WEIGHTED BLANKET EFFICACY FOR REDUCING ANXIETY AND ANGER IN ADULT PSYCHIATRIC PATIENTS

by

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Restraint and seclusion continue to be used to manage aggressive and self-injurious behaviors in psychiatric patients on the inpatient psychiatric unit. This intervention can cause both physiological and psychological injuries to the patient. The individual may experience feelings of humiliation, anger, shame, as well as re-traumatization for those individuals with a trauma history. Physical injuries such as broken bones, lacerations, shortness of breath may occur.

Over the course of psychiatric history, the use of restraints and seclusion has been viewed as barbaric and brutal by others, while others see the practice as beneficial and therapeutic and necessary for the safety of the individual and staff. In recent years, this practice has been closely monitored since individuals have died while in restraints or seclusion.

This concern over the use of restraint and seclusion has caused clinicians (nursing, occupational therapists, and others) to find alternative interventions. One intervention that has been used by occupational therapists is the weighted blanket (WB). The purpose of this dissertation was to research the effects of the WB with the adult population on an inpatient

psychiatric unit. The focus was to explore if the WB decreased anxiety and anger in this population.

The results of this research showed that there was a decrease in anxiety and anger for those participants who used the WB for 30 minutes. These findings were supported by the results of other research conducted since 2008.

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DEDICATION

This dissertation is dedicated to my late parents who always had faith in me and encouraged me along the way as I pursued my career in nursing. I miss you both and wish you were here to see how much I have achieved.

To my husband Ed, my daughter Diana, my son Edward, my sister Jennifer, and my son-in-law Sam who supported and encouraged me over the years in my journey towards my PhD.

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CHAPTER 1: INTRODUCTION

RESEARCH PROBLEM

Restraints and seclusion have a negative effect on patients that can be both physical and psychological: physical injuries may occur, and patients may re-experience feelings of past traumatic events (Masters, 2017). Some patients have expressed feelings of humiliation, anger, and shame in response to restraint and seclusion, while others may also feel disrespect, loss of control, and dignity (Tingleff et al., 2017). Yet, restraints and seclusion continue to be used to manage violent behaviors with adult psychiatric patients (Blairs et al., 2007; Holmes et al., 2015; Wu, 2015; Goulet & Larue, 2016). These violent behaviors often begin when a person experiences anxiety and anger causing restraint or seclusion to be used to manage these behaviors (Granic, 2014; Masters, 2017; Perkins et al., 2012).

According to the Center for Medicare and Medicaid Services, restraints are devices that are applied to a person's wrists and ankles that restrict the person from moving; restraint may also involve a person who holds another person, restricting them from moving. Seclusion is when a person is involuntarily put in a room with the door locked or open but is unable to leave (USDHHS, 2018). The practice of and controversies surrounding restraint usage to manage anger, aggressive and violent behaviors date back over three centuries to the time of Pinel, a psychiatrist in the 18th century who opposed the usage of restraints (Masters, 2017).

Over the course of history, restraints have, at times, been "synonymous with brutal custodial care" (Appelbaum, 1999, p. 881). While some believe that restraints are beneficial and therapeutic (Masters, 2017) and view restraints as necessary to ensure safety (Perkins et al., 2012), the risks associated with restraints in adults with psychiatric diagnoses remain. The

Hartford Courant exposé described a 50-state survey conducted from 1988 to 1998 reporting that 142 children, adolescents and adults died while in restraints (Weiss et al., 1998). The outcry resulting from this publication prompted Congress to introduce bills that would support regulations requiring monitoring of restraints in all areas, not just psychiatric settings (Applebaum, 1999).

The changes in restraint regulations meant that inpatient and residential settings began to explore alternatives to restraint use. Huckshorn (2004) offered a brief timeline of events related to seclusion and restraints from 1996 to 2003. The National Association of State Mental Health Program Directors (NASMHPD) and the Substance Abuse and Mental Health Services Administration (SAMHSA) launched regional training sessions and conferences beginning in 2003 which focused on information relevant to restraint reduction initiatives including trauma-informed care, use of sensory modalities for restraint reduction, and assumptions about seclusion and restraints (NASMHPD, 2006).

Alternative interventions that have been used in the past to avoid seclusion and restraint have been focused on decreasing an individual's experience of anxiety and anger. Some of these alternative interventions have been verbal de-escalation, medication management, and cognitive-behavioral therapy. Additional interventions have included staff education in caring for the agitated person, sensory/comfort rooms, groups facilitated by a peer specialist (person with mental illness), and recovery-based programming (non-pejorative language) (Gaynes et al., 2017).

Tina Champagne, an occupational therapist with psychiatric experience who has published several articles on weighted blankets (WB) and sensory modalities, noted that the use of sensory modalities by occupational therapists (OTs) has proven helpful in avoiding restraint

use with some patients (T. Champagne, personal communication, July 21, 2019). Weighted modalities, specifically the weighted vest and the WB, are among those interventions originally used by occupational therapists with children and adolescents with developmental and sensory disorders. In these populations, the weighted vest (WV) and the WB have been shown to offer calming effects (Edelson et al., 1999; Fertel-Daly et al., 2001; Olson & Moulton, 2004a; Olson & Moulton, 2004b). The calming effect of the WB may be due to sensory integration and deep touch pressure stimulation (see sensory integration theory later in this chapter).

GAPS IN THE LITERATURE

Weighted vests/blankets (WV/WB) have been studied for the past 20 years (Fertel-Daly et al., 2001; Olson & Moulton, 2004a; Olson & Moulton, 2004b; Gringras et al., 2014; VandenBerg, 2001). Most of these studies have been conducted on the use of WVs with children primarily in classroom settings and the results have been mixed. (Fertel-Daly et al., 2001; Olson & Moulton, 2004a; Olson & Moulton, 2004b; Davis et al., 2013; Gringras et al., 2014; Losinski et al., 2017; VandenBerg, 2001). The WB and WV have not been studied with children or adolescents in a psychiatric unit.

Since 2008, WVs/WBs have been studied with adults in a variety of settings as an intervention to decrease anxiety (Mullen et al.., 2008; Champagne et al., 2015; Chen et al., 2013; Chen et al., 2016; Ackerley et al., 2015; Reynolds et al., 2015; Vinson et al., 2020; Becklund et al., in press). Many of these studies were conducted in dental offices or clinic settings. Of the nine studies, only two were conducted on inpatient psychiatric units. The results of the eight studies on adults showed the WVs/WBs were effective interventions to decrease anxiety (Mullen et al., 2008; Champagne et al., 2015; Chen et al., 2013; Chen et al., 2016; Ackerley et al., 2015;

Reynolds et al., 2015; Vinson et al., 2020; Becklund et al., in press). As mentioned earlier, the WB is a non-invasive, non-pharmacologic, self-directed, and least restrictive intervention.

The published scientific research on the effectiveness of the WV with child, adolescent, or adult patients have not been conducted on an inpatient psychiatric unit. Most of the literature on the WV has been done primarily with children in a school or outpatient setting. The literature on WB use as an intervention with adults in an inpatient psychiatric unit is limited to one study published in 2015. Although the Champagne et al. (2015) study had positive results, they were not statistically significant, and the sample size was small. Another gap in the literature relates to the length of time a patient should use the blanket and the most effective ratio of blanket weight to the patient's body weight (Olson & Moulton, 2004a). A third gap in the literature about the WB is whether it would decrease a patient's length of stay on the inpatient psychiatric unit.

Based upon an extensive review of the literature, further research is needed on the safety and efficacy of WBs as an alternative to restraint and/or seclusion in decreasing anxiety, anger, and aggression among psychiatric inpatients. The WV will be eliminated from the study at this time to focus on one weighted modality. Another reason to eliminate the WV is that the inpatient psychiatric unit only has WBs that can be used for the study. Additionally, it is important for research to focus on determination of the proper ratio of blanket weight to the patient's body weight and the most effective duration of WB application to achieve therapeutic goals.

Chapter one outlines the introduction, purpose, conceptual and theoretical framework, and research questions. Chapter two presents the background, significance, and review of the literature. Chapter three includes the research design and methods, in addition to a summary of

the Emergency Department (ED) pilot study that guided the changes to the dissertation study. Chapter four consists of manuscript A entitled "Effectiveness of the WB with psychiatric patients in the ED: A pilot study" conducted in the spring of 2019 by the principal investigator which focused on psychiatric patients in the ED using the WB. Chapter 5 consists of manuscript B entitled "Use of the WB to decrease anxiety and anger in adult inpatient psychiatric patients." that provides the findings and discussion of the dissertation study.

LONG TERM OBJECTIVE

The purpose of this study was to expand the research about the use of the WB with adults in an inpatient psychiatric setting. The long-term goal was to increase awareness and knowledge about the effectiveness of the WB as an alternative intervention to decrease feelings of anxiety and anger among adult psychiatric inpatients.

CONCEPTUAL MODEL AND THEORETICAL FRAMEWORK

The conceptual and theoretical frameworks underpinning this study are emotional dysregulation, trauma theory, and sensory integration theory. Individuals may experience a wide range of emotions throughout each day that can include happiness, sadness, anxiety, and anger. At times, feelings of anxiety and/or anger may contribute to an individual losing control. With this understanding, a search of the literature was conducted using keywords "emotion" and "regulation". This first exploration highlighted research on the concept of emotion regulation/dysregulation. In addition, trauma theory and sensory integration theory were revealed to be relevant and were added as frameworks for this study. Each will be reviewed individually, followed by discussion of how they are interrelated for this study. A concept map of emotion dysregulation and trauma theory is included in appendix A.

Emotional Dysregulation

"The ancient Greek philosophers conceptualized the emotions as irrational, animistic, visceral phenomena that interfered with the higher-order processes of thought and reason" (Cole et al., 1994, p. 73). Emotions, emotional regulation, and emotional dysregulation are all complex processes. The literature included the terms emotion or emotional with regulation or dysregulation. The word emotional will be used consistently throughout this study to maintain consistency. According to Gross (1998), emotional regulation research began in the 1970's in many areas of psychology including cognitive, developmental, social, personality, clinical, biological, and health, which have all explored how emotions are regulated. Emotional regulation has been defined as a process of how a person influences when and how they experience emotions and how these emotions are expressed (Gross, 1998). Emotional dysregulation as defined in the literature varies but can be considered as "a maladaptive pattern of regulating emotions" (Hilt et al., 2011, p. 160), "an impaired ability to regulate unwanted emotional states" (Dadomo et al., 2016, p. 1) or the inability to manage the expression of negative emotions (Gross, 1998; You et al., 2018).

The concept of emotional dysregulation can be found in other frameworks such as emotion theory, developmental research on emotion regulation, and clinical research and practice (Cole et al., 1994). The conceptual model of emotional dysregulation is at the core of how a person's response to feelings of anxiety, anger and their aggressive behaviors are related to and part of their impulsivity and inability to regulate their emotions. For this study, the concept of emotional dysregulation was explored by developing the antecedents, attributes, consequences, internal and external factors, assumptions, proposition, and empirical referents (Walker & Avant, 2011). The antecedents for the concept of emotional dysregulation are psychiatric diagnoses

(i.e., borderline personality disorder, schizophrenia, depression, bipolar disorder, anxiety, etc.), and the ability to manage their emotions due to brain development (HPA axis, amygdala, hippocampus) (Henry et al., 2007; Hilt et al., 2011), genetics, and/or environmental and situational factors (internal and external). These factors may manifest themselves in infancy and continue into adulthood, causing an impact on the management of a person's emotional state. For some individual's, these emotional states can be adaptive and maladaptive coping strategies which may be related to difficult life events or suppressed feelings (Sutton et al., 2013; Selby et al., 2008), poorly developed relationships, overwhelming feelings, and difficulty concentrating (Hilt et al., 2011).

The attributes for this concept are the inability to tolerate stress, misinterpretation of emotional and/or social cues, impulsivity versus inhibition, temperament, and negative attitudes. The consequences associated with this concept are self-harm, including broken bones from kicking or punching objects, attempting to cut or hang oneself and the potential to harm others. The outcomes would be behavioral issues and an increase in emotion/physical energy. The internal factors of emotional dysregulation are issues related to self-image, abandonment, and uncertainty. The external factors are stressors (personal, financial), trauma history (sexual, physical, emotional abuse, neglect), alcohol and/or drug use, and decreased family and social support.

The propositions for this concept are first that emotional regulation and dysregulation are a balance between coping skills and impaired social functioning. The second proposition is that there is a relationship between anxiety, aggression, trauma, and coping skills. Emotional dysregulation has several empirical referents for each of the attributes beginning with the inability to tolerate stress (uncomfortable feelings, frustration), interpretation of emotional and

social cues (eye contact, personal space), impulsivity versus inhibition (acting without thought, risky behavior), temperament (character traits, moodiness), and negative attitudes (cynical, glass is half empty, blaming others). Personal space or the distance between persons is dependent on such factors as whether they are family, friends, or strangers, as well as cultural influences, and whether there are obvious signs of aggression or anger. People tend to be closer to family and further away when someone shows anger or aggression. The assumptions for this concept are first that people should be able to self-regulate their emotions and behaviors. The second assumption is that personal experience, the environment, and genetics can influence whether a person can or will be emotionally regulated.

Anytime a person ruminates or constantly replays situations, has negative thoughts about situations or tries to control these feelings, emotion dysregulation may occur (Selby, et.al., 2008; Gratz & Roemer, 2004). If a person can become aware of their feelings and learn how to manage them in a healthy adaptive way, this will eventually help in emotion regulation (McLaughlin et al., 2011). Unresponsiveness or neglect from caregivers as well as abuse, childhood neglect and maltreatment, can also have an impact on a person's ability to manage their emotions and may result in emotion dysregulation (Hilt et al., 2011).

New technological advances have provided scientists with innovative information about the brain. The hypothalamic-pituitary-adrenocortical (HPA) axis has been linked to stress (Hilt et al., 2011; Neumann et al., 2010) and has also been linked to conduct disorder in young children with aggressive behaviors (Cappadocia et al., 2009). The HPA axis may also influence emotional regulation and emotional dysregulation, especially if there is repeated, or "prolonged activity of this neuroendocrine axis" (Hilt et al., 2011, p. 163). The amygdala has also been found to respond to emotional stimuli and can be viewed as a "starting point for developing a

brain-system-level model of vigilance and negative emotional states and for identifying abnormalities within these systems that are responsible for emotional dysregulation" (Donegan et al., 2003, p. 1285). Early life stress can play a role in anxiety and depression and may cause changes in the HPA axis (Neumann et al., 2010).

Emotional dysregulation is a common feature and symptomatology of psychopathology due to the impairment or function of emotional regulation (Cole et al., 1994; Cappadocia et al., 2009) and can primarily be found within most of the psychiatric disorders (Gross, 1998; González et al., 2017; Meyer et al., 2016). Part of emotional dysregulation is evidence of anxiety, aggression, and behavioral responses that, if intense, can result in maladaptive coping responses and psychiatric disorders (Meyer et al., 2016). Emotional dysregulation (or emotion disturbances or emotional deficits) is a diagnostic criterion in psychiatric disorders such as conduct disorder, borderline personality disorder (BPD), depression, eating disorders, post-traumatic stress disorder (PTSD), anxiety disorder, antisocial personality disorder and bipolar disorder (Neumann et al., 2010). As Neumann (2010, p. 1) stated, "this is not surprising, given the fact that neural circuits regulating emotions and social behaviours are highly interconnected." Indeed, many psychiatric disorders have been related to intense and/or severe emotional disturbances or fluctuations along with impaired social functioning (Neumann et al., 2010). Psychologists have been studying both emotion regulation and emotion dysregulation for many years in children, adolescents, and adults. Marsha Linehan (1993) has done extensive research on emotional dysregulation with people experiencing BPD and has developed dialectical behavioral therapy as an intervention to aid those with BPD (Corrigan et al., 2011).

When an individual is trying to control the expression of their emotions, then dysregulation may occur (Gratz & Roemer, 2004), potentially leading to poor relationships, poor

concentration, feeling overwhelmed, engagement in destructive behaviors (Hilt et al., 2011) and an inability to distinguish or process emotional cues in the environment (McLaughlin et al., 2011). "Under-regulation of emotions, particularly anger, usually becomes aggression as a way to terminate difficult emotional situations, while over-regulation contributes to aggression by increasing physiological arousal and raising the likelihood of activating suppressed emotional triggers" (Sutton et al., 2013, p. 501).

