Ream (2012) reports that meditation is highly effective in decreasing negative mood states as well as decreasing the risk of relapse in chemically dependent clients. Each participant experienced a decrease in negative affect and percent change ranged from -41% to -29%. The overall percent change in negative affect over the 8 sessions was -35%.

Three out of four participants reported that positive affect decreased. Only one participant experienced an increase in positive affect over the course of 8 sessions based on the results of the PANAS. In addition, mean scores for positive affect also decreased from 26.25 to

24.8125 over the course of the study. Past research does not indicate an improvement in positive affect while using complementary and alternative medicine practices such as meditation, guided imagery, massage, or biofeedback. However, it does suggest improved mood and a positive effect on dopamine. Studies suggest that sound therapy has a positive effect on dopamine, eliciting a response on the pleasure center of the brain as well as minimizing the stress response and elicits an endorphinergic response (Morse et al. 2011). As stated by P3, she found it difficult to identify those things related directly to positive affect, as she had historically categorized anything positive into one category and learned over the course of the study how to begin identifying these separately. The results of this study are consistent with other studies using CAM practices. These studies (Reader, Young & Connor, 2005; Scott, Kaiser, Othmer, & Sideroff, 2005; Temme, L. J., Fenster, J., & Ream, G. L., 2012) looked at decreased negative emotions and mood disturbances, not increased positive affect. Based on the literature review, there was little research on using CAM practices for directly improving positive affect in participants with substance use disorders. It is also important to point out the results of the PANAS on positive affect are not consistent with the participants qualitative responses to their experience with the BTS. Qualitative results indicated a positive impact on mood and positive emotions.

These findings are important for those working in substance use treatment facilities because they indicate that the BTS may be effective in helping decrease negative affect. It is important to note that there was little improvement in positive affect (only one participant indicated an improvement in positive affect). While this may be concerning, it can also be noted that there is little focus on positive affect in other research studies, which could suggest a need for further research specifically related to positive affect and complementary and alternative medicine practices. Much of the research indicates a decrease in negative affect, rather than an

increase in positive affect. These findings suggest that there is still a positive impact on the participant because there is a decrease in negative affect or mood disturbances. In addition, these findings suggest it is important for substance use programs to focus more on a strength based approach rather than a symptom reduction approach noted by Kelly, (1997).

### **Changes in Perceived Stress**

Three out of four participants reported a decrease in perceived stress. Mean perceived stress scores decreased from 22.25 to 17.4375 over the course of the study. Mean percent change for perceived stress was -23.5%. These results are consistent with past research. Lake (2006) found therapeutic benefits of meditation including the person's ability to change the affective and bodily experience during times of stress, shifting the person's ability to see feelings as interim rather than reality. Morse et al. (2011) found that music therapy may also reduce the risk for relapse through an improved emotional and physiological response to environmental and emotional stressors and triggers related to drug craving and drug seeking behaviors. Three out of 4 participants experienced a decrease in perceived stress when completing the PSS, however, the one participant who did not indicate a change when completing the surveys noted several times in her interview that the BTS was calming, relaxing, and decreased her stress. This inconsistency was pointed out in the interview and the participant said she felt like she may not have been alert enough when completing the posttest questionnaires. While this may be accurate, her results were relatively consistent with other participants as it relates to the other questionnaires.

Study findings are important for those working in the substance use treatment field because they indicate that the BTS may be helpful in decreasing perceived stress, which is often times a precursor for relapse (Froilán-Dávila, 2014). This suggests a need for further research

regarding the effectiveness of the BTS for relapse prevention. Using the BTS seems to have helped calm and relax participants immediately following the session and often for the remainder of the day. Further research with a longer study duration may be necessary to indicate how effective the BTS for long term improvement. It was, however, noted by each participant that the BTS was helpful in giving them a “break” or “time to debrief” which is consistent with the 12 step fellowship philosophy of “Pause when agitated or doubtful”. This philosophy helps those in 12 step fellowships to take a moment to reflect prior to acting, often in the case of relapse (Gorski, 1986).