It is important for staff (nurses, mental health associates, social workers, occupational and recreational therapists) to understand emotional dysregulation so effective treatment plans and intervention strategies can be developed to aid the individual in coping with their emotions as well as improving their relationships with others.

Trauma Theory

Trauma theory has relevance to this research due to the percentage of patients admitted to behavioral health (BH) units who have had some form of trauma during their lifetime (Cusack et al., 2018). People with a history of trauma may experience a wide variety of emotions and emotional dysregulation. Trauma may result in ongoing psychological and physical distress that can affect the survivor throughout their lifespan (D'Andrea et al., 2011). According to van der Kolk (2014), traumatic experiences have an impact on our mind, our body, our emotions, the ability to feel joy, happiness, and our relationships, but also have a role in our biology and immune system.

Judith Herman developed trauma theory (1992) from her extensive literature review and clinical observations of survivors who experienced trauma during captivity, the Holocaust, the military, sexual abuse, domestic violence as well as other forms of mistreatment. Herman's clinical observations led her to identify three broad areas of disturbance common in victims of

repeated or prolonged trauma: symptomatology (or symptoms), characterology (individual character/personality), and vulnerability with a focus on terror, hyperarousal, intrusion, and constriction (Herman, 1992). Emotional dysregulation, trauma and emotional regulation are all interrelated in the person's central nervous system (Henry et al.,2007; van der Kolk, 2006) and autonomic nervous system (Porges, 1995). Other areas of the brain that play a role in trauma consist of the hypothalamic-pituitary-adrenal (HPA) axis, amygdala, hippocampus, corpus callosum, neurotransmitters, and the thalamus (Henry et al., 2007; Hilt et al., 2011). "Long after a traumatic experience is over, it may be reactivated at the slightest hint of danger and mobilize disturbed brain circuits and secrete massive amounts of stress hormones. This precipitates unpleasant emotions, intense physical sensations, and impulsive and aggressive actions" (van der Kolk, 2014, p.2).

Sensory Integration Theory

Sensory Integration Theory was developed by Dr. A. Jean Ayres, an occupational therapist, beginning in the 1960's based on her work on neurobiology and motor control theories (Smith Roley et al., 2007). According to Ayres (1972), sensory integration organizes all the sensations that enter the body, and the brain acts as the traffic controller that helps to sort these sensations by making the parts into a whole, so everything makes sense. As stated by Ayres, "sensory integration is the process of organizing sensory inputs so that the brain produces a useful body response and also useful perceptions, emotions, and thoughts" (Ayres, 1979, p.28). In addition to the central nervous system, sensory integration also includes sound, tactile or touch, proprioception, sight, and the vestibular system, which provide information for the body to adapt to the information that the body receives (Ayres, 1979).

Deep touch pressure stimulation is related to sensory integration theory (Olson & Moulton, 2004a; Losinski et al., 2016; Losinski et al., 2017) due to the sensation of proprioception and its effects on muscle contraction and joint movement (Ayres, 1972). Deep pressure tends to have a calming and relaxing effect for a person (Grandin, 1992). This calming effect is due to deep touch pressure stimulation and proprioception (Ayres, 1972; VandenBerg, 2001) that provides information to the sensory areas of the brain (VandenBerg, 2001) especially the reticular formation receives sensory information that can decrease activating stimulation (Ayres, 1972; VandenBerg, 2001). Some examples of deep touch pressure stimulation may include hugging, squeezing, holding, stroking, and other interventions that offers a calming and relaxing effect (Krauss, 1987; Grandin, 1992; VandenBerg, 2001). This calming effect may produce a decrease in a person's heart rate, respiratory rate, and blood pressure (Bestbier& Williams, 2017) as well as having "an inhibitory effect on the central nervous system" (Sylvia et al., 2014, p.72) and activates the limbic system to modulate arousal levels, thus decreasing anxiety and aggression (VandenBerg, 2001). The autonomic nervous system, which includes the sympathetic and parasympathetic systems, also plays a role in adaptation of anxiety and stress related to the effect of deep touch pressure stimulation (Chen et al., 2016). As written in an article by VandenBerg, "deep pressure is registered in the limbic system, hippocampus, and reticular activating system and may stimulate production of neurotransmitters to modulate arousal levels, similar to the effects of medications" (VandenBerg, 2001, p. 622).

In summary, sensory integration theory, emotional dysregulation, and trauma theory are all interrelated due to the connection of the brain and central nervous system and influence how an individual responds to stressors and negative emotions. The conceptual model of emotional dysregulation influenced the design for this research by reason of its focus on anxiety and anger

that can be quantified with a pre- and post-test design. The effects of trauma have shown that there are changes in the brain along with an increase in stress hormones. These changes affect how the brain communicates and filters information, which causes a person to be hypervigilant, tend to repeat problems, and difficulty learning from their experiences (van der Kolk, 2014). The WB, which offers deep pressure input associated with Sensory Integration Theory, served as the intervention modality in this study. Outcomes were evaluated based on the effectiveness of the WB in decreasing anxiety and anger behaviors. Since anger and feelings of anxiety can be measured during data collection and analyzed, this study employed quantitative methods (Ponterotto, 2005; Rolfe, 2013).

RESEARCH QUESTIONS

The research questions and methods for this study were developed based on a WB pilot study conducted by the principal investigator in the ED during the spring of 2019. The following research questions (RQ) were formulated to explore safety and efficacy of the WB as an alternative intervention to restraint/seclusion with adult patients on an inpatient psychiatric unit:

- RQ #1: How effective is the WB as an alternative intervention in managing anxiety and anger among adult patients admitted to a behavioral health (BH) unit?
- RQ #2: Does the WB decrease the Visual Analog Scale (VAS) anxiety score for participants who scored 4 or above pre-intervention?
- RQ #3: What is the relationship between the use of the WB and the measurement of anxiety and/or anger using the Patient-Reported-Outcomes Measurement Information System (PROMIS) measurement tools in the adult BH patient?
- RQ #4: What is the relationship between anxiety and anger using the VAS and the PROMIS measurement tools?

- RQ # 5: What is the relationship between psychiatric diagnoses and the results on the Adolescent/Adult Sensory Profile (A/A SP)?
- RQ # 6: What responses do the participants provide in the exit survey about the WB?

THEORETICAL & OPERATIONAL DEFINITIONS FOR VARIABLES

The table below includes the theoretical and operational definitions for the variables that were used in this study. These variables included anxiety, anger, trauma history, age, gender, BH diagnoses, marital history, and restraint/seclusion history. Each of these variables were measured with specific tools, as shown in Table 1or gathered through chart review.

Table 1: Variables, Theoretical and Operational Definitions

Variable	Theoretical Definition	Operational Definition/Measurement Tool	Measure
Anxiety	"fear (fearfulness, feelings of panic), anxious misery (worry, dread), hyperarousal (tension, nervousness, restlessness) and somatic symptoms related to arousal (cardiovascular symptoms, dizziness)" (Cella, et al, 2010, p. 1182)	1.Patient Self -Report of Anxiety-utilizing PROMIS Emotional Distress-Anxiety Scale-Short Form 4a	Pre- and post-test Scale 1-5
Anger	"angry mood (irritability, reactivity), negative social cognition (interpersonal sensitivity, envy, vengefulness), verbal aggression, and efforts necessary to control angry mood (Cella, et al, 2010, p.1182)	1.Self -Report of Anger-utilizing PROMIS Emotional Distress-Anger Scale	Pre- and post-test Scale 1-5
Age	Demographic	Adult who is 18 years old or older	1=18-23years 2=24-29 3=30-35 years 4=36-41 years 5=42-47 years

			6=48-53 7=54-59 8=60-65 9=66+ years
Gender	Demographic	Male or Female	1= Male 2=Female 3=Unknown
Weight	Demographic	Chart Review	1=100-125 pounds (lb.) or 45.4-56.7 kilograms (kg) 2=126-150 lb. or 57.2-68 kg 3=151-175 lb. or 68.5-79.4 kg 4=176-200 lb. or 79.8-90.7 kg 5=201-225 lb. or 91.2-102.1 kg 6=226-250 lb. or 102.5-113.4 kg 7=greater than 251 lb. or 113.9 kg
Behavioral Health Diagnosis	Demographic	Diagnosed with depression, bipolar disorder, schizophrenia, schizoaffective disorder, borderline personality disorder	1=Depression 2=Bipolar 3=Schizophrenia 4=Schizoaffective 5=Borderline Personality Disorder 6=Other
Marital Status	Demographic	Single, married, separated, widowed, or divorced	1=Single

			2=Married 3=Separated 4=Divorced 5=Widowed
Restraint and seclusion history	Demographic	1. Assess if participant has a current history of restraint and/or seclusion through chart review. 2. Yes or No Response on exit survey	1= Yes 2= No

CHAPTER 2: REVIEW OF THE LITERATURE

BACKGROUND AND SIGNIFICANCE

Anxiety and aggressive behaviors among patients in hospital settings are often seen in the ED (Wilson et al., 2012) and on admission to psychiatric units (Master, 2017; Perkins et al.,2012). Experiences of agitation in and aggression from patients are common occurrences for staff working on an inpatient BH unit and can lead to potential staff injuries, causing an unsafe milieu (Abderhalden et al., 2008; Garriga et al., 2016; Iozzino et al., 2015; Petit et al., 2017; Stewart & Bowers, 2013; Whittington & Richter, 2005). According to Iozzino et al. (2015), one in five or 20% of patients who are admitted to an inpatient psychiatric unit have committed acts of violence while in the hospital. Also, 80% of nursing staff and 41% of clinical staff working on an inpatient psychiatric unit have experienced aggressive behaviors from the patients in their care (Dack et al., 2013). Staff management of the care of their patients with these aggressive behaviors can be challenging (Blair et al., 2017). Anxiety may be a prelude to aggressive behaviors, with signs such as swearing, yelling, verbal threats, clenched fists, and punching walls (Granic, 2014).

Determination of effective treatment modalities for aggressive behaviors by patients are essential for protecting all patients, staff, and visitors. Current treatment protocols rely on restraints, seclusion, and pharmacological interventions, which affect patients psychologically and physiologically (Wilson et al., 2018). For some patients, the experience of restraints can be re-traumatizing and have long term effect on their treatment (Cusack et al., 2018; Tingleff et al., 2017; Wilson et al., 2018). For others, restraints and seclusion have caused many to die (Weiss et al., 1998). Staff may also use restraint or seclusion based on the patients' level of violence, staff fear of aggression, and ineffective management of patient aggression and violence (Jacob et

al., 2016). The use of restraints and seclusion can increase the risk of injury to patients and staff, but also affect the therapeutic relationship between the patient and the nurse (Bowers, 2014); the staff may feel discouraged by the increase in use of restraints and seclusion and their increased risk for injuries (Taylor et al., 2012).

Currently, verbal de-escalation techniques, medications, cognitive behavioral therapy, journaling, sensory/comfort rooms, and stress balls are interventions used to aid in decelerating patients' aggressive behaviors (Gaynes et al., 2017). However, these interventions are not always effective (Whittington & Richter, 2005). An alternative treatment is the weighted blanket (WB) that has been used by occupational therapists, especially with children with developmental disorders (Davis et al., 2013; Edelson et al., 1999; Fertel-Daly et al., 2001; Losinski et al., 2017; VandenBerg, 2001). Although it has not routinely been used to decrease anxiety among psychiatric patients, the WB has been found to have a calming effect on patients (Edelson, et al., 1999; Fertel, et al, 2001; Olson & Moulton, 2004a; Olson & Moulton, 2004b).

Review of the Literature

To inform the proposed research, relevant literature about alternative interventions, weighted vests (WV) and WB will be reviewed and evaluated.

WEIGHTED VEST/INFLATED VEST

Findings from research on weighted modalities within the child and adolescent populations have been mixed; this may be due to small sample sizes within the studies, limited patient exposure to the WV/WB, or to the setting of the study. Weighted vests are designed from cotton material which have equally distributed removable glass-beads or crushed stone sewn into them or with removable weights found inside pockets in the front, side and back of the vests.

Research by Hodgetts et al. (2010) sought to determine if the pressure from the WV would decrease restlessness, impulsivity and emotional lability and increase the time sitting among 10 children with autism and whether teachers viewed the WV as an intervention to improve the students' productivity in the class. According to the authors, the teachers were asked about the child's behavior when wearing the WV, but they did not discuss what the teachers thought (Hodgetts et al., 2010). In this study, five percent of the child's weight was used as the base weight of the vest. However, based on the parent's preference a few of the participants used the weighted vest that was greater than five percent of their weight. For these participants, the weight of the vest ranged between two to six pounds and was worn for five minutes. The authors found that the effectiveness of the WV was mixed, and they noted that there was uncertainty about how often the vest should be worn and how much weight should be used with each child (Hodgetts et al., 2010).

Fertel-Daly et al., (2001) explored the effectiveness of the WV on children with pervasive developmental disorders. The purpose of their study was to see if wearing the WV would increase the participants' attention to a task (motor skills) and decrease their self-stimulating behaviors (Fertel-Daly et al., 2001). The researchers noted that the WV was beneficial (calming effect) for the five preschoolers who wore one-pound WVs for two-hour periods of time. They found that the WV showed the participants had an increase in their attention to task during the study. However, the participants were not able to maintain their attention to task once the WV was not used. They also noted that there was a decrease in distractions when the WV was used (Fertel-Daly et al., 2001). One earlier study (Edelson et al., 1999) primarily focused on the application of deep pressure stimulation by using Temple

Grandin's hug machine with 14 children between the ages of 4-13 with autism. These researchers found that the hug machine offered a calming effect for the participants.

Research by Lin et al., (2014) explored the effects of the WV on 110 children with attention deficit hyperactivity disorder (ADHD) and focused on attention, impulsivity, and ability to complete tasks. The WV used for the study had 18 pockets with 0.25 and 0.50-pound weights for each pocket. The weight chosen for the blanket was calculated to be 10% of the child's body weight; the WV could weigh between 4.5 to 9 pounds. The researchers found the children showed improvements in on-task behaviors and attention, and they recommended the use of WV for children with ADHD. The VandenBerg study (2001) used the weighted vest with four children with difficulties with attention. Their findings were consistent with those of Lin et.al (2014) in that the children showed improvements with their on-task behaviors while wearing the WV (VandenBerg, 2001).

In the research by Davis et al. (2013), only one child with autism was recruited for a study focused on whether the WV would decrease aggressive and self-injurious behaviors. The researchers found that the WV did not decrease the concerning behaviors; however, the child had worn the WV for seven months prior to the study.

Losinski and colleagues (2017) conducted a study with three children with autism in an elementary school setting that used a variation of the WV and in addition to other interventions. The research explored three different interventions: (a) a compression vest, (b) a weighted blanket (WB) with a fixed six-pound weight, and (c) an exercise bike (Losinski et al., 2017). The authors did not find that the compression vest, WB, or exercise bike were effective. However, they noted that the children may have influenced this result either using or seeing the WB and compression vest in their classroom setting (Losinski et al., 2017).

While the research by Davis et al. (2013) and Losinski et al. (2017) did not show that use of the WV was effective, there were extraneous variables that may have influenced these outcomes.

An alternative to the WV is a vest which has an inflatable bladder inside that is controlled by pumping the bladder to the individual's desired comfort level. Research by Reynolds et al. (2015) was the only study that could be found with adults that used this inflated vest. The focus of this study was on deep pressure stimulation and participant performance while playing a game using electrodermal activity as one of the study measures (Reynolds et al., 2015). The authors found that the inflatable vest supported their hypothesis about the effects of deep pressure stimulation on the parasympathetic nervous system and autonomic arousal causing a calming effect for the participants (Reynolds et al., 2015).

WEIGHTED BLANKETS

Weighted blankets are of a comforter-like design consisting of cotton material filled with poly-beads or crushed stone with the weight evenly distributed throughout. WBs function through deep touch pressure stimulation (Losinski et al., 2017; Olson & Moulton, 2004a). The first WB study conducted with adults was in a college setting with students wearing the blanket in a lying down position for five minutes (Mullen et al., 2008). This study measured anxiety with the state trait anxiety inventory (STAI-10) (Speilberger et al., 1970) and electrodermal activity (EDA) and found that using a 30-pound WB was a safe and effective intervention in reducing anxiety among the participants. Mullen and colleagues (2008). The authors replicated the research done by Mullen et al, (2008), using patients in an inpatient BH unit and found that the WB was also safe and effective in reducing anxiety with this population (Champagne et al., 2015). Additionally, the researchers of these studies used electrodermal activity (EDA) as a

measure for anxiety but did not find it to be a conclusive measure of anxiety by itself. Champagne et al. (2015) noted that regardless of the person's diagnosis, the WB was an effective intervention for reducing anxiety.