### **Changes in Overall Wellbeing**

Study participants reported a decrease in all measures on the BTS pre/posttest for overall wellbeing. This questionnaire measured Anger, Anxiety, Depression, Fear, Stress, Muscle Tension, Headaches, and Body Aches. These findings are consistent with the past research regarding the use of complementary and alternative medicine practices for overall wellbeing. Froilán-Dávila (2014) found that guided imagery was beneficial in helping client’s focus, be in the present moment, and improve their overall sense of wellbeing. According to Morse, Giordano, Perrine, Downs, Waite, Madigan, Bailey...Blum (2011) sound therapy strongly modulates activity in a network of mesolimbic structures involved in reward processing. This research found that clients who utilized sound therapy showed significant improvement in ten withdrawal symptoms including stress, depression, cravings, mood swings, anxiety, resentment, anger, fear, body aches, and headaches.

Stress rated the highest mean score pre-test (3.375) and had a 47% decrease. This finding is not consistent with the PSS results, with only a 23% decrease in perceived stress. The way in stress was measured in the PSS was different than the one measure on the BTS pre/post which could have led to this difference in reporting. In addition, P2 who had no change on the PSS had

a markedly different posttest stress score (3.25 to 1.25) on the BTS pre/posttest. This would suggest a difference in the way that the participant perceives the word “stress” and how the PSS defines it.

Another difference to point out is the decrease in physical symptoms (Headache, muscle tension, and body aches), but how little difference was noted in the interviews. These inconsistencies would suggest a need for further research regarding the impact of the BTS on physical symptoms of PAWS.

Study findings regarding overall wellbeing are important for substance use treatment providers because they suggest that there was a positive impact in overall wellbeing when using the BTS. Continued use of the BTS in treatment settings may be an effective tool for supporting PAWS.

### **Delimitations and Limitations**

The primary strength of this research study was the mixed methods approach that was used. This method allowed for a detailed and rich subjective account of the experience for each of the participants which would not have been uncovered had this been only a quantitative study. However, there were limitations to this study as well. As a result of the small sample size, only descriptive statistics could be presented, therefore not allowing for generalizable findings across the substance use population.

This study relied upon self-reported data collection, which introduced participant bias into the study. It was noted that not all participants had the same level of insight or ability to identify emotions or responses to the BTS. Consequently, the participants may have over-stated or under-stated their responses in the pre- and posttest questionnaires. It was noted during the interviews that each participant has a very different way of expressing their experience and were often unable to identify change as it related to emotional responses. It was also noted that some

of the interview responses did not correlate to the pre- and posttest responses. For example, P2 acknowledged how helpful the BTS was in decreasing her stress level, however, the PSS results suggested there was no change in her perceived stress levels. This was also noted in the PANAS pre- and posttests. Participants acknowledged an increase in positive affect during their interviews, however, the results of the PANAS suggested that there was actually a decrease in positive affect, rather than the suspected increase.

Another bias could have been the participant's understanding of the questions in the pre- and posttests. For example, P3 pointed out in her interview that in completing the PANAS, she realized that there were many different emotions beyond mad, sad, and glad. She found that it was difficult at first to identify these, but as the study went on, she was able to better differentiate between the emotions. Other participants did not notice and therefore may not have had the insight to do so.

Another delimitation to this study is that it did not analyze the data collection of HRV, while this was part of the BTS and data was collected in HeartMath, it was excluded due to the primary objective of this study to address the BTS impact on PAWS and limiting the specific aims to three rather than including an additional measure. This measure may have been helpful though in identifying in a more objective way, the impact of the BTS on physiological responses due to PAWS. None of the participants indicated a change in physical symptoms, so this could have provided an additional data set to look more specifically at any physical changes due to the BTS.

### **Suggestions for Further Research**

More research is needed to confirm and expand upon the results of this study. This study was exploratory in nature and provided a solid foundation for understanding the impacts of the BTS on PAWS. Because this study was very thorough and took a deep look at each case study,

quantitatively and qualitatively, it would be helpful to the substance use community to address PAWS in a more general way. To this end, more research is needed to gather further data from a greater number of participants to be able to confirm or deny the effectiveness of the BTS on PAWS and to generalize this to the broader substance using population. This research suggests that there is a positive and beneficial impact of the BTS on PAWS, however, due to limitations of this study, it is suggested that additional research be conducted to further understand these impacts and to allow for more generalizable results.

A primary suggestion for further research would be an increased sample size to allow for greater significance of these results as well as more generalizable information. A larger sample size would also provide the opportunity to expand the statistical analysis of the data. This would allow for the calculation of inferential statistics to determine whether these results were in fact significant. Preferably, a larger sample size would include more participants for more than one collection site. Because the BTS is being used in many treatment settings across the United States, it would be possible to collect data from other locations. This study could also be expanded across levels of care. For this particular study, only participants in Intensive Outpatient and Partial Hospitalization were studied. Participants from detox or residential setting could be studied as well. In addition, only females were studied, further research could include males in this study as well for a more generalizable population.

In the future, a randomized control trial could be done to include a control group to determine whether the posttest results from the BTS were significant compared to those only receiving the control.

Another suggestion for further research could include a preliminary interview to gather further information about the participants PAWS symptoms as well as their levels of insight and emotional intelligence to determine the accurate levels of change that occurred over time. It may

able be beneficial to gather subjective details posttest throughout the course of the study to better understand the changes that were occurring for each participant.

For future studies, it may be important to look for treatment settings that offer longer lengths of stay to be able to expand this research study to 8 or 12 weeks. Because PAWS lasts for 18-24 months, gather more information on each participant could provide a more significant study that is more generalizable across the substance use population.

## **Summary**

This mixed methods study researched the impact of the BTS on PAWS for four participants in an outpatient substance use treatment setting. Demographic data was collected for each participant, pre- and posttest questionnaires were completed for understanding the impact of the BTS on positive and negative affect, perceived stress, as well as overall wellbeing. After the completion of 8 sessions of the BTS, 2 sessions weekly for 4 weeks, a semi-structured interview was completed with each participant to gather subjective data on their unique experiences with the BTS. Descriptive statistics were calculated for the quantitative data and qualitative data was examined using thematic analysis.

Results indicated that all participants reported a decrease in negative affect. Three out of four participants reported a decrease in perceived stress as well as a decrease in positive affect. All participants reported an increase in overall wellbeing as well as improvements in four out of six PAWS symptoms with the exception of sleeping restfully and physical coordination. Participants interview results indicated an improvement in PAWS symptoms as well as a beneficial emotional and behavioral shift as a result of the BTS.

It can be concluded that the BTS does have a beneficial impact on PAWS symptoms and upon further research, may be effective treatment modality for those recovering from substance

use disorders and experiencing symptoms of PAWS. However, further research is needed to deepen the understanding the BTS on PAWS, using a larger sample size, expanding the length of the study, gathering more pre-intervention data, expanding the study setting, including a control group, and calculating inferential statistics. It would be recommended for treatment settings interested in implementing the use of the BTS in their clinical program to utilize the study protocol set forth in this study because it did suggest a beneficial impact for all the participants.

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## Appendices

### Recruitment Poster

**Are You Still Having Trouble Sleeping? Trouble Dealing with Emotions? A Hard Time with Stress? We're doing a study here that may help!**

Each participant will complete 8 BioSound Therapy sessions over a 4-week period. To participate, you must be in treatment for a substance use disorder and have at least 30 days clean and sober.

**The BioSound® Therapy System is a comfortable vibrational bed. Each session has audio and visual components to help you!**

The BioSound® Therapy System includes:

- Biofeedback
- Music therapy
- Sound massage
- Guided imagery

If interested, please email Dixie Brown at [dixie.brown@saybrook.edu](mailto:dixie.brown@saybrook.edu) for further information and to schedule a time for screening!

**Client Demographics Form**

Name:  
Study Number:  
Gender:  
DOB:  
Age:  
Address:  
City/State/Zip:  
Country:  
Home Phone:  
Mobile Ph.:  
Email:

Ethnicity:  
Height:  
Weight:  
School Grade:

**Emergency Contact Information**

Emergency Contact:  
Relationship:  
Name:  
Address:  
United States  
Home Phone:  
Mobile Phone:  
Home Email:  
Home Fax:  
Briefly describe the relationship:

**Additional Demographics**

Current Occupation:  
Level of Education Completed:

## Participation Screening Form

### Substance Use Disorder History

Drug of Choice 1:

Drug of Choice 2:

Drug of Choice 3:

Date of Last Use:

Have you ever been treated for a substance abuse issue (If so, how many times?):

Longest period of sobriety:

----- **If less than 30 days, exclude ----- >30 days – continue**

Do you have other addictive behaviors?