Other studies explored the effects of WBs on the autonomic nervous system of participants in a dental facility (Chen et al., 2013; Chen et al., 2016). In the Chen et al. (2013) research, the participants were in a dental office for routine treatments while subjects in the Chen et al. (2016) study were having tooth extractions. In both studies, the researchers adjusted the weight of the WB to 10% of the participants' body weight. Anxiety measurements included the use of electrodermal activity and heart rate variability. The authors found that both participant anxiety and heart rate decreased with use of the WB as compared to baseline measurements (Chen et al., 2013). In the Chen et al. (2016) study conducted during wisdom tooth extractions, the measures used were heart rate variability (HRV), including heart rate/low frequency (LF), heart rate/ high frequency (HF) and the LF/HF-HRV ratio to measure anxiety. The researchers found that the use of the blanket during the treatment phase was associated with a decrease in heart rate variability (Chen et al., 2016). Both found that the WB was effective as a calming intervention and that it also augmented the action of the autonomic nervous system.

Ackerley et al. (2015) and Gringras et al. (2014) studied the use of the WB with participants who experience insomnia or were diagnosed with a sleep disorder. The Ackerley et al. (2015) study was conducted in Sweden with an adult population with chronic insomnia. The WBs used for this study had chains sewn into them and were available in three different weights. The study design consisted of a baseline phase (no WB) followed by a testing phase (2 weeks sleeping with the blanket) and then a post-phase (no WB). The authors found that participants had improved sleep and felt refreshed in the morning when using the WB (Ackerly et al., 2015).

The authors concluded that the WB was an effective modality without adverse effects (Ackerley et al., 2015). The Gringras et al. (2014) study was conducted with children who were diagnosed with autism spectrum disorders (ASD). The authors noted that many children with ASD also have a history of sleep disturbances (Gringras et al., 2014). The researchers did not see an effect with the WB; however, the parents described their children as calmer when using the WB (Gringras et al., 2014).

A few recent studies have been conducted about the use of the WB in adults. One of these studies focused on WB use with chemotherapy patients (Vinson et al., 2020). Their study focused on the effectiveness of the WB in decreasing anxiety in cancer patients that were receiving chemotherapy in an outpatient setting and they measured the participants anxiety with the State-Trait Anxiety Inventory for Adults Form Y-1 (STAI-AD) and the visual analog scale for anxiety (VAS-A). This study had 58 participants with 38 of them were females. Their results showed participants who used the WB had a statistically significant decrease in anxiety compared to those that did not use the blanket (Vinson et al., 2020).

Another study was conducted on an inpatient psychiatric unit with 61 participants using a 14-pound WB, a 20-pound WB, and a 5-pound weighted lap pad for 20 minutes and 61 participants who did not use the WB (Becklund et al., in press). They used the STAI: Y-6 a shortened version of the STAI to measure participant anxiety. They had more female participants than males in both groups. They found that participants who were in the weighted modality group had a significant decrease in anxiety and pulse rate. They also noted that this finding was consistent with Mullen et al., 2008 and Champagne et al., 2015 (Becklund et al., in press).

A systematic review of WB was conducted and published in 2020 and focused on eight WB studies (Eron et al., 2020). In their review, they found that the WB shows that it can reduce or relieve anxiety but there were inconclusive results for those with insomnia or sleep disturbances. They also noted that only 4 of the studies were of high quality and that many studies used a variety of different measures of anxiety which they felt was difficult to compare outcome measures (Eron et al., 2020).

Kristiansen et al. (2020) developed a protocol for their study using a ball blanket on participants with insomnia and depression in a multicenter trial. They began recruiting participants in November 2019 and will conclude their study in May 2021 with a randomized crossover design (Kristiansen et al., 2020).

PROPOSAL

The overall goal of this study was to determine if the WB was a safe and effective alternative to restraint/seclusion in management of anxiety and anger in adults on an inpatient psychiatric unit. The research proposal was designed to address the gap in the literature about the use and effectiveness of the WB as an intervention in decreasing feelings of anxiety and anger among the adult psychiatric inpatients. Dissemination of the research findings from this study will contribute to the knowledge and science of nursing through presentations at conferences and publication of manuscripts in peer-reviewed nursing journals.

CHAPTER 3: RESEARCH DESIGN & METHODOLOGY

OVERVIEW OF PILOT STUDY

A pilot study was conducted in the emergency department (ED) in the spring of 2019 at an academic Medical Center in the southeast using a 15-pound WB among participants having psychiatric diagnoses such as depression and schizophrenia to evaluate effectiveness in reducing anxiety and anger. Fifteen participants were recruited and completed the study. The study had three arms which included a control (no WB or NWB) group, a group that used the blanket for 15minutes, and a group who used it for 30 minutes. The measurement tools included the following: the PROMIS Emotional Distress-Anxiety, PROMIS Emotional Distress-Anger, Brøset Violence Checklist (BVC) (Linaker & Busch-Iversen, 1995; Almvik, Woods, & Rasmussen, 2000), Visual Analog Scale, exit survey and WB survey. The results of this study are summarized in the following paragraphs but are also included in-depth in manuscript A (chapter 4). The PROMIS Emotional Distress-Anxiety and the PROMIS Emotional Distress-Anger measures were given to the participants before the intervention. There were no significant differences between the groups before the intervention.

For the control (NWB) group (N=5), there was a 2-point decrease between pre- and post-anxiety scores (67.7 to 65.6) and a 7-point decrease between pre- and post-anger scores (70.18 to 63.08). Scores might have been affected by participants receiving medications prior to the study.

For the WB for 15 minutes group (N=4), there was a 6-point decrease in anxiety scores (72.85 to 66.17) and a 1-point increase in post-anger (64.32) when compared to pre-anger (63.83) scores. This may have been related to one patient who had higher scores on the PROMIS Emotional Distress-Anger post-test.

For the WB 30 minutes group (N=6), There was a 4-point decrease between participants' pre-and post-anxiety scores (67.5 to 63.5). There was also a 6-point decrease between pre-and post-anger (67.5 to 63.5) scores.

Overall, for the two WB groups (N=10) the participant pre- and post-anxiety scores showed decreases after using the WB. This decrease supports the potential effectiveness of the WB in decreasing anxiety. However, due to the small sample size, this research did not demonstrate that there were statistically significant decreases in anxiety. Further research is needed with a larger sample size to determine if use of the WB can result in statistically significant decreases in anxiety in adults.

Brøset Violence Checklist (BVC) pre-intervention and post-intervention scores for all participants were zero or absent for all 6 elements, showing that the participants were not at risk for violence during the time of assessment.

The results from this pilot study informed the research questions, method, and measurement tools to be used for the dissertation study. Since no useful data was gleaned from the administration of the Brøset Violence Checklist (BVC) in the pilot study, the researcher eliminated it as a data collection tool for the major study. Both the PROMIS Emotional Distress-Anxiety and the PROMIS Emotional Distress-Anger scales were kept as data collection instruments. The decision to implement use of the WB for 30 minutes for study participants was based upon anecdotal participant feedback that 15 minutes was not long enough.

METHODS

The following sections focus on the quantitative methods that were used to explore the specific research questions for this study. Quantitative methods provide the researcher with alternative explorations of a phenomenon to advance the science of nursing, offer new

knowledge about a phenomenon and potentially answer research questions. Quantitative methods tend to focus on measurements and statistical analysis. Qualitative responses were obtained from participants who used the WB, as well as relaxation techniques employed.

RESEARCH DESIGN

This study employed a quasi-experimental, non-equivalent pre-test-post-test design using a 15-pound WB. The study also included responses from participants who completed an exit survey or questionnaire on paper.

Intervention and Procedure

The rationale for using the 15-pound WB was to have a predetermined amount of weight for each participant that would be as close as possible to 10% of his/her body weight following researcher recommendations (Mullen et al., 2008; Champagne et al., 2015). This was necessary since the WB cannot be adjusted to add or decrease the amount of weight within the blanket.

The investigator prepared individual data collection folders for each participant which included the pre and post-test forms, VAS, and exit survey. A step-by-step outline of the research protocol is included in Appendix B. In the study design, there were two groups; one of the groups had the treatment/intervention (WB) group and the other group did not receive the WB intervention. Both groups received the same measures/instruments and exit survey. The only difference is the non-WB(NWB) group did not respond to questions on the exit survey that pertained to the WB. The participants were placed in either the WB group or the NWB group based on their self-scoring on the visual analog scale (VAS) rating form for anxiety (Appendix C). Participants who scored their anxiety on the VAS a four or greater were placed in the WB group and the participants with a VAS score of three or less were placed in the NWB. The

rationale for these cutoff scores on the VAS anxiety measure was determined based on results of the ED pilot study which showed that most participants scored their level of anxiety at four or greater. All participants were given the pre-tests (PROMIS- Emotional Distress Anxiety and pre-test PROMIS- Emotional Distress Anger scales) before the study began. Immediately after completing the pre-test scales, the participants in the WB group used the blanket for 30 minutes while the NWB group were informed that they could relax in their room, journal, color, read, or do another activity for 30 minutes.

VARIABLES, INSTRUMENTS AND MEASURES:

The variables that were examined in this study, as well as the instruments and measures to be used are listed in Table 2. The measures are described in detail, including reliability and validity, in the section titled "Measures."

Table 2: Variables and Measures

Variable	Measure	Level of Measurement
Anxiety	Patient-Reported Outcomes Measurement Information System (PROMIS): Emotional Distress Anxiety	Continuous
Anger	Patient-Reported Outcomes Measurement Information System (PROMIS): Emotional Distress Anger	Continuous
Behavioral responses to sensory experiences	Adolescent/Adult Sensory Profile	Continuous
Weighted Blanket (WB) Perceptions	Exit Survey/Questionnaire (Self-report)	Continuous
Demographic Variables		
Age	Self-report	Continuous

Sex/Gender	Self-report	Dichotomous
Weight	Chart review	Dichotomous
Restraint and seclusion History	Self-report and chart review	Continuous

Measures

PROMIS Scales

The pilot study completed in the ED in the spring of 2019 supported the use of the Patient-Reported Outcomes Measurement Information System (PROMIS) short form for anxiety (Appendix D) for measurement of participant anxiety. The PROMIS Emotional Distress-Anxiety short form is available in paper format with four, five, six, seven or eight questions. The eight-question short form was used in this study. Pilot study findings also supported use of the PROMIS Emotional-Distress-Anger short form (Appendix E) to determine levels of anger in participants. This instrument is available in paper format with five questions for the participants to complete. These self-report tools were designed as part of the National Institute for Health (NIH) initiative "to improve self-reported outcomes" (Pilkonis et al., 2011, p. 263). The PROMIS Emotional Distress-Anxiety and PROMIS Emotional Distress-Anger scales were chosen because they allow self-report from the person's perspective, can be completed either electronically or in paper version, and have been evaluated in a variety of settings. Both scales are based on a 5-point rating scale. The PROMIS Emotional-Distress-Anger short form has a correlation of 0.96 for the short form and reliability of 0.93 for the full bank of questions. The PROMIS Emotional Distress-Anxiety short form correlation score was 0.96 and reliability was 0.89 (Cella et al., 2010, p.1190).

Adolescent/Adult Sensory Profile

Another assessment tool used in this study was the Adolescent/Adult Sensory Profile (A/A SP) (Appendix F). The rationale for adding this assessment tool was to help answer the research question about the relationship between the sensory profile and psychiatric diagnoses. The A/A SP is a self-questionnaire/report tool that was based on Dunn's (1997) Sensory Processing Model (Brown et al., 2001). The sensory profile was initially researched with infants and children and responses provided by the child's caregiver on a 125-item tool with frequency ratings of almost never, seldom, occasionally, frequently and almost always (Dunn, 1997). The A/A SP includes 60 sensory experiences (taste/smell processing, movement processing, visual processing, touch, activity level and auditory processing) and the individual chooses the behavioral responses and frequency from the following: almost never, seldom, occasionally, frequently and almost always (Brown et al., 2001).

Responses to the A/A SP are divided into four quadrants: low registration, sensation seeking, sensory sensitivity, and sensation avoiding. Low registration can be defined as an inability to recognize stimuli due to high neurological threshold; the person may appear dull, uninterested, withdrawn, self-absorbed, and unmotivated (Brown et al, 2001; Dunn,1997; Engel-Yeger & Dunn, 2011). Sensation seeking can be defined as having a high threshold with active responses to counteract these thresholds; individuals classified as sensation seeking may be fidgety, restless, touching objects, easily distracted, and chew on objects (Brown et al., 2001; Dunn,1997; Engel-Yeger & Dunn, 2011). Sensory sensitivity can be defined as behaviors that are due to low neurological threshold, which may be detected as hyperactive, distracted, fussy, and uncomfortable with sensations (Brown et al, 2001; Dunn, 1997; Engel-Yeger & Dunn,

2011). Sensation avoiding can be defined as having a low neurological threshold and the person may be resistant, unwilling to join others in activities, introverted or introspective, and withdrawn (Brown et al., 2001; Dunn, 1997; Engel-Yeger & Dunn, 2011).

According to Brown et al. (2001), the A/A SP instrument went through several steps to establish reliability and validity. The first step to showing reliability was to engage an expert panel to review the content of the tool. Their second step was to complete item reliability and factor analysis of the tool. Their third step was establishment of the construct validity of the tool by looking at the preferences in sensory processing patterns which were measured using skin conductance. Step four consisted of establishing he psychometric properties of the revised version and whether the reliability of the tool had improved. The authors noted that the item reliability coefficient alpha ranged from .77 to .78 for low registration, sensory sensitivity, sensation avoiding and sensation seeking (Brown et al, 2001). The Sensory Profile can also assess how an individual will respond or react to their environment, process this information, and cope with anxiety and other sensory stimuli (Engel-Yeger & Dunn, 2011). The purpose of using the A/A SP for patients on an inpatient psychiatric unit is to assess their sensory processing ability so that information can be provided to occupational therapists to use in treatment planning. If a patient is experiencing an increased or decreased amount of sensory input, they may not feel safe or they may feel they are losing control, which may increase feelings of anxiety and/or agitation that may lead to restraint or seclusion (Anderson et al., 2017). Individuals with sensory processing disorders tend to have lower thresholds for sensory stimuli and those with schizophrenia and bipolar disorder usually have higher scores in the sensation avoiding quadrant of the A/ASP (Andersen et al., 2017)

SETTING AND SAMPLE

The study was conducted on the 52-bed behavioral health (BH) unit at an academic Medical Center, which is situated within a level one trauma facility. This unit is divided into four separate units: a 23-bed adult unit, a 14-bed psychiatric-medical unit, a 5-bed acute unit, and a 10-bed mental illness/intellectual disability (MI/ID) unit. The 23-bed adult unit consists of adults aged 18 or older with the most common psychiatric diagnoses of depression, bipolar disorder, schizophrenia, and schizoaffective disorder. The 14-bed psychiatric-medical unit is identical to the adult unit with the addition of a medical condition in patients that require wound care, dialysis, or intravenous fluids. Those with more complex medical care issues are transferred to a medicine unit until their care is less acute. The 5-bed acute unit has patients resembling the patients on the adult unit but includes patients showing blatant psychotic or manic behavior requiring a smaller unit that has less stimulation. The 10-bed MI/ID unit treats adults 18 or older who have a mental illness like the patients on the adult unit but also has an intelligence quotient (IQ) under 70. The BH unit began using the WB in the fall of 2015 as a small test of change among a few patients.

According to Polit and Beck (2017), consecutive sampling is recruitment of all eligible participants from a specific area or population. Consecutive sampling was used in the inpatient BH unit to recruit participants if they met the inclusion criteria for this study. Participants met the inclusion criteria for the study if they were 18 years or older, able to speak, read, and write in English (clinical research interpreters are not available), admitted with a psychiatric diagnosis (depression, bipolar, schizophrenia, or schizoaffective disorders) and/or history of anxiety, agitation or aggressive behaviors, admitted to the BH unit for a minimum of 24 hours, cognitively intact (based on chart review and/or consultation with the psychiatrist), non-combative, and medically stable. Criteria for exclusion from the study were having methicillin-

resistant staphylococcus aureus (MRSA), inability to lift and remove the WB, presence of open wounds and/or incontinence, physically threatening, less than 18 years of age, and cognitively impaired or lacking in decision-making abilities as reviewed in the medical record or by consultation with the psychiatrist.