### Substance Dependency

Increased Tolerance History of Withdrawal

Use more than intended Unsuccessful attempts to stop

Great deal of time using/recovering important obligations/activities given up

Continued use despite knowledge of exacerbation

### Withdrawal Symptoms: Specify Current or Past

Tremor Current Past

Agitation Current Past

Insomnia Current Past

Mood Swings Current Past

Irritability Current Past

Fatigue Current Past

Poor Concentration Current Past

Low Motivation Current Past

Delirium Tremors Current Past

Seizures Current Past

-----If yes, Exclude -----If no, Continue

### Mental Health Treatment History

Have you received mental health services or are you currently receiving services:

Do you have any history of psychosis? If so, please explain:

----- **Exclude if not substance induced**

Do you have any history of suicide? Current suicidal ideation? If so, please explain:

----- **Exclude if active -----If no, Continue**

**Medical:**

Do you have any medical problems?

Please explain:

Are you pregnant?

-----If yes, Exclude -----If no, Continue

Do you have history of seizures?

-----If yes, Exclude -----If no, Continue

Do you have history of Traumatic Brain Injury?

-----If yes, Exclude -----If no, Continue

### **Medications**

List all prescription and non-prescription medications, vitamins, home remedies, birth control pills, herbs that you are taking:

Medication

Purpose

Dose

Times per Day

### **Allergy Information:**

Medication Allergy

Food Allergy

Environmental Allergy

### **Risk Factors**

Have you or are you engaged in any risky behaviors: (Eating Disorders, Self-injury, Violence, Etc.)

Please detail, including what the current status of these issues is for you:

## Informed Consent

### Introduction:

My name is Dixie Brown. I am doctoral student at Saybrook University in California. I am conducting a research study on The Impact of the BioSound Therapy System on Post Acute Withdrawal Syndrome Symptoms. I am completing this research as part of my doctoral degree. I invite you to participate.

### Activities:

If you participate in this research, you will be asked to:

- Sign an informed consent
- Sign a HIPAA Authorization Form
- Complete screening questions

If you are chosen to complete this research, you will be asked to:

- Complete 3 pre-test Questionnaires

**Positive and Negative Affect Schedule-** This questionnaire uses a number of words that describe different feelings and emotions that you will rate based on how you feel in that moment or in the past week.

**Perceived Stress Scale-** This questionnaire asks you to rate how stressful situations in your life seem to you.

**Overall Wellbeing Scale-** This questionnaire asks you to rate physical and emotional pain you are experiencing in that moment.

- Complete a 5-minute Heart Rate Variability (HRV) Biofeedback session

Heart Rate Variability Biofeedback connects a sensor to your finger to measure your pulse. You will practice breathing while your pulse is being measured and displayed on a television monitor.

- Complete a 30-minute Sound Massage

A sound massage is completed on a vibrational platform and headphones, that uses sound and vibrations for 30 minutes. The sound and vibrations may be adjusted for your comfort level.

- Complete a 30-minute Guided Imagery session

A guided imagery session lasts 30 minutes and uses music and words to guide you through using your imagination to visualize a positive change in your life.

- Complete a 5-minute HRV Biofeedback session
- Complete 3 Posttest Questionnaires (Same as Pre-Test)
- After the 8 sessions are completed, you will also complete a 1.5-hour long interview with this researcher to answer questions on your experience with the BioSound Therapy System

I hope to include 3 participants in this research who will complete a total 8 sessions. Participants will complete 2 sessions weekly for one month. Each session will be approximately one hour and 45 minutes including time for assessment before and after each session.

**Eligibility:**

You are eligible to participate in this research if you:

1. Have a substance use disorder
2. Are actively involved in treatment
3. Are 18 years or older

You are not eligible to participate in this research if you:

1. Have a seizure disorder
2. Are pregnant
3. Have a traumatic brain injury
4. Have a psychotic disorder

**Risks:**

There are moderate risks in this study. Some possible risks include: increased symptoms of anxiety or PTSD.

To decrease the impact of these risks, you can: skip any item in the survey, stop participation in the BioSound at any time, refuse to answer any interview question, and follow up with primary therapist in your treatment program.

Should any adverse effects occur during the study, please notify this researcher immediately as well as your primary therapist and clinical director.

**Benefits:**

If you decide to participate, there are many benefits you may receive from using the BioSound Therapy System. One of the benefits is the calming effect the system has on participants. The idea of the system is to help you with any negative feelings, anxiety, depression, or stress you may be having by using music therapy to bring you into a relaxed state. The music is composed with specific rhythms that help the body relax. Research in music therapy suggests it has helped people become more involved in treatment. Music therapy also helps reduce depression and anxiety. Once you reach this relaxed state, then a guided meditation with positive affirmations will be played for you. The guided imagery is meant to help with guilt, fear, shame and trauma. The soothing vibrations and music may help you overcome negative patterns of thought and behavior. From there an inspirational video will be played for you to finish out the session. A heart rate variability biofeedback program is also used to teach you certain skills that can help you manage your emotions.

**Confidentiality:**

The information you provide will be kept confidential to the extent allowable by law. Some steps I will take to keep your identity confidential are: I will use a number to identify you.

The people who will have access to your information are: myself, my intern, my dissertation chair, and my dissertation committee.

I will secure your information with these steps: Using coded identification, locking the computer file with a password, and transporting it in a locked case, etc.

I will keep your data for 7 years. Then, I will delete electronic data and destroy paper data.

**Compensation:**

To thank you for your willingness to participate, you will be given a \$25 Target gift card upon completion.

**Audiotaping:**

I would like to use a voice recorder to record your responses during the interview. You can still participate if you do not wish to be recorded.

Please sign here if I can record you:

**Mandated Reporting:**

I am required to report suspicion of child or elderly abuse to: Department of Human and Health Services.

If I am concerned you might hurt yourself, I must get help for you. I will: Communicate directly with your primary therapist, create a safety plan, and take any necessary actions to provide medical support for you.

If I am concerned you might hurt someone else, I will: Contact the Department of Human and Health Services.

**Additional Costs:**

There are no anticipated financial costs to you.

**Termination of Participation:**

I may stop your participation, even if you did not ask me to, if: symptoms increase to a point you no longer feel comfortable participating or for any other reason you no longer feel safe participating.

If you decide to stop participation, you may do so by: Contacting me directly and put in writing your discontinuation of participation. If so, I will not the information I gathered from you.

**New Findings:**

Sometimes during a study, we learn new information. This information may come from our research or from other researchers. If new information might relate to your willingness to participate, I will give you that information as soon as possible.

**Contact Information:**

If you have questions for me, you can contact me at: [REDACTED]

My dissertation chair's name is Rob Kallmeyer. He works at Saybrook University and is supervising me on the research. You can contact him at: [REDACTED].

If you have questions about your rights in the research, or if a problem has occurred, or if you are injured during your participation, please contact the Institutional Review Board at: sirb@saybrook.edu or 510-593-2935.

**Voluntary Participation:**

Your participation is voluntary. If you decide not to participate, or if you stop participation after you start, there will be no penalty to you, your treatment program at this site will not be impacted in any way. You will not lose any benefit to which you are otherwise entitled.

**Signature:**

A signature indicates your understanding of this consent form. You will be given a copy of the form for your information.

Participant Signature	Printed Name	Date
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Researcher Signature	Printed Name	Date
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## Confidentiality Agreement

It is understood and agreed to that participants of the Saybrook University Doctoral Research performed by Dixie Brown may provide certain information that is and must be kept confidential. To ensure the protection of such information, and to preserve any confidentiality necessary under HIPAA, it is agreed that

1. The Confidential Information to be disclosed can be described as and includes:  
Any information provided by participants, the researcher, from electronic data collection, from interviews, from questionnaires, or the BioSound Therapy System, or any other form of information obtained during the course of this study is designated as “Confidential Information” at the time of its disclosure.
2. The Recipient agrees not to disclose the confidential information obtained during the duration of this study to anyone unless required to do so by law.
3. This Agreement states the entire agreement between the parties concerning the disclosure of Confidential Information. Any addition or modification to this Agreement must be made in writing and signed by the parties.
4. If any of the provisions of this Agreement are found to be unenforceable, the remainder shall be enforced as fully as possible and the unenforceable provision(s) shall be deemed modified to the limited extent required to permit enforcement of the Agreement as a whole.

**WHEREFORE**, the parties acknowledge that they have read and understand this Agreement and voluntarily accept the duties and obligations set forth herein.