DATA COLLECTION

The primary investigator (PI) obtained approval from the University Medical Center Institutional Review Board (UMCIRB 19-001265) prior to beginning the study (Appendix G). The research team included the principal investigator (PI) and two occupational therapy students from East Carolina University (ECU). The occupational therapy students completed all necessary requirements to conduct research on the BH unit and were supervised by the ECU faculty in the occupational therapy department and the PI.

All blank forms were placed into separate folders for each participant, coded and placed in a locked container and placed in a locked cabinet for only the PI to access. The PI recruited and obtained informed consent (Appendix H) from each participant on the BH adult unit at Vidant Medical Center. During recruitment of the participant (day one), the PI had each participant complete the PROMIS Emotional Distress-Anxiety and the PROMIS Emotional Distress-Anger scales (pre-test) in addition to completing the VAS form. The participant's rating of their anxiety on the VAS form determined if they were in the WB group or not. The PI supplied the Adolescent/Adult Sensory Profile (A/A SP) for each participant on day one and the OT students and the PI collected the form on day two or day three depending on when the participant had completed it. On day five or day of discharge from the hospital, the participant completed the PROMIS Emotional Distress-Anxiety and the PROMIS Emotional Distress-Anger scales (post-test). The PI also supplied the intervention and collected the data.

The participants were asked to complete an exit survey (see Appendix I). Data collected was placed in a locked container that was kept in a locked file cabinet in the PI's office. The forms that the PI used to make sure all data was collected can be found in Appendix J and K. Appendix K is a sample of the Excel spreadsheet that was kept on the secure East Carolina University Piratedrive by the PI.

DATA ANALYSIS

The data were analyzed utilizing SPSS version 23. Descriptive statistics were used to summarize demographic data such as age, gender, and sensory profiles of the study participants. Independent-samples t-tests was used to compare baseline mean anxiety, anger, and sensory profile scores between blanket users and blanket non-users. Paired sample t-tests were used to compare anxiety and anger scores at 30 minutes between blanket users and non-users. In addition, paired sample t-tests were used to compare anxiety and anger scores at 30 minutes within groups based on specific sensory profiles and blanket use and nonuse. Pearson correlations were used to explore relationships between the continuous measures of age, anxiety, anger, and sensory profile scores.

CHAPTER 4: MANUSCRIPT A
EFFECTIVENESS OF THE WEIGHTED BLANKET

Abstract

Background: Restraint and seclusion continue to be used with patients demonstrating aggressive and violent behaviors while in the emergency department (ED) and as inpatients on behavioral health (BH)units. The use of sensory interventions such as the weighted blanket (WB) is garnering interest as alternatives to aid in managing anxiety, anger, and aggressive behaviors. Reports of the effectiveness of the WB have primarily been anecdotal and results of research with children have been mixed. Only one study has been conducted with the weighted blanket with adults on an inpatient psychiatric unit. **Aims:** The aim of this pilot study was to assess the effectiveness of the WB by determining whether it decreases anxiety and/or anger in adult ED patients with pre-existing psychiatric diagnoses. **Methods:** The study used a quasi-experimental, non-equivalent control group design with pre-tests and post-tests for anxiety and anger. The intervention was a 15-pound WB. Participants (N = 15) were in one of three groups which included no weighted blanket (NWB), WB for 15 minutes, or WB for 30 minutes. **Results:** All three groups showed a decrease in anxiety and anger scores**.** However, participants in the WB groups had a greater decrease in anxiety and anger post-test scores. **Conclusions:** The small sample size in this study did not allow for the determination of any differences between groups on anxiety or anger scores that could be viewed as a significant finding.

Keywords: anxiety, anger, weighted blanket (WB), adults, psychiatric, emergency department (ED)

INTRODUCTION

Adult psychiatric patients often experience anxiety and agitation potentially causing harm to self and others; this may be seen in the emergency department (ED) (Weiland, Ivory, & Hutton, 2017) as well as on psychiatric units (Llor-Esteban, Sánchez-Muñoz, Ruiz-Hernández, & Jiménez-Barbero, 2017). A variety of reasons or triggers may cause a person to grapple with feelings of anxiety and/or agitation, leading to the experience of emotional dysregulation, which is an inability to regulate emotions (Dadomo et al., 2016). The ability to manage one's emotions is a complex process that includes many factors, such as the environment, genetics, and brain development; these play a role in how a person responds to anxiety and anger. Emotional dysregulation may lead to behavioral responses becoming extremely intense and maladaptive, resulting in psychiatric disorders (Meyer et al., 2016).

Another factor that potentially affects emotional regulation is whether a person has experienced a traumatic event. "Trauma sets the stage for ongoing psychological and physical distress, which can mutually affect one another, possibly for the duration of the survivor's life span" (D'Andrea, Sharma, Zelechoski, & Spinazzola, 2011, p.378-379). Emotional dysregulation, trauma and emotional regulation are all interrelated in the person's central nervous system (Henry, Sloane & Black-Pond, 2007; van der Kolk, 2006) and autonomic nervous system (Porges, 1995).

Individuals requiring treatment for psychiatric illness are often first seen in the ED (Wilson, Pepper, Currier, Holloman & Feifel, 2012). This may be a lengthy process requiring evaluation by the psychiatric team and waiting for an available bed on an inpatient psychiatric unit. Emergency department and psychiatric nursing staff have an increased risk that the patients in their care will become aggressive (Llor-Esteban et al., 2017). These behaviors may lead to

negative consequences or outcomes such as restraint or seclusion, injury to patients and/or staff that may have an impact on their safety and well-being (Abderhalden et al., 2004).

For centuries, patient restraints existed in mental health institutions as a safety measure to control violent and aggressive behaviors (Masters, 2017). Seclusion and restraint are not therapeutic or calming interventions for patients; however, in situations of imminent risk of harm to self or others they may become necessary to protect the patient (Mohr, 2010). Seclusion and restraints have a negative impact on patients in the hospital. and some of these may include psychological, physical, and re-traumatization (Wilson, Rouse, Rae, & Kar, 2018). In recent years, the focus has shifted away from restraints and seclusion to patient-centered, trauma-informed, and recovery-based care to aid patients with anxiety, anger, violent and aggressive behaviors to cope by using alternative interventions (Champagne, Mullen, Dickson, & Krishnamurty, 2015; Espinosa et al., 2015; Gaynes et al., 2017). Interventions that occupational therapists have used to help decrease anxiety and agitation are sensory modalities, such as the weighted blanket (WB). The WB is a comforter-like blanket that has weights (crushed stones) sewn into the blanket. The pressure from the WB is thought to aid with relaxation. The WB may be one intervention that can be used to help calm patients as they wait for evaluation, treatment, or admission, but this intervention has not been researched that much with adult patients.

The aim of this pilot study was to assess the effectiveness of the WB in adult patients in the ED with pre-existing psychiatric diagnoses and was it a helpful intervention to manage anxiety, anger and/or aggression. A second aim of the study was to assess that the measurement scales used in the study were effective to evaluate anxiety anger, and aggression. The research questions for this study were:

- Did the WB aid the patient in the ED in managing their behaviors of anxiety, agitation, and/or aggression?
- Are the Patient-Reported Outcomes Measurement Information System (PROMIS) Emotional Distress-Anxiety, PROMIS Emotional Distress-Anger short forms, and the Brøset Violence Checklist (BVC) effective scales to measure anxiety, agitation, and/or aggression in ED patients for this study?
- What were the participants responses about the use of the WB in the exit survey?

METHODS

The method employed in this study was a quasi-experimental, non-equivalent control group design with a pre-test and post-test. An exit survey was also used to collect data from participants in their own words who used the WB during the study as a qualitative method. The exit survey was given to the participant in paper form so they could respond to the questions and return to the PI when completed. The intervention used was a 15-pound WB. Prior to the study, approval was obtained through the University Medical Center Institutional Review Board (UMCIRB).

Sample and Setting

The pilot study took place at a Level 1 Trauma Center ED in eastern North Carolina. Consecutive sampling was used and patients that presented to the ED within the previous 24-48 hours were screened to take part prior to the consent process. The principal investigator (PI) spoke with the psychiatric consult liaison psychiatrist (when available), psychiatric triage team and ED nurse in the screening process. After the screening process, the PI approached individuals separately to see if they were interested in the WB research project. If they were

interested, they were given the informed consent document to review and ask the PI any questions they had about participation in the study.

The participants in this study were patients that were evaluated in the ED for a psychiatric illness. The inclusion criteria were adults aged 18 or older who were able to speak, read, and write in English (clinical research interpreters were not available), in the ED for at least 24 hours with a psychiatric diagnosis (depression, bipolar, schizophrenia, or schizoaffective disorders) and/or history of anxiety, agitation or aggressive behaviors, cognitively intact, non-combative (not physically threatening), and medically stable. Excluded from the study were patients less than 18 years of age or who were positive for methicillin-resistant staph aureus (MRSA), unable to lift and remove the WB, had open wounds and/or incontinence, were verbally and physically threatening, or were cognitively impaired or lacking in decision-making abilities as reviewed in the medical record or by consultation with the psychiatrist.

Measures

The participants completed the Patient-Reported Outcomes Measurement Information System (PROMIS) anxiety and anger scales. These self-report tools were designed as part of the National Institute for Health (NIH) initiative "to improve self-reported outcomes" (Pilkonis, Choi, Reise, Stover, Riley & Cella, 2011. p.263). The PROMIS Emotional Distress-Anxiety short paper form with eight questions was used in this study. The PROMIS Emotional-Distress-Anger short paper form with five questions was also used. The reliability of the PROMIS Emotional-Distress-Anger was 0.93and the reliability for the PROMIS Emotional-Distress-Anxiety was 0.89 (Cella et al., 2010). Both forms were completed as pre- and post-tests regardless of which group the participant was assigned to. The PI contacted the PROMIS website and received permission to use the paper version of the PROMIS Emotional-Distress-

Anger and the PROMIS Emotional-Distress-Anxiety even though both versions are in the public domain.

The Brøset Violence Checklist (BVC) was completed by the primary investigator (PI) on each participant pre- and post-intervention. The BVC was used in this study as an objective tool to measure aggression and violence, it was not used to exclude any participants from this study. The BVC is a tool that assesses a person's observable behaviors of aggression and violence (Abderhalden et al., 2006, p.2); it was developed in Brøset, Norway beginning in 1987 and from 1988-1993 (Linaker and Busch-Iversen, 1995). The researchers who developed the tool found that the most common observable behaviors occurring within the first 24 hours of admission were confusion, irritability, making physical and verbal threats, and attacking objects (Almvik, Woods, & Rasmussen, 2000, p.1285). The sensitivity and specificity for the BVC are 0.63 and 0.92 for the cutoff score of 2 or greater and the receiver operating characteristic (ROC) analysis and the area under the curve (AUC) results were 0.82 (SE=0.04) with a 95% CI of 0.75 to 0.89, $p<0.001$" (Almvik, et.al., 2000, p. 1290-1291). The PI obtained permission from Dr. Roger Almvik to use the paper version of the BVC for the pilot study.

The exit survey consisted of ten questions, with the first six questions completed by both the NWB and WB groups. The remaining questions were completed by the WB group and focused on what participants liked and found helpful about the WB.

Procedure

The intervention used in this pilot study was a 15-pound WB. The predetermined amount of weight used was to be as close as possible to 10% of their body weight which is based on researcher recommendations (Mullen et al., 2008; Champagne et al., 2015). The WB material is

cotton on both sides and the weights are crushed stone evenly distributed and sewn inside the blanket by the manufacturer. The WB looks like a comforter that is 42 inches by 50 inches. The informed consent signed by each participant included the purpose of the study information on the blanket, such as its weight and composition.

Each participant was randomly assigned to be in the control group (no blanket) or to wear the blanket for 15 or 30 minutes, which was determined when the PI opened each participant's research folder. The PI only knew which participants would receive the blanket when a participant's folder was opened. The folders were made up with all the documents in them prior to the beginning of the study and a random index card was attached to the inside of the folder with "no blanket," "15" and "30". The folders were shuffled and labeled/coded with non-identifying numbers. Demographic information about each participant was accessed from the electronic health record. Medical co-morbidities were not collected as part of this study. After informed consent was obtained, the PI provided each participant with the PROMIS Emotional Distress-Anxiety and PROMIS Emotional Distress-Anger scales; then, based on the group they were randomly assigned to, the participant either received the blanket or not. For those in the WB groups, the PI placed the blanket from the participants' collar bone to their feet while each was lying down on a hospital bed. The participants were told to lie under the WB, but they could roll on their side with the blanket laying across their back as well as their chest if this position felt more comfortable to them. At the end of the allotted time for each group, participants were given the PROMIS Emotional Distress-Anxiety and PROMIS Emotional Distress-Anger scales to complete again along with the paper exit survey. The no-weighted blanket (NWB) participants completed these scales 30-minutes after completing the first scales. If participants used the WB, they completed a survey about the blanket.

DATA ANALYSIS

The principal investigator entered the demographic data and responses from the scales into an excel spreadsheet on a secure computer drive. IBM SPSS (version 23) was used to conduct all analyses. Descriptive means, paired t-tests, and standard deviations were used to describe the weighted and non-weighted groups regarding pre- and post-anxiety and anger scores, and age. Frequencies were used to describe gender, depression status, and age distribution. The exit survey/questionnaire was reviewed to provide qualitative responses for the study and will be discussed in the results section.

RESULTS

A total of 23 patients in the ED were approached and only 15 agreed to participate and signed informed consent. Of the 15 participants, 73.3% were males and 26.7% were females. Also, 12 of the 15 (80%) participants had a diagnosis of depression. The other 3 participants' diagnoses were schizoaffective disorder, schizophrenia, and anxiety. Three of the participants also had substance use disorders and two had alcohol abuse along with their primary diagnoses. Of the 8 patients who declined to participate, some did so due to lack of interest in the study; one patient initially was interested, but then found out they would be discharged soon from the ED while another was interested but did not feel they were up to answering the questionnaires.

Table 3 depicts the demographic information for the participants in this study which shows that 67% of the participants were between the ages of 20 to 39. The mean age of the participants was 35 years old and the mean weight in kilograms was 92.986 or 204.6 pounds. Of the 14 participants, only 3 were under the 10% body weight for the 15-pound WB; however, only two of these used the WB and both were able to tolerate the weight without any complaints.

Table 4 depicts both the individual pre-and post-test scores for anxiety and anger along with the group mean scores for no blanket (NWB, 15-minute WB and 30-minute WB groups. In the NWB group (N=5), there was a 2-point decrease between pre- and post-anxiety scores (67.7 to 65.6) and a 7-point decrease between pre- and post-anger scores (70.2 to 63.1). A decrease in scores could be explained if anxiolytic medications were administered to participants around the time that this data was collected. However, one participant had an increase in their post-anxiety test score (74.1 to 83.1) though there was no change between their pre- and post-test anger scores. The reason for this is unknown. This participant's diagnosis was depression with suicidal ideation. For the participants who used the WB for 15 minutes (N=4), there was a 6-point decrease in group mean pre- and post-test anxiety scores (72.9 to 66.2), and a 1-point increase in group mean post-test anger (64.3) when compared to group mean pre-anger (63.8) scores. This may have been related to one patient who had higher scores on the PROMIS Emotional Distress-Anger post-test. This participant's primary diagnosis was depression and substance induced psychotic disorder with hallucinations. For the group that used the WB for 30 minutes (N=6), there was a 4-point decrease between participants' pre-and post-anxiety scores (69.0 to 64.9). There was also a 4-point decrease between pre-and post-anger (66.4 to 61.9) scores. Overall, for the two WB groups (N=10) participant pre- and post-anxiety group mean scores showed decreases after using the WB. Brøset Violence Checklist (BVC) (Linaker & Busch-Iversen, 1995; Almvik, Woods, & Rasmussen, 2000) pre-intervention and post-intervention scores for all participants were zero or absent for all 6 elements, showing that the participants were not at risk for violence during the time of assessment.