Recipient of Confidential Information:

Name (Print or Type):

Signature:

Date:

Researcher:

Name (Print or Type):

Signature:

Date:

## HIPAA Release

---

### Authorization for the Use of Protected Health Information

#### The Impact of the BioSound Therapy System on Post Acute Withdrawal Syndrome

##### **Request for Use of Protected Health Information**

State and federal privacy laws protect the use and release of your health information. Under these laws, your health care provider cannot release your health information to the research team unless you give your permission. If you decide to give your permission for the use of your health information, you must sign this form in addition to the Informed Consent form above. The research team will use and protect your information as described in the Informed Consent Form. However, once your health information is released, it may not be protected by the same privacy laws. The research team will not share it with anyone else without your permission or without removing any information which may identify you.

##### **What Health Information Is Being Requested**

If you give your permission by signing this form, you are allowing Dixie Brown from Saybrook University to access your medical records housed with your health care provider, which contains protected health information. This includes health information in your medical records and other information that could potentially identify you. However, if this information is ever shared, it will not be identifiable to you or else your permission will be sought prior to release. By signing this form, you are giving your health care provider permission to release the following information to the researcher:

Your Name	Your Date of Admission	Your Date of
Discharge		
Your Diagnosis	Your Age	Your Age
when Diagnosed		
Types of Treatment Received	Past Hospitalizations	Mental Health
Information		
Treatment Progress	Medical History	Psychiatric
History		

##### **How Will my Protected Health Information Be Used?**

Your Protected Health Information will only be used for the purposes described in the Informed Consent form. There is a chance that it will be viewed by others who have the legal right to oversee the research, such as the Saybrook University Institutional Review Board, the Office of Human Research Protection, or the Department of Health and Human Services.

##### **Permission Expiration**

Your permission for the researchers to use this information expires at the conclusion of this research. However, once researchers remove any potentially identifying information from your protected health information, they may retain that deidentified information forever.

You can also cancel your permission at any time. To do this, please write to your researcher via email at [REDACTED]. Canceling your permission will NOT cause you to lose out

on any treatment with your health care provider. Please sign below only if you agree to allow your protected health information to be used in the research described in the Informed Consent form.

\_\_\_\_\_  
Patient Name

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness (other than family) Name

\_\_\_\_\_  
Witness Signature

\_\_\_\_\_  
Date

## Site Permission Letter



April 3, 2018

RE: Dixie Brown

To Whom It May Concern:

Dixie Brown has been granted permission from Willow Place, Asheville, North Carolina, to recruit and collect data from participants within the treatment program and to use facility space for the purposes of research and dissertation studies.

If you have any further questions, please contact me at 561-346-1715 or [francis@willowplaceforwomen.com](mailto:francis@willowplaceforwomen.com)

Thank you,

A handwritten signature in black ink, appearing to read "Francis Ward". The signature is fluid and cursive, with a large initial "F" and "W".

Francis Ward  
Owner

## The Positive and Negative Affect Schedule

### PANAS Questionnaire

This scale consists of a number of words that describe different feelings and emotions. Read each item and then list the number from the scale below next to each word. **Indicate to what extent you feel this way right now, that is, at the present moment *OR* indicate the extent you have felt this way over the past week (circle the instructions you followed when taking this measure)**

1	2	3	4	5
Very Slightly or Not at All	A Little	Moderately	Quite a Bit	Extremely
_____ 1. Interested			_____ 11. Irritable	
_____ 2. Distressed			_____ 12. Alert	
_____ 3. Excited			_____ 13. Ashamed	
_____ 4. Upset			_____ 14. Inspired	
_____ 5. Strong			_____ 15. Nervous	
_____ 6. Guilty			_____ 16. Determined	
_____ 7. Scared			_____ 17. Attentive	
_____ 8. Hostile			_____ 18. Jittery	
_____ 9. Enthusiastic			_____ 19. Active	
_____ 10. Proud			_____ 20. Afraid	

### Scoring Instructions:

Positive Affect Score: Add the scores on items 1, 3, 5, 9, 10, 12, 14, 16, 17, and 19. Scores can range from 10 – 50, with higher scores representing higher levels of positive affect. Mean Scores: Momentary = 29.7 ( $SD = 7.9$ ); Weekly = 33.3 ( $SD = 7.2$ )

Negative Affect Score: Add the scores on items 2, 4, 6, 7, 8, 11, 13, 15, 18, and 20. Scores can range from 10 – 50, with lower scores representing lower levels of negative affect. Mean Score: Momentary = 14.8 ( $SD = 5.4$ ); Weekly = 17.4 ( $SD = 6.2$ )

**Copyright © 1988 by the American Psychological Association. Reproduced with permission. The official citation that should be used in referencing this material is Watson, D., Clark, L. A., & Tellegan, A. (1988). Development and validation of brief measures of positive and negative affect: The PANAS scales. *Journal of Personality and Social Psychology*, 54(6), 1063–1070.**

## Perceived Stress Scale

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, you will be asked to indicate by circling *how often* you felt or thought a certain way.