The participants who used the WB responded to two questions on the exit survey: "What did you like about the WB ?" and "Did it seem to help, why or why not?" (see Table 5 and 6).

The responses provided here are direct written quotes from the participants including their spelling errors. For the first question, the participants stated, “it was relaxing,” "it was good time to relax," "the calmness that the WB (undecipherable word) worked," "it's somewhat helpful," "good reflection," "nice to know myself more,” “it was calm, felt like a hug,” “it was simple and straight forward,” and “I liked the weighted blanket.” For the second question, the participants stated, “it felt comforting,” “it was comfortable almost like the weight helps me to focus on that instead of any anxiety,” "because the wite was relaxing and it fill good on my body," “it was very comfortable almost like the weights help calm my whole body totally,” "helped me feel less fidgety-less leg movement/adjusting," "I felt cozy and pretected," "I think time just calmed me down/it could be a mind thing," and “I felt comforted and not alone. I also felt grounded.” The theme (s) from the participants comments related to the blanket was relaxing, comforting, and calming. The PI did not ask the participants who completed the written survey to expand on their statements, so it is not known how they formed their responses. The PI also did not ask the participants if they had used a WB before.

DISCUSSION

Paired t-tests were used to evaluate for pre-post change scores which found the following information. There were no significant reductions in pre-to-post anxiety scores in the no blanket group ($p = .489$), 15-minute blanket usage group ($p = .250$), or the 30-minute blanket usage group ($p = .201$). Similarly, there were no significant reductions in pre-to-post anger scores in the no blanket group ($p = .382$), 15-minute blanket usage group ($p = .839$), or the 30-minute blanket usage group ($p = .126$). Based on this information and the overall small group sample sizes, this research cannot state that there were significant decreases in anxiety or anger.

The problem of the small sample size was compounded by the study decision to include groups of participants who would use the WB for 0, 15, or 30 minutes; as a result, group comparisons could not be made since there were so few participants in each group.

The decrease in pre- and post-test scores for anxiety and anger when using the WB supports the hypothesis that WB use will decrease anxiety and anger; however, this cannot be stated definitively based on this study. For the second research question, the PROMIS Emotional Distress-Anxiety and the PROMIS Emotional Distress-Anger short forms were the appropriate tools to measure anxiety and anger with the ED participants for this study. However, while the Brøset Violence Checklist (BVC) has been shown to be an applicable tool in other studies to measure aggression and violence, it was not the appropriate tool for this study. The reason the BVC was not appropriate for this study was because it was completed at the start of the study and 30 to 60 minutes later. This did not allow adequate time to see whether the participant exhibited observable signs of aggression.

In this pilot study, the participant comments that the WB helped comfort them and decrease their feelings of anxiety supports the premise that the WB is a useful intervention to use for some participants.

There were several limitations to this pilot study. One limitation was the small sample size. The NWB and WB groups were also small and did not allow for identification of significant findings in reduction of anxiety and or anger. A second limitation of the current study was use of the BVC: although it is a validated measure for aggression and violence, it is designed to be used over time and not for a 30-to-60-minute observation of patient behaviors. A third limitation of this study were the questions on the exit survey/questionnaire which should have been designed to focus on participant responses to the WB's effectiveness in reducing their

feelings of anxiety and anger. A fourth limitation is that the PI did not track the timing of medications administered to participants during this study; these medications may have had an impact on participant levels of anxiety and/or anger. A fifth limitation was not collecting medical co-morbidities on each participant since these may have influenced their levels of anxiety and/or anger. A procedural limitation in this study was the number of blankets available for the PI to use since these were borrowed from the BH unit where inpatient use was a priority.

One recommendation for future studies would be to have more WBs available for immediate use in areas where patients and staff might find them helpful. A second recommendation would be to include documentation of co-morbidities and use of illicit drugs prior to admission to determine whether these might have an impact on the effectiveness of the WB. A third recommendation would be to evaluate the effectiveness of the WB over several days and whether the participant used the WB only during the day, at bedtime, or both.

In conclusion, the goal for nurses working in the ED or in BH, is to provide our patients with coping strategies and alternative interventions that can aid them in managing their symptoms and behaviors while supporting patient-centered, trauma-informed care, and recovery-based treatment. The WB is a non-invasive, non-pharmacologic, and innovative intervention that can be used with individuals who have psychiatric disorders to decrease anxiety and anger in the ED or on inpatient BH units. The WB is also an intervention that is self-directed by the individual using it. An individual can use the WB for short periods during the day or they can choose to sleep with it at night, which offers them some control of their treatment while they are hospitalized.

Limited research has been conducted on WB use in adults with psychiatric disorders and healthy adults. More research on WB in a variety of settings where care is provided for adults

with mental health conditions is needed with larger sample sizes to determine if the WB can decrease anxiety and anger in this population. Another research goal is to see if the WB can have an impact on decreasing the use of restraint and seclusion for patients with acute psychiatric illnesses. Future research might also include the concept of trauma-informed care and whether the WB is an effective intervention for individuals with a trauma history.

Table 3		
Demographic Characteristics of Participants (N=15)		
Characteristic	n	%
Gender		
Male	11	73.3
Female	4	26.7
Depression		
Yes	12	80
No	3	20
Age		
20-24	3	20
25-29	5	33.3
30-39	2	13.3
40-50	2	13.3
51-60	3	20

Table 4: Pre and Post Anxiety Scores and Demographics

	Anxiety			Anger					
	Pre	Post	Pre-Post	Pre	Post	Pre-Post	Gender	Age	Depression
No Blanket									
1	65.6	61.4	4.2	65.0	69.4	-4.4	M	20	Yes
2	70.8	66.6	4.2	69.4	65.0	4.4	M	54	No
3	67.7	61.4	6.3	56.8	56.8	0	M	58	Yes
4	60.4	54.4	5.0	76.8	41.3	35.5	F	51	Yes
5	74.1	83.1	-9.0	82.9	82.9	0	M	39	Yes
Group M	67.7	65.6	2.1	70.2	63.1	7.1			
Group SD	5.2	10.6	6.3	10.1	15.4	16.2			
15 Minute									
1	74.1	68.7	5.4	62.9	59.8	4.1	M	28	Yes
2	76.7	56.4	20.3	58.8	56.8	2.0	M	29	No
3	68.7	67.7	1.0	56.8	58.8	-2.0	M	41	Yes
4	71.9	71.9	0	76.8	82.9	-6.1	F	24	No
Group M	72.9	66.2	6.7	63.8	64.3	-0.5			
Group SD	3.4	6.8	-3.4	9.0	12.4	-3.4			

30 Minute									
1	54.3	53.2	1.1	71.7	52.7	19.0	M	29	Yes
2	80.0	80.0	0	82.9	82.9	0	M	43	Yes
3	54.3	56.4	-1.1	50.6	50.6	0	M	28	Yes
4	71.9	66.6	5.3	62.9	56.8	6.1	F	32	Yes
5	64.5	47.8	16.7	52.7	44.0	8.7	M	24	Yes
6	80.0	78.2	1.8	69.4	69.4	0	F	25	Yes
Group M	69.0	64.9	4.1	66.4	61.9	4.5			
Group SD	8.1	10.4	-2.3	10.4	13.4	-3.0			

Table 5

Exit Survey Question 1: What did you like about this study?
"it was relaxing"
"it was good time to relax"
"it was calm, felt like a hug"
"The calmness that the weighted blanket ____worked"
"How good it fill"
"I liked the weighted blanket"
"stay warm"
"it was simple and straight forward"
"Good reflection"
"It was different"
"the blanket"
"nice to know myself more"
"it's somewhat helpful"
"under a blanket so I was warm"

Table 6

Exit Survey Question 2: Did it seem to help, why or why not?
"feel good"
"felt comforting. (I only tested for 15 minutes)"
"it was very comfortable almost like the weights help calm my whole body totally"
"Because the wite was relaxing and it fill good on my body"
"The weight helps me focus on that instead of any anxiety"
"helped me to relax"
"I felt comforted, and not alone. I also felt grounded."
"I felt cozy and pretected"
"helped me feel less fidgety-less leg movement/adjusting"
"I think time just calmed me down/it could be a mind thing"

CHAPTER 5: MANUSCRIPT B
USE OF THE WEIGHTED BLANKET TO DECREASE ANXIETY AND ANGER IN ADULT INPATIENT PSYCHIATRIC PATIENTS

Abstract

Many individuals on an inpatient psychiatric unit have difficulty managing their feelings of anxiety, anger, aggression, and self-injury. The aim of this study was to explore the effects of the weighted blanket (WB) with adults on an inpatient psychiatric unit. A quasi-experimental, non-equivalent control group design with a pre-test and post-test for anxiety and anger was used. Participants were also surveyed to gather data on their perceptions of the WB. The intervention was a 15-pound WB. Participants (N =22) were in one of two groups which included no weighted blanket (NWB) or WB use for 30 minutes.

INTRODUCTION

Individuals admitted to an inpatient psychiatric unit may experience anxiety and agitation with the potential to cause harm to self and others (Llor-Esteban et al., 2017). A person may have a variety of precipitating factors or triggers that cause feelings of anxiety and/or agitation leading to emotional dysregulation, or the inability to regulate their emotions (Dadomo et al., 2016). This emotional dysregulation can be observed in mood and anxiety disorders (Neacsiu et al., 2018). An individual's ability to manage or cope with emotions of anxiety, frustration, anger, and agitation is a complex process, which may be influenced by the environment, genetics, and brain development. If emotional dysregulation becomes overwhelming, severe, and/or maladaptive, an individual may develop psychiatric disorders (Meyer et al., 2016).

The experience of a traumatic event in an individual's life is another factor that may influence emotional regulation. "Trauma sets the stage for ongoing psychological and physical distress, which can mutually affect one another, possibly for the duration of the survivor's life span" (D'Andrea et al., 2011, p.378-379). The nervous system that helps to regulate an individual's emotions and their social behaviors are interconnected (Neumann et al., 2010). In van der Kolk's (2014) book, he expands on the autonomic nervous system and how the sympathetic and parasympathetic nervous systems work in conjunction to help an individual manage responses to their environment.

BACKGROUND

Anger, aggression, and anxiety are often linked together (Granic, 2014). Anxiety disorders are prevalent in the United States and can be problematic for some individuals (Neacsiu et al., 2018) while others may have difficulty regulating their feelings of anger

(Versella et al., 2016).

On inpatient psychiatric units, the way to manage anger and aggression historically has been to use restraints or seclusion as safety measures; however, whether the use of restraint and seclusion is a therapeutic intervention has been debated for over a hundred years (Masters, 2017). Most have found that restraints are not therapeutic, calming, or reasonable interventions for patients with a mental illness (Masters, 2017; Mohr, 2010), though they may be necessary to protect patients who are at imminent risk of harming themselves or others (Mohr, 2010). The use of seclusion and restraints have a negative impact, on both the patient and the staff member(s) which may include psychological and physical effects, and re-traumatization of the patient (Wilson et al., 2018). The focus in mental health treatment of patients has shifted toward approaches that are patient-centered, trauma-informed, and recovery-based to aid patients who are experiencing anxiety, anger, violent and aggressive behaviors to cope by using alternative interventions (Champagne et al., 2015; Espinosa et al., 2015; Gaynes et al., 2017). Occupational therapists have been using sensory modality interventions such as the weighted blanket (WB) to help decrease anxiety and agitation in clients. Kristiansen et al. (2020) noted that the WB helps the patient to be self-aware of their body and can help to decrease restlessness, stress, and anxiety while providing them a sense of security, calmness, and improved sleep. The WB composition may vary depending on the vendor, but it is a comforter-like blanket that has weights (crushed stones or glass beads) sewn into the blanket. The amount of weights in the blanket also vary depending on the vendor but for this study 15-lb WB were used. The weight from the blanket is thought to aid with relaxation.

The aim of this study was to explore the effectiveness of the WB as an alternative intervention for adults on an inpatient psychiatric unit. Another aim of this study was to explore whether the WB was effective in decreasing anxiety and/or anger with adult patients on an inpatient psychiatric unit. A third aim of the study was to see if there was a relationship between the participants psychiatric diagnosis and the adolescent/adult sensory profile.

METHODS

A quasi-experimental, non-equivalent control group design with pre-tests and post-tests was used. A 15-pound weighted blanket (WB) was employed for the intervention. The amount of the WB was chosen since it is the closest to 10 percent of an adult's body weight which is supported by the Mullen et al study (2008). An exit survey was used to obtain qualitative data from the participants about the WB. Prior to the study, approval was obtained through the University Medical Center Institutional Review Board (UMCIRB).

Sample and Setting

The study took place on an inpatient behavioral health (BH) unit in eastern North Carolina. The inpatient psychiatric unit is a 52-bed unit comprised of four distinct units that care for adult psychiatric patients, intellectually disabled and mental illness patients, patients with psychiatric and medical conditions, and patients with an acute psychiatric condition (very psychotic, manic, and aggressive). Consecutive sampling was used, and patients admitted to the inpatient BH unit were screened for appropriateness prior to being approached about the study. The principal investigator (PI) spoke with the psychiatrist and/or psychiatric nurse in the screening process. The PI then approached each person separately in their room to see if they were interested in the WB research study. All interested persons were given the informed

consent document to review and to ask questions of the PI before consenting to take part in the study.

The participants in this study were patients admitted to the inpatient psychiatric unit. For inclusion in the research, participants had to be age 18 or older, able to speak, read, and write in English (clinical research interpreters were not available), admitted to the inpatient psychiatric unit with a psychiatric diagnosis (depression, bipolar, schizophrenia, or schizoaffective disorders), and/or history of anxiety, agitation, or aggressive behaviors, cognitively intact, non-combative (not physically threatening), and medically stable. Patients were excluded if they were less than 18 years of age, positive for methicillin-resistant staph aureus (MRSA), unable to lift and remove the WB, had open wounds and/or incontinence, were verbally and/or physically threatening, or were cognitively impaired or lacking in decision-making abilities as reviewed in the medical record or by consultation with the psychiatrist and/or psychiatric nurse.

Measures

The participants completed the Patient-Reported Outcomes Measurement Information System (PROMIS) Emotional Distress anxiety and anger scales. These self-report tools were designed as part of the National Institute for Health (NIH) initiative "to improve self-reported outcomes" (Pilkonis et al., 2011. p.263). The PROMIS Emotional Distress-Anxiety short paper form used in this study consisted of eight questions while the PROMIS Emotional-Distress-Anger short paper form consisted of five questions. All participants completed both forms as pre- and post-tests. Another measure that was used in this study was the Adolescent/ Adult Sensory Profile (A/A SP). The A/A SP is a questionnaire/report tool that was based on Dunn's (1997) Sensory Processing Model (Brown et al., 2001). The A/A SP is also a self-rated report that is given to an individual to respond to and has a total of 60 statements. The A/A SP has

been used by occupational therapists since it was developed. This measure was used only at post-test to determine the participant's current sensory processing patterns and the relationship to their psychiatric diagnosis.

Procedure

The PI made up folders for each of the participants that held all the documents in them prior to the beginning of the study. The folders were coded with non-identifying numbers such as BH 001. Demographic information (age, gender, and weight) about each participant was accessed from the electronic health record. The informed consent and all study documents were completed in each participant's assigned patient room.

After informed consent was obtained, each participant was given the visual analog scale (VAS) for anxiety and anger as a screening tool. Based on their VAS anxiety score they were assigned to the no weighted blanket (NWB) or weighted blanket (WB) group. If the participant rated their anxiety a 4 or greater, they were put into the WB group. If the participant rated their anxiety less than 4, they were assigned to the NWB group. The PI then provided each participant with the PROMIS-Emotional Distress Anxiety and Anger scales to complete. For those in the WB group, the PI placed the blanket from the participants' collar bone to their feet while each was lying down on a bed in their assigned patient room. The PI explained to the participants that they could lie under the WB or roll onto their side with the blanket laying across their back as well as their chest if this position felt more comfortable to them. The NWB group had the choice to stay in their room, walk around the unit, or do some form of relaxation of their choosing for 30 minutes. At the end of 30 minutes for both groups, the PI gave the participants the VAS form to complete. Also, on the VAS form were two questions, one did they use the WB

and how they used it, while the second question was for the NWB participant and what relaxation technique was used during the 30 minutes of the study.

After the participants completed the VAS form, the PI then handed them the Adolescent/ Adult Sensory Profile (A/ASP) to complete. They were informed that they had two days to complete the A/ASP. At day five or the day of discharge, whichever came first, they were given the PROMIS-Emotional Distress Anxiety and Anger scales to complete again along with the exit survey. The timing of this was either the afternoon/evening before their discharge or the day of their discharge. The time between the intervention and completing the exit survey varied because of differences in discharge dates. For some patients, the exit survey was completed on day 2 or day 3 of the study. Others completed the exit survey on day 4 or day 5.

DATA ANALYSIS

Demographic data responses from the scales were entered into an excel spreadsheet on a secure computer drive. All analyses were conducted using IBM SPSS (version 24; IBM Corp., Armonk, New York) with the level of significance (p) set to less than .05. Descriptive statistics summarized demographic, pre-, and post-VAS anxiety, and anger scale scores, and pre- and post-PROMIS anxiety and anger scale scores in the non-intervention and WB intervention groups. Paired-sample t-tests were used to compare pre-to-post change scores in both groups, and Spearman correlations were used to examine the intercorrelations of the pre- and post-scale scores in both groups.

RESULTS

A total of 40 patients on the inpatient psychiatric unit were approached to take part in the study. Eighteen patients declined to take part in the study; nine did not give the PI a reason for

declining, three said “no thank you,” one stated they were “too overwhelmed,” four were sleeping when approached, one asked the PI to come back later, but was discharged the following day. Twenty-two agreed to participate and signed informed consents. Table 7 summarizes the demographic information for the participants in this study. Of the 22 participants, 18.2% (4) were males and 81.8% (18) were females, 72.7% (16) had a diagnosis of depression, 22.7% (5) had a diagnosis of bipolar disorder, and 4.5% (1) had a diagnosis of schizoaffective disorder. Several of the participants had other psychiatric diagnoses listed on their electronic health records in addition to multiple medical diagnoses. The participants between the ages of 18 to 23 were 40.9% or 9 out of 22. Of the 22 study participants, 59.1% (13) had a trauma history, 36.3% (8) did not have a trauma history, and 4.5% (1) was unknown if they had trauma history. There were 7 participants on day 2 and day 3, 6 participants on day 4, and 3 participants on day 5 who completed the exit survey and the PROMIS-Emotional Distress Anxiety and Anger scales.

PROMIS-EMOTIONAL DISTRESS ANXIETY AND ANGER SCALES

For the WB group, there were statistically significant reductions in the VAS anxiety and anger scores, and the PROMIS anxiety and anger scale scores (Table 8). There was an average 10.3% reduction in anxiety scores, and a 12.5% reduction in anger scores for the blanket users. For the NWB group, there were slight pre to post-test changes in VAS anxiety and anger scores, and small reductions in the PROMIS anxiety and anger scale scores. The was an average 4.3% reduction in anxiety scores, and an average of 5.6% reduction in anger scores for the NWB group. None of the score changes in the comparison group were statistically significant.

Overall, the intercorrelations in the non-intervention group were much higher, with many medium and large correlations, compared to the WB group. The non-intervention group had a

large pre-VAS anxiety and pre-anxiety scale score correlation (.59) and a large pre-VAS anger and pre-anger scale score correlation (.53), compared to medium correlations of .38 and .44 in the WB group. Pre-anxiety scale and pre-anger scale scores in the non-intervention group had a large correlation (.67) compared to a small correlation (.29) in the WB group. In the non-intervention group, there was a large correlation between pre-anxiety scale and post-anxiety scale scores (.79) and a medium correlation (.46) between pre-anger scale and post-anger scale scores, compared to a small (.19) correlation between pre- and post-anxiety scale scores, and a large (.58) correlation between pre- and post-anger scale scores in the blanket group (Tables 9 and 10).

For the NWB users, half had normal or mild baseline distress levels, and the others had moderate or severe anxiety distress. All the normal and mild distress patients were normal or mild at discharge. Four of the patients had minor changes in their anxiety scores, and two had more substantial changes, one with a moderate baseline distress had a 7.2-point reduction and one with a normal baseline distress had a 10.7-point reduction. For the 16 WB users, half of that group had moderate anxiety distress at baseline and the other half had severe anxiety distress. Of the eight with moderate baseline distress, 5 remained at moderate distress at discharge and three were mild or normal at discharge. Four of the moderate baseline patients had small anxiety score changes, with an average change of 1.3 points, while 4 had an average reduction of 9.1 points from baseline to discharge. For the eight patients with severe anxiety distress at baseline, 1 remained severe at discharge, 5 had moderate distress, and two had mild distress at discharge (Table 11).

For the six NWB users, 4 patients had normal or mild anger distress at baseline and two patients had moderate distress. At discharge, five of the patients had normal anger distress and one patient remained at moderate distress. Two of the patients had no anger scale score change, two had small anger scale increases in baseline to discharge, and two had scale score decreases greater than 10-points. Of the 16 WB users, five of the patients had normal or mild anger baseline distress, nine had moderate distress, and two had severe baseline distress. Of the five with normal or mild baseline distress, all had normal anger distress at discharge. Of the 11 patients with moderate or severe baseline anger distress, seven had normal or mild distress at discharge, and four had moderate discharge distress. Both severe baseline anger distress patients had normal distress at discharge. Of the five normal or mild baseline distress patients, three had reductions in their anger scale scores, one had a small gain, and one had no change. In the 11 moderate or severe baseline distress patients, six patients had score reductions of at least 8 points, with an average reduction of 14.7 points. The other six patients had an average reduction of 3.4 points (Table 12).

ADULT/ADOLESCENT SENSORY PROFILE

Psychiatric diagnoses according to the Diagnostic Statistical Manual (DSM-5), and Adolescent/Adult Sensory Profile (A/A SP) were collected to see if there were any patterns in sensory processing based on diagnosis. One of the challenges to comparing diagnosis to the A/A SP was many of the participants had multiple diagnosis. Therefore, there was not a straightforward way to compare one diagnosis with another. There was one participant who did not complete the A/A SP during the study due to feeling too overwhelmed by the number of statements on the questionnaire. The remaining participants (N=21) were grouped based on combinations of diagnoses: depression only (N=7), depression and anxiety (n=7), depression and

bipolar (N=2), depression and post-traumatic stress disorder (N=1), depression and borderline personality disorder (N=1), and anxiety without depression (N=3). Sensory processing patterns were reviewed by these 6 groups and then also reviewed grouping all patients together with a DSM-5 diagnosis.

Within the *low registration area*, overall, 10/20 patients scored *similar to most people*. Four scored *more than most people* and 5 scored *much more than most people*. Only one scored less than most people. It is important to note that for this sensory area, scores were unable to be calculated for one participant because all portions of the "sensory avoidance" category were not completed on the A/A SP. No patterns noted for any one specific diagnostic group. These participants that score above the mean have high sensory thresholds and they respond passively to environmental stimuli. Scoring in more and much more than most people indicates that participants may miss cues more than others in their environment. A benefit for this group is that they may find it easier to focus even when there are distractions since they do not notice these cues. In addition, they may not react as quickly to stimuli in the environment since they do not notice it as quickly (Dunn, 2014).

Within the area of *sensation seeking*, overall, 6/21 patients scored *similar to most people* and 2 scored *more than most people*. However, 7 scored *less than most people* and 5 scored *much less than most people*. No patterns were noted for any one specific diagnostic group. The majority (n=12) scored below the average meaning that they do not actively engage in the environment. They may require additional input and effort to engage them (Dunn, 2014).

Within the area of *sensory sensitivity*, overall, 6/20 *scored similar to most people*, 2 scored *less than most people*, 6 scored *more than most people*, and 6 scored *much more than most people*. The majority (n=12) scored above the mean. These individuals have low

thresholds for sensory input and generally respond passively to the input. Those scoring above the mean tend to respond more quickly to stimuli than others because of the low threshold and thus may respond to things that others do not even detect. A strength for those who demonstrate sensory sensitivity is that in some areas these individuals will be detail oriented (Dunn, 2014). It is important to note that there is one score missing from a participant within the Depression Only group; therefore, one score from this group was not collected. There are no patterns noted across the diagnostic groups in this area.

Within the area of *sensation avoidance*, 8/21 scored *similar to most people* while 2 scored *more than most people* and 11 scored *much more than most people*. Therefore, the majority scored above the mean (n=13). This category is characterized by individuals who have low sensory thresholds who actively avoid sensory input. These individuals prefer to be alone in an environment that has little sensory stimuli. These individuals may appear stubborn and they do not like change (Dunn, 2014).

Overall, it was difficult to ascertain any distinctions between diagnostic groups with a small sample size. Since depression was the most common diagnosis across the participants (n=18), the four categories were also reviewed for patients who all had depression and showed no clear patterns in any of the quadrants.

Exit Survey

The participants were asked on the exit survey the following questions: "If you used the WB, did it seem to help, why or why not?" "Have you ever used relaxation techniques to calm yourself when upset?" "If yes, what was used?," "How do the relaxation techniques or coping strategies compare with the use of medication?" The responses provided by the participants are direct quotes and include their spelling errors. The PI did not follow-up or ask additional

questions based on their written comments. For the first question, the participants stated, “the weight helped my body relax,” "I makes me feel safe and secure", "I felt calm and restful," "it provided a feeling of security and safety,” “Seemed to calmed me down and feel safe and secure,” “I felt calmer, as if someone was holding me. It was comforting.,” and “It calmed me down a little bit.”

For the second question, 13.6% (3) of participants had not previously used relaxation techniques while 86.4 % (19) used relaxation techniques. The participants that had used relaxation techniques used stress balls, coloring, writing, breathing techniques, listening to music, counting, meditation, walking, guided imagery, playdough, working out, walks on the beach, and rubbing their dog. As far as the comparison of relaxation techniques and medication, the participants stated, “Great my mood is way better,” "calm, faster, natural," “the work together and help,” "I felt like something was calming me, saying I got you," "The medication works better because I need to work on and practice my coping strategies more," "very relaxing plus it doesn’t take long compare to the meds," and “The relaxation techniques work faster, but their effects do not last as long as the effects of the medication.”

DISCUSSION

As noted in the results section, there was a 10.3% decrease in the VAS, as well as the pre- and post-test scores for anxiety and anger for the participants who used the WB. This supports the aim of the study which was to determine if the WB can decrease anxiety and anger in some patients; however, due to the small sample size, this cannot be stated definitively based on this study. The participant comments about the WB also support the use of the WB as a helpful intervention as it was calming, comforting, and helpful in decreasing feelings of anxiety for most of the participants. Due to the small sample size, it is unclear if there is a relationship

between the participants psychiatric diagnosis (DSM-5) and the A/A SP. Therefore, only general statements can be made about sensory processing patterns of those who have at least one DSM-5 diagnosis. This study indicated that in general, participants tended to be average too high in low registration, sensation avoiding, and sensory sensitivity while they tended to be average to low in sensation seeking. This study supports previous studies (Table 13) on DSM-5 diagnosis and sensory processing (Engel-Yeger, et al., 2016; Brown et al., 2002, Panagiotidi et al., 2018; Riele & Anderson, 2009; and Engel-Yeger et al., 2013).

The WB may not be the preferred sensory input choice for some participants based on their sensory processing information from the A/A SP. Some of the participants may benefit from other sensory modalities. Further research would be needed to evaluate this relationship.

More research on the WB should be conducted to determine if the WB is an effective intervention to decrease anxiety and anger in the adult behavioral health population.

Limitations and Recommendations

There were several limitations to this study. One limitation of the study design was not allowing for flexibility in the length of time that the WB was used. The importance of this would be to evaluate if there was a change over time in participant anxiety and/or anger scores. A second limitation was the decreased census on the BH unit during the study timeframe which may have contributed to the small sample size. This coincided with the COVID-19 pandemic which affected recruitment. A third limitation in this study were the questions on the exit survey which did not help to provide detailed responses from the participants on the effectiveness of the WB.

Some recommendations for future WB research would be to increase the number of participants recruited for the study to determine if the WB is an effective intervention to reduce anxiety and anger over time. A second recommendation would be to explore if certain psychiatric diagnoses and/or trauma history influence the use of the WB for participants. A third recommendation would be to research the effectiveness of the WB in adults with autism. A fourth recommendation would be to study whether the WB can prevent patients from experiencing the use of restraint and seclusion during their acute psychiatric hospitalization. A fifth recommendation would be to research the WB in adults with insomnia to evaluate if the WB is an effective intervention to improve sleep outcomes.

In conclusion, the WB provides psychiatric nurses with an alternative intervention that could be used to help their patients manage and cope with their symptoms of anxiety, anger and/or aggressive behaviors. As psychiatric nurses, it is important to provide interventions that supports patient-centered, trauma-informed care and recovery-based treatment. The WB is an alternative intervention for individuals to use as a calming measure. The WB is an intervention that is self-directed by the patient to use whenever they chose to whether it is for short periods of time during the day or to sleep with it at night. It also provides deep pressure stimulation that can aid in decreasing an individual's feelings of anxiety and anger. It is also non-invasive and non-pharmacologic, which is important for many individuals who would like to use alternative interventions instead of taking medications to manage their symptoms of anxiety, and anger, on inpatient BH units. The research in using the WB in adults in the inpatient psychiatric setting as well as other inpatient settings has been limited.

Table 7

Demographic Characteristics of Participants (N=22)

Characteristic	n	%
Gender		
Male	4	18.2
Female	18	81.8
Primary Diagnosis		
Depression	16	72.7
Bipolar	5	22.7
Schizoaffective	1	4.5
Age		
18-23	9	40.9
24-29	1	4.5
30-35	4	18.2
36-41	2	9.1
42-47	2	9.1
48-53	0	0
54-59	4	18.2
60-65	0	0
66+	0	0

Table 8

Pre and Post Score Changes in Weighted Blanket and Non-Blanket Users

	Pre		Post		Pre – Post				
Variable	M	SD	M	SD	M	SD	t	p	η^2
Blanket									
VAS anxiety	6.94	1.48	3.44	2.42	3.50	1.90	7.38	<.001	.78
PROMIS anxiety	71.62	5.35	64.26	6.16	7.36	6.20	4.75	<.001	.60
VAS anger	4.13	2.50	1.69	2.09	2.44	2.13	4.58	<.001	.58
PROMIS anger	61.31	10.13	53.64	8.46	7.66	7.45	4.12	.001	.53
Non-Blanket									
VAS anxiety	1.83	1.47	1.50	2.07	0.33	1.51	0.54	.61	.06

PROMIS anxiety	61.47	8.99	58.82	13.01	2.65	5.11	1.27	.26	.24
VAS anger	0.53	1.22	0.83	2.04	-0.30	0.82	1.00	.36	.17
PROMIS anger	51.68	11.75	48.82	10.11	2.87	8.69	0.81	.45	.12

Note. Blanket group df = 15. Non-blanket group df = 5.

Table 9

Spearman Intercorrelations of Pre and Post Anxiety and Anger VAS Scales, PROMIS Anxiety, and PROMIS Anger Scales for Weighted Blanket Group (n = 16)

Measure	1	2	3	4	5	6	7	8
1. Pre-VAS anxiety	__							
2. Pre-VAS anger	.08	__						
3. Pre-PROMIS anxiety	.38	-.33	__					
4. Pre-PROMIS anger	-.18	.44	.29	__				
5. Post-VAS anxiety	.50*	-.20	.38	-.24	__			
6. Post-VAS anger	.15	.42	-.06	.18	.34	__		
7. Post-PROMIS anxiety	-.24	-.34	.19	.12	.00	-.38	__	
8. Post-PROMIS anger	-.06	.17	.31	.58*	-.37	-.05	.39	__

*p < .05.

Table 10

Spearman Intercorrelations of Pre and Post Anxiety and Anger VAS Scales, PROMIS Anxiety, and PROMIS Anger Scales for Comparison Group (n = 6)

Measure	1	2	3	4	5	6	7	8
1. Pre-VAS anxiety	__							
2. Pre-VAS anger	.42	__						
3. Pre-PROMIS anxiety	.59	.65	__					

4. Pre-PROMIS anger	.63	.53	.67	__				
5. Post-VAS anxiety	.88*	.70	.52	.52	__			
6. Post-VAS anger	.42	1.00**	.65	.53	.70	__		
7. Post-PROMIS anxiety	.75	.54	.79	.37	.75	.54	__	
8. Post-PROMIS anger	.49	.65	.94**	.46	.52	.65	.88*	__

* $p < .05$. ** $p < .01$.