Name\_\_Date\_\_

Age\_\_Gender (*Circle*):     M     F     Other \_

0 = Never     1 = Almost Never     2 = Sometimes     3 = Fairly Often     4 = Very Often

1. In the last month, how often have you been upset because of something that happened unexpectedly?     0    1    2    3    4
2. In the last month, how often have you felt that you were unable to control the important things in your life?     0    1    2    3    4
3. In the last month, how often have you felt nervous and “stressed”?     0    1    2    3    4
4. In the last month, how often have you felt confident about your ability to handle your personal problems?     0    1    2    3    4
5. In the last month, how often have you felt that things were going your way?     0    1    2    3    4
6. In the last month, how often have you found that you could not cope with all the things that you had to do?     0    1    2    3    4
7. In the last month, how often have you been able to control irritations in your life?     0    1    2    3    4
8. In the last month, how often have you felt that you were on top of things?     0    1    2    3    4
9. In the last month, how often have you been angered because of things that were outside of your control?     0    1    2    3    4
10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?     0    1    2    3    4

**BioSound Therapy System Pre / Post**

Rate how you are feeling right now.

With pink being the least intense and red being the most intense, fill in each scale with a mark.

It is important to mark every scale somewhere.

For example- if you are feeling very anxious you would mark as follows:



Anxious



Stressed



Angry



Depressed



Fearful



Body  
Aches



Muscle  
Tension



Headache



Name: \_\_\_\_\_ Therapist: \_\_\_\_\_ Date: \_\_\_\_\_

Comments:

\_\_\_\_\_

## **Qualitative Interview Question Guide**

### **Open Ended Questions-**

Tell me about your experience with BTS

What stood out to you most about your experience?

Did you notice anything over the course of the sessions that may have changed for you?

Let's talk about the PANAS scale we used that looked at the different feelings and emotions you experience, I see that (change occurred with this emotion), can you tell me a little more about that?

Let's talk about the Perceived Stress scale we used that looked at stressful situations in your life, I see that (change occurred here), can you tell me a little more about that?

Let's talk about the BTS pre/posttest scale we used that looked at the different physical and emotional experiences you have, I see that (change occurred here), can you tell me a little more about that?

Do you have any other thoughts or comments about how the BTS affected your recovery process or symptoms of PAWS?

Any final thoughts you would like to share with me?

Additional Questions That May be Used for Probing to gather more subjective information on quantitative questionnaires responses and aforementioned Open-Ended Questions-

I see the BTS affected your anxiety. How did the BTS affect your anxiety?

I see the BTS affected your stress level. How did the BTS affect your stress level?

I see the BTS affected your anger. How did the BTS affect your anger?

I see the BTS affected your depression. How did the BTS affect your depression?

I see the BTS affected your level of fear. How did the BTS affect your level of fear?

I see the BTS affected your physical symptoms. How did the BTS affect physical symptoms such as muscle tension, headaches, body aches?

I see the BTS affected your sleep. How did the BTS affect your sleep?

I see the BTS affected your alertness. How did the BTS affect your alertness?

One of the symptoms of PAWS is your ability to regulate emotions. How did the BTS affect your ability to regulate emotions?

One of the symptoms of PAWS is your ability to cope with life stressors. How did the BTS affect your ability to cope with life on life's terms?

I see the BTS affected your interest in things. How did the BTS affect your sense of interest in things?

I see the BTS affected your enthusiasm. How did the BTS affect your sense of enthusiasm about life?

One of the symptoms of PAWS is your ability to pay attention to things. How did the BTS affect your attention scan?

One of the symptoms of PAWS is your ability to think clearly. How did the BTS affect your ability to think clearly?

One of the symptoms of PAWS is your ability to remember things. How did the BTS affect your memory? Or ability to remember things?

I see the BTS affected your sense of control. How did the BTS affect your ability to feel a sense of control in your life?