Table 11

Listing of Pre and Post Anxiety Distress Categories and Anxiety Scale Scores of Patients Not Using and Using Weighted Blanket

Blanket	Pre-Distress	Pre-Anxiety	Post-Anxiety	Pre – Post	Post-Distress
No Blanket					
1.	Normal	47.8	37.1	10.7	Normal
2.	Mild	59.4	59.4	0.0	Mild
3.	Mild	58.4	59.4	-1.0	Mild
4.	Moderate	60.4	53.2	7.2	Normal
5.	Moderate	69.8	71.9	-2.1	Severe
6.	Severe	73.0	71.9	1.1	Severe
Blanket					
1.	Moderate	68.7	68.7	0.0	Moderate
2.	Moderate	68.7	64.5	4.2	Moderate
3.	Moderate	68.7	58.4	10.3	Mild
4.	Moderate	63.5	53.2	10.3	Normal
5.	Moderate	67.7	68.7	-1.0	Moderate
6.	Moderate	67.7	61.4	6.3	Moderate
7.	Moderate	68.7	59.4	9.3	Mild
8.	Moderate	69.8	67.7	2.1	Moderate
9.	Severe	73.0	57.4	15.6	Mild
10.	Severe	76.7	66.6	10.1	Moderate
11.	Severe	70.8	67.7	3.1	Moderate
12.	Severe	71.9	59.4	12.5	Mild
13.	Severe	83.1	78.2	4.9	Severe
14.	Severe	70.8	68.7	2.1	Moderate
15.	Severe	83.1	60.4	22.7	Moderate
16.	Severe	73.0	67.7	5.3	Moderate

Table 12

List of Pre and Post Anger Distress Categories and Anger Scale Scores of Patients Not Using and Using Weighted Blanket

Blanket	Pre-Distress	Pre-Anger	Post-Anger	Pre – Post	Post-Distress
No Blanket					
1.	Normal	32.9	32.9	0.0	Normal
2.	Normal	44.0	50.0	-6.0	Normal
3.	Normal	50.6	54.7	-4.1	Normal
4.	Mild	56.8	44.0	12.8	Normal
5.	Moderate	62.9	48.4	14.5	Normal
6.	Moderate	62.9	62.9	0.0	Moderate
Blanket					
1.	Normal	44.0	48.4	-4.4	Normal
2.	Normal	41.3	41.3	0.0	Normal
3.	Normal	50.6	48.4	2.2	Normal
4.	Normal	48.4	32.9	15.5	Normal
5.	Mild	56.8	52.7	4.1	Normal
6.	Moderate	65.0	58.8	6.2	Mild
7.	Moderate	60.8	62.9	-2.1	Moderate
8.	Moderate	65.0	50.6	14.4	Normal
9.	Moderate	69.4	56.8	12.6	Mild
10.	Moderate	69.4	60.8	8.6	Moderate
11.	Moderate	65.0	50.6	14.4	Normal
12.	Moderate	69.4	65.0	4.4	Moderate
13.	Moderate	65.0	58.8	6.2	Mild
14.	Moderate	65.0	62.9	2.1	Moderate
15.	Severe	74.1	54.7	19.4	Normal
16.	Severe	71.7	52.7	19.0	Normal

Table 13: Adolescent/Adult Sensory Profile

Diagnosis	Sensory Processing Pattern Found in Literature	Article
Bipolar Disorder and Major Depressive Disorder	Higher scores: sensory sensitivity, sensation avoiding, and low registration. Lower scores: sensation seeking	Engel-Yeger et al., 2016 & Brown et al., 2002
Schizophrenia	Higher scores: sensation avoiding and low registration. Lower scores: sensation seeking	Brown et al., 2002
Attention Deficit Hyperactivity Disorder	Higher scores: sensory sensitivity	Panagiotidi et al., 2018
Obsessive Compulsive Disorder	Higher scores: low registration, sensory sensitivity, and sensation avoiding. Lower scores: sensation seeking.	Riele & Anderson, 2009
Post-Traumatic Stress Disorder	Higher scores: sensory sensitivity, low registration, and sensation avoiding. Lower scores: sensation seeking.	Engel-Yeger et al., 2013

REFERENCES

Abderhalden, C., Needham, I., Dassen, T., Halfens, R., Haug, H., & Fisher, J. (2006). Predicting inpatient violence using an extended version of the Brøset-violence-checklist: instrument development and clinical application. *Bio Med Central Psychiatry, 6*(17), 1-9. doi: 10.1186/1471-244X-6-17

Abderhalden, C., Needham, I., Dassen, T., Halfens, R., Haug, H.-J., & Fischer, J. E. (2008). Structured risk assessment and violence in acute psychiatric wards: Randomized controlled trial. *The British Journal of Psychiatry,193*, 44-50. https://doi.org/10.1192/bjp.bp.107.045534

Abderhalden, C., Needham, I., Miserez, B., Almvik, R., Dassen, T., Haug, H. J., & Fischer, J. E. (2004). Predicting inpatient violence in acute psychiatric wards using the Brøset-violence-checklist: a multicenter prospective cohort study. *Journal of Psychiatric and Mental Health Nursing, 11*, 422-427. doi:10.1111/j.1365-2850.2004.00733.x

Ackerley, R., Badre, G., & Olausson, H. (2015). Positive effects of weighted blanket on insomnia. *Journal of Sleep Medicine & Disorders*, *2*(3),1-7. Retrieved from https://www.jscimedcentral.com/SleepMedicine/sleepmedicine-2-1022.pdf

Almvik, R., Woods, P., & Rasmussen, K. (2000, December). The Brøset-violence-checklist: sensitivity, specificity, and interrater reliability. *Journal of Interpersonal Violence, 15*(12), 1284-1296. https://doi.org/10.1176/ps.50.7.881

Andersen, C., Kolmos, A., Andersen, K., Sippel, V., & Stenager, E. (2017). Applying sensory modulation to mental health inpatient care to reduce seclusion and restraint: A case control study. *Nordic Journal of Psychiatry, 71*(7), 525-528. https://doi.org/10.1080/08039488.2017.1346142

Appelbaum, P. S. (1999). Seclusion and Restraint: Congress reacts to reports of abuse. *Psychiatric Services*, *50*(7), 881-882, 885. https://doi.org/10.1176/ps.50.7.881

Ayres, A. J. (1972). *Sensory integration and learning*. Los Angeles, Ca: Western Psychological Services.

Ayres, A. J. (1979). *Sensory integration and the child*. Los Angeles, Ca: Western Psychological Services.

Becklund, A. L., Rapp-McCall, L., and Nudo, J. (in press). Using weighted blankets in an inpatient mental health hospital to decrease anxiety. *Journal of Integrative Medicine.* https://doi.org/10.1016/j.joim.2020.11.004

Bestbier, L., & Williams, T. I. (2017). The immediate effects of deep pressure on young people with autism and severe intellectual difficulties: Demonstrating individual differences. *Occupational Therapy International, 2017*, Article ID 75349727 pages. https://doi.org/10.1155/2017/7534972

Blair, E. W., Wooley, S., Szarek, B. L., Mucha, T.F., Dutka, O., Schwartz, H. I., Wisniowski, J., & Goethe, J. W. (2017). Reduction of seclusion and restraint in an inpatient psychiatric setting: A pilot study. *Psychiatric Quarterly, 88*, 1-7. https://doi.org/10.1007/s11126-016-9428-0

Blairs, S., Slater, S. & Hare, D. J. (2007). The clinical application of deep pressure with a man with autism presenting with severe anxiety and challenging behavior. *British Journal of Learning Disabilities, 35*, 214-220. https://doi.org/10.1111/j.1468-3156.2007. 00452.x

Bowers, L. (2014). Safewards: A new model of conflict and containment on psychiatric wards. *Journal of Psychiatric and Mental Health Nursing, 21*, 499-508. https://doi.org/10.1111/jpm.12129

Brown, C., Cromwell, R. L., Filion, D., Dunn, W., & Tollefson, N. (2002). Sensory processing in schizophrenia: Missing and avoiding information. *Schizophrenia Research, 55*(1), 187-195. https://doi.org/10.1016/S0920-9964(01)00255-9

Brown, C., Cromwell, R. L., Filion, D., Dunn, W., & Tollefson, N. (2002). Sensory processing

Brown, C., Tollefson, N., Dunn, W., Cromwell, R., & Filion, D. (2001). The adult sensory profile: Measuring patterns of sensory processing. *The American Journal of Occupational Therapy, 55*, 75-82. https://doi.org/10.5014/ajot.55.1.75

Cappadocia, M. C., Desrocher, M., Pepler, D., & Schroeder, J. H. (2009). Contextualizing the neurobiology of conduct disorder in emotion dysregulation framework. *Clinical Psychology Review*, *29*, 506-518. https://doi.org/10.1016/j.cpr.2009.06.001

Cella, D., Riley, W., Stone, A., Rothrock, N., Reeve, B., Yount, S., Amtmann, D., … Hays, R. on behalf of the PROMIS group. (2010). The patient-reported outcomes measurement information system (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. *Journal of Clinical Epidemiology, 63*, 1179-1194. https://doi.org/10.1016/j.jclinepi.2010.04.011

Champagne, T., Mullen, B., Dickson, D., & Krishnamurty, S. (2015). Evaluating the safety and effectiveness of the weighted blanket with adults during an inpatient mental health hospitalization. *Occupational Therapy in Mental Health*, *31*(3), 211-233. https://doi.org/10.1080/0164212X.2015.1066220

Chen, H., Yang, H., Chi, H., & Chen, H. (2013). Physiological effects of deep touch pressure on anxiety alleviation: The weighted blanket approach. *Journal of Medical and Biological Engineering*, *33*(5), 463-470. https://doi.org/10.5405/jmbe.1043

Chen, H.-Y, Yang, H., Meng, L., Chan, P., Yang, C., & Chen, H.- M. (2016). Effect of deep pressure input on parasympathetic system in patients with wisdom tooth surgery. *Journal of the Formosan Medical Association, 115*, 853-859. https://doi.org/10.1016/j.jfma.2016.07.008

Cole, P. M., Michel, M. K., & Teti, L.O. (1994). The development of emotion regulation and dysregulation: A clinical perspective. *Monographs of the Society for Research in Child Development,* 59(2/3), 73-100. https://doi.org/10.2307/1166139

Corrigan, F. M., Fisher, J. J., and Nutt, D. J. (2011). Autonomic dysregulation and the Window of Tolerance model of the effects of complex emotional trauma. *Journal of Psychopharmacology, 25*(1), 17-25. https://doi.org/10.1177/0269881109354930

Cusack, P., Cusack, F. P., McAndrew, S., McKeown, & Duxbury, J. (2018). An integrative review exploring the physical and psychological harm inherent in using restraint in mental health inpatient settings. *International Journal of Mental Health Nursing, 27*(3), 1162-1176. https://doi.org/10.1111/inm.12432

D'Andrea, W., Sharma, R., Zelechoski, A.D., & Spinazzola, J. (2011). Physical health problems after single trauma exposure: When stress takes root in the body. *Journal of the American Psychiatric Nurses Association, 17*(6), 378-392. https://doi.org/10.1177/1078390311425187

Dack, C., Ross, J., Papadopoulos, C., Stewart, D., & Bowers, L. (2013). A review and meta-analysis of the patient factors associated with psychiatric in-patient aggression. *Acta Psychiatrica Scandinavica,127*, 255-268. https://doi.org/10.1111/acps.12053

Dadomo, H., Grecucci, A., Giardini, I., Ugolini, E. Carmelita, A., & Panzeri, M. (2016). Schema therapy for emotional dysregulation: Theoretical implication and clinical applications. *Frontiers in Psychology, 7*:1987. https://doi.org/10.3389/fpsyg.2016.01987

Davis, T. N., Dacus, S., Strickland, E., Copeland, D., Chan, J. M., Blenden, K., ... Christian, K. (2013). The effects of a weighted vest on aggressive and self-injurious behavior in a child with autism. *Developmental Neurorehabilitation*, *16*(3), 210-215. https://doi.org/10.3109/17518423.2012.753955

disorder. *American Journal of Occupational Therapy, 63*(2)*,* 138-145. https://doi-org.jproxy.lib.ecu.edu/10.5014/ajot.63.2.138

Donegan, N. H., Sanislow, C. A., Blumberg, H. P., Fulbright, R. K., Lacadie, C., Skudlarski, P., ... Wexler, B. E. (2003). Amygdala hyperactivity in borderline personality disorder: implications for emotional dysregulation. *Biological Psychiatry*, *54*(11), 1284-1293. https://doi.org/10.1016/S0006-3223(03)00636-X

Dunn, W. (1997). The impact of sensory processing abilities on the daily lives of young children and their families: A conceptual model. *Infants and Young Children, 9*(4), 23-35. https://doi.org/10.1097/00001163-199704000-00005

Dunn, W. (2014). *Sensory Profile 2.* NCS Pearson.

Edelson, S. M., Edelson, M. G., Kerr, D. C., & Grandin, T. (1999). Behavioral and physiological effects of deep pressure on children with autism: A pilot study evaluating the efficacy of Grandin's hug machine. *The American Journal of Occupational Therapy*, *53*(2), 145-152. https://doi.org/10.5014/ajot.53.2.145

Engel-Yeger, B. & Dunn, W. (2011). The relationship between sensory processing difficulties and anxiety level in healthy adults. *British Journal of Occupational Therapy, 74*(5), 210-216. https://doi.org/10.4276/030802211X13046730116407

Engel-Yeger, B. & Dunn, W. (2011). The relationship between sensory processing difficulties and anxiety level in healthy adults. *British Journal of Occupational Therapy, 74*(5), 210-216. https://doi.org/10.4276/030802211X13046730116407

Espinosa, L., Harris, B., Frank, J., Armstrong-Muth, J., Brous, E., Moran, J., & Giorgi-Cipriano, J. (2015). Milieu improvement in psychiatry using evidence-based practices: The long and winding road of culture change. *Archives of Psychiatric Nursing*, *29*, 202-207. doi: 10.1016/j.apnu.2014.08.004

Fertel-Daly, D., Bedell, G., & Hinojosa, J. (2001). Effects of a weighted vest on attention to task and self-stimulatory behaviors in preschoolers with pervasive developmental disorders. *The American Journal of Occupational Therapy*, *55*(6), 629-640. https://doi.org/10.5014/ajot.55.6.629

Ganic, I. (2014). The role of anxiety in the development, maintenance, and treatment of childhood aggression. *Development and Psychopathology (26), 1515-1530.* https://doi.org/10.1017/S0954579414001175

Garriga, M., Pacchiarotti, I., Kasper, S., Zeller, S. L., Allen, M. H., Vázquez, …Vieta, E. (2016). Assessment and management of agitation in psychiatry: Expert consensus. *The World Journal of Biological Psychiatry, 17*(2), 86-128. https://doi.org/10.3109/15622975.2015.1132007

Gaynes, B. N., Brown, C. L., Lux, L. J., Brownley, K. A., Van Dorn, R. A., Edlund, M. J., … Lohr, K.N. (2017). Preventing and de-escalating aggressive behavior among adult

psychiatric patients: A systematic review of the evidence. *Psychiatric Services*, *68*(8), 819-831. https://doi.org/10.1176/appi.ps.201600314

González, A., del Río-Casanova, L., & Justo-Alonso, A. (2017). Integrating neurobiology of emotion regulation and trauma therapy: reflections on EMDR therapy. *Reviews in Neuroscience, 28*(4), 431-440. https://doi.org/10.1515/revneuro-2016-0070

Goulet, M-H & Larue, C. (2016). Post-seclusion and/or restraint review in psychiatry: A Scoping review. *Archives of Psychiatric Nursing, 30*, 120-128. https://doi.org/10.1016/j.apnu.2015.09.001

Grandin, T. (1992). Calming effects of deep touch pressure in patients with autistic disorder, college students, and animals. *Journal of Child and Adolescent Psychopharmacology, 2*(1), 63-72. https://doi.org/10.1089/cap.1992.2.63

Granic, I., (2014). The role of anxiety in development, maintenance, and treatment of childhood aggression. *Development and Psychopathology, 26*, 1515-1530. https://doi.org/10.1017/S0954579414001175

Gratz, K. L., & Roemer, L. (2004). Multidimensional assessment of emotion regulation and dysregulation: Development, Factor structure, and initial validation of the difficulties in emotion regulation scale. *Journal of Psychopathology and Behavioral Assessment*, *26*(1), 41-54. https://doi.org/10.1023/B: JOBA.0000007455.08539.94

Gringras, P., Green, D., Wright, B., Rush, C., Sparrowhawk, M., Pratt, K., ... Wiggs, L. (2014). Weighted Blankets and sleep in autistic children-A randomized controlled trial. *Pediatrics*, *134*, 298-306. https://doi.org/10:1542/peds.2013-4285

Gross, J. J. (1998). The emerging field of emotion regulation: An integrative review. *Review of General Psychology, 2*(3), 271-299. https://doi.org/10.1037/1089-2680.2.3.271

Henry, J., Sloane, M., & Black-Pond, C. (2007). Neurobiology and neurodevelopmental impact of childhood traumatic stress and prenatal alcohol exposure. *Language, Speech, and Hearing Services in Schools, 38*, 99-108. https://doi.org/10.1044/0161-1461(2007/010)

Herman, J. (1992). Complex PTSD: A syndrome in survivors of prolonged and repeated trauma. *Journal of Traumatic Stress, 5*(1), 377-391. https://doi.org/10.1002/jts.2490050305

Hilt, L. M., Hanson, J. L., & Pollak, S. D. (2011). Emotional dysregulation. In B. B. Brown & M. J. Prinstein (Eds.), *Encyclopedia of Adolescence* (Vol. 3, pp 160–169). New York, NY: Elsevier.

Hodgetts, S., Magill-Evans, J., & Misiaszek, J. (2010). Effects of weighted vests on classroom behavior for children with autism and cognitive impairments. *Research in Autism Spectrum Disorders, 5*, 495-505. https://doi.org/10.1016/j.rasd.2010.06.015

Holmes, D., Murray, S. J. & Knack, N. (2015). Experiencing seclusion in a forensic psychiatric setting: A phenomenological study. *Journal of Forensic Nursing, 11*(4), 200-213. https://doi.org/10.1097/JFN.0000000000000088

Huckshorn, K. (2004). Reducing seclusion and restraint in mental health settings: core strategies for prevention. *Journal of Psychosocial Nursing, 42*(9), 22-33. https://doi.org/10.3928/02793695-20040901-05

in schizophrenia: Missing and avoiding information. *Schizophrenia Research, 55*(1), 187-195. https://doi.org/10.1016/S0920-9964(01)00255-9

Iozzino, L., Ferrari, C., Large, M., Nielssen, O. & de Girolamo, G. (2015). Prevalence and risk factors of violence by psychiatric acute inpatients: A systematic review and meta-analysis. *PLoS ONE, 10*(6): e0128536. https://doi.org/10.1371/journal.pone.0128536

Jacob, T., Sahu, G., Frankel, V., Homel, P., Berman, B., & McAfee, S. (2016). Patterns of restraint utilization in a community hospital's psychiatric inpatient units. *Psychiatric Quarterly, 87*, 31-48. https://doi.org/10.1007/s11126-015-9353-7

Krauss, K. E. (1987). The effects of deep pressure touch on anxiety. *The American Journal of Occupational Therapy*, *41*(6), 366-373. https://doi.org/10.5014/ajot.41.6.366

Kristiansen, S. T., Videbech, P., Bjerrum, M. B., & Larsen, E. R., (2020). The efficacy of ball blankets on insomnia in depression in outpatient clinics: study protocol for a randomized crossover multicentre trial. *Trials, 21*: 720, 1-11. https://doi.org/10.1186/s13063-020-04638-y

Lin, H., Lee, P., Chang, W., & Hong, F. (2014). Effects of weighted vests on attention, impulse control, and on-task behavior in children with attention deficit hyperactivity disorder. *The American Journal of Occupational Therapy*, *68*, 149-158. https://doi.org/10.5014/ajot.2014.009365

Linaker, O. M. & Busch-Iversen, H. (1995). Predictors of imminent violence in psychiatric inpatients. *Acta Psychiatrica Scandinavica, 92*, 250-254. https://doi.org/10.1111/j.1600-0447.1995.tb09578.x

Linehan, M. M. (1993). *Cognitive- behavioral treatment of borderline personality disorder*. New York: Guilford Press.

Llor-Esteban, B., Sánchez-Muñoz, M., Ruiz-Hernández, J., Jiménez-Barbero, J. (2017). User violence towards nursing professionals in mental health services and emergency units. *The European Journal of Psychology Applied to Legal Context,* 9, 33-40. doi: 10.1016/j.epal.2016.06.002

Losinski, M., Cook, K., Hirsch, S., & Sanders, S. (2017). The effects of deep pressure therapies and antecedent exercise on stereotypical behaviors of students with autism spectrum disorders. *Behavioral Disorders, 42*(4), 196-208. https://doi.org/10.1177/0198742917715873

Losinski, M., Sanders, S. A., & Wiseman, N. M. (2016). Examining the use of deep touch pressure to improve the educational performance of students with disabilities: A meta-analysis. *Research and Practice for Persons with Severe Disabilities, 41*(1), 3-18. https://doi.org/10.1177/1540796915624889

Losinski, M., Sanders, S. A., & Wiseman, N. M. (2016). Examining the use of deep touch pressure to improve the educational performance of students with disabilities: A meta-analysis. *Research and Practice for Persons with Severe Disabilities, 41*(1), 3-18. https://doi.org/10.1177/1540796915624889

Masters, K. J. (2017). Physical restraint: A historical review and current practice. *Psychiatric Annals*, *47*(1), 52-55. https://doi.org/10-3928/00485713-20161129-01

McLaughlin, K. A., Hatzenbuehler, M. L., Mennin, D. S., & Nolen-Hoeksema, S. (2011). Emotion dysregulation and adolescent psychopathology: A prospective study. *Behavior Research and Therapy*, *40*, 544-554. https://doi.org/10.1016/j.brat.2011.06.003

Meyer, N., Richter, S., Schreiber, R. S., Kloke, V., Kaiser, S., Lesch, K., & Sachser, N. (2016). The unexpected effects of beneficial and adverse social experiences during adolescence on anxiety and aggression and their modulation by genotype. *Frontiers in Behavioral Neuroscience*, *10*(97), 1-16. https://doi.org/10.3389/fnbeh.2016.00097

Meyer, N., Richter, S., Schreiber, R. S., Kloke, V., Kaiser, S., Lesch, K., & Sachser, N. (2016). The unexpected effects of beneficial and adverse social experiences during adolescence

on anxiety and aggression and their modulation by genotype. *Frontiers in Behavioral Neuroscience*, *10*, 1-16. doi: 10.3389/fnbeh.2016.00097

Mohr, W. K. (2010). Restraints and the code of ethics: An uneasy fit. *Archives of Psychiatric Nursing,* 24(1), 3-14. doi: 10.1016/j.apnu.2009.03.003

Mullen, B., Champagne, T., Krishnamurty, S., Dickson, D., & Gao, R. X. (2008). Exploring the safety and Therapeutic effects of deep pressure stimulation using a weighted blanket. *Occupational Therapy in mental Health*, *24*(1), 65-89. https://doi.org/10.1300/J004v24n01_05

National Association of State Mental Health Program Directors (NASMHPD). (2006). *Training Curriculum for the reduction of seclusion and restraint: Creating violence free and coercion free mental health treatment environments*. Alexandria, VA: National Technical Assistance Center (NTAC).

Neacsiu, A. D., Rompogren, J., Eberle, J. W., & McMahon, K. (2018). Changes in problematic anger, shame, and disgust in anxious and depressed adults undergoing treatment for emotion dysregulation. *Behavior Therapy*,49, 344-359. https://doi.org/10.1016/j.beth.2017.10.004

Neumann, I. D., Veenema, A. H., & Beiderbeck, D. I. (2010). Aggression and anxiety: social context and neurobiological links. *Frontiers in Behavioral Neuroscience*, *4*(12), 1-16. https://doi.org/10.3389/fnbeh.2010.00012

Olson, L. J., & Moulton, H. J. (2004a). Occupational therapists' reported experiences using weighted vests with children with specific developmental disorders. *Occupational Therapy International*, *11*(1), 52-66. https://doi.org/10.1002/oti.197

Olson, L. J., & Moulton, H. J. (2004b). Use of weighted vests in pediatric occupational therapy practice. *Physical & Occupational Therapy in Pediatrics*, *24*(3), 45-60. https://doi.org/10.1300/J006v24n03 04

Panagiotidi, M., Overton, P. G., & Stafford, T. (2018). The relationship between ADHD traits and sensory sensitivity in the general population. *Comprehensive Psychiatry*, *80*, 179-185. https://doi-org.jproxy.lib.ecu.edu/10.1016/j.comppsych.2017.10.008

Perkins, E., Prosser, H., Riley, D., & Whittington, R. (2012). Physical restraint in a therapeutic setting: A necessary evil? *International Journal of Law and Psychiatry*, *35*, 43-49. https://doi.org/10.1016/j.ijlp.2011.11.008

Petit, S. A., Bowers, L., Tulloch, A., Cullen, A. E., Moylan, L. B., Sethi, F.… Stewart, D. (2017). Acceptability and use of coercive methods across differing service configurations with and without seclusion and/or psychiatric intensive care units, *Journal of Advanced Nursing, 73*(4), 966-976. https://doi.org/10.1111/jan.13197

Pilkonis, P. A., Choi, S. W., Reise, S. P., Stover, A. M., Riley, W. T., Cella, D., on behalf of the PROMIS Cooperative Group (2011). Item banks for measuring emotional distress from the patient-reported outcomes measurement information system (PROMIS®): Depression, Anxiety, and Anger. *Assessment*, *18*(3), 263-283. https://doi.org/10.1177/107319111141667

Polit, D. F., & Beck, C. T. (2017). *Nursing Research: Generating and assessing evidence for nursing practice* (10th ed.). Philadelphia: Wolters Kluwer

Ponterotto, J. G. (2005). Qualitative research in counseling psychology: A primer on research paradigms and philosophy of science. *Journal of Counseling Psychology*, *52*(2), 126-136. https://doi.org/10.1037/0022-0167.52.2.126

Porges, S. W. (1995). Orienting in a defensive world: Mammalian modifications of our evolutionary heritage: A Polyvagal Theory. *Psychophysiology, 32*, 301-318. https://doi.org/10.1111/j.1469-8986.1995.tb01213.x

Reynolds, S., Lane, S. J., & Mullen, B. (2015). Effects of deep pressure stimulation on physiological arousal. *The American Journal of Occupational Therapy*, *69*(3), p1-p.5. https://doi.org/10.5014/ajot.2015.015560

Riele, E., & Anderson, D. (2009). Adolescent/Adult Sensory Profile and obsessive-compulsive

Rolfe, G. (2013). Philosophical basis for research. In Curtis, E. A. and Drennan, J. (Eds.), *Quantitative health research* (pp.11-28). New York: McGraw-Hill.

Selby, E. A., Anestis, M. D., & Joiner, T. E. (2008). Understanding the relationship between emotional and behavioral dysregulation: Emotional cascades. *Behavior Research and Therapy*, *46*, 593-611. https://doi.org/10.1016/j.brat.2008.02.002

Serafini, G. (2016). Extreme sensory processing patterns and their relations with clinical conditions among individuals with major affective disorders. *Psychiatry Research, 236,* 112-118. doi: https://doi-org.jproxy.lib.ecu.edu/10.1016/j.psychres.2015.12.022

Smith Roley, S., Mailloux, Z., Miller-Kuhaneck, H., & Glennon, T. (2007). Understanding Ayres Sensory Integration®. *OT Practice*, *12*(17), CE1-CE8. Retrieved from http://search.proquest.com.jproxy.lib.ecu.edu/docview/1680132679?accountid=10639

Speilberger, C.D., Gorsuch, R. L., & Luchene, R. E. (1970). *State-trait anxiety inventory.* Palo Alto, CA. Consulting Psychology Press.

Stewart, D. & Bowers, L. (2013). Inpatient verbal aggression: Content, targets, and patient characteristics. *Journal of Psychiatric and Mental Health Nursing, 20*, 236-243. https://doi.org/10.1111/j.1365-2850.2012. 01905.x

Sutton, D., Wilson, M., Van Kessel, K., & Vanderpyl, J. (2013). Optimizing arousal to manage aggression: A pilot study of sensory modulation. *International Journal of Mental Health Nursing*, *22*, 500-511. https://doi.org/10.1111/inm.12010

Sylvia, L. G., Shesler, L. W., Peckham, A. D., Grandin, T., & Kahn, D. A. (2014). Adjunctive deep touch pressure for comorbid anxiety in bipolar disorder: Mediated by control of sensory input? *Journal of Psychiatric Practice, 20*(1), 71-77. https://doi.org/10.1097/01.pra.0000442942. 01479.ce

Taylor, K., Mammen, K., Barnett, S., Hayat, M., dosReis, S., & Gross, D. (2012). Characteristics of patients with histories of multiple seclusion and restraint events during a single psychiatric hospitalization. *Journal of the American Psychiatric Nurses Association, 18*(3), 159-165. https://doi.org/10.1177/1078390311432167

Tingleff, E. B., Bradley, S. K., Gildberg, F. A., Munksgaard, G., & Hounsgaard, L. (2017). "Treat me with respect". A systematic review and thematic analysis of psychiatric patients' reported perceptions of the situations associated with the process of coercion. *Journal of Psychiatric Mental Health Nursing, 24*, 681-698. https://doi.org/10.1111/jpm.12410

U. S. Department of Health and Human Services. (2018). *Center for Medicaid and State Operations/Survey & Certification Group, Hospitals – Restraint/Seclusion Interpretive Guidelines & Updated State Operations Manual (SOM) Appendix A.* A-0159 §482.13(e)(1) Definitions. (i) and A-0162 §482.13(e)(1)(ii). Retrieved from https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter08-18.pdf

Van der Kolk, B. A. (2006). Clinical implications of neuroscience research in PTSD. *Annals New York Academy of Sciences, 1071*(1)-277-293. https://doi.org/10.1196/annals.1364.022

Van der Kolk, B. A. (2014). The body keeps the score: Brain, mind, and body in the healing of trauma. Viking Penguin, New York.

VandenBerg, N. L. (2001). The use of a weighted vest to increase on-task behavior in children with attention difficulties. *The American Journal of Occupational Therapy, 55*(6), 621-628. https://doi.org/10.5014/ajot.55.6.621

Versella, M. V., Piccirillo, M. L., Potter, C. M., Olino, T. M., & Heimberg, R. G., (2016). Anger profiles in social anxiety disorder. *Journal of Anxiety Disorders, 37,* 21-29. https://doi.org/10.1016/j.janxdis.2015.10.008

Vinson, J., Powers, J., & Mosesso (2020). Weighted blankets: anxiety reduction in adult patients receiving chemotherapy. *Clinical Journal of Oncology Nursing,* 24(4), 360-368. https://doi.org/10.1188/20.CJON.360-368

Walker, L. O., & Avant, K. C. (2011). *Strategies for theory construction in nursing* (5th ed.). New York: Prentice Hall.

Weiland, T. J., Ivory, S., & Hutton, J. (2017). Managing acute behavioural disturbances in the emergency department using the environment, policies and practices: A systematic review. *Western Journal of Emergency Medicine, 18*(4), 647-661. https://doi.org/10.5811/westjem.2017.4.33411

Weiss, E. M., Altimari, D., Blint, D. F., & Megan, K. (1998, October 11-15). Deadly restraint: a Hartford Courant investigative report. *Hartford Courant*. Retrieved from www.charlydmiller.com/LIB05/1998hartfordcourant11.html

Whittington, R. & Richter, D. (2005). Interactional aspects of violent behavior on acute psychiatric wards. *Psychology, Crime & Law,11*(4), 377-388. https://doi.org/10.1080/106831605000255372

Wilson, C., Rouse, L., Rae, S., & Kar Ray, M. (2018). Mental health inpatients' and staff members' suggestions for reducing physical restraint: A qualitative study. *Journal of Psychiatric and Mental Health Nursing, 25*(3)188-200. https://doi.org/10.1111/jpm.12453

Wilson, P., Pepper, D., Currier, G. W., Holloman, G. H., & Feifel, D. (2012). The psychopharmacology of agitation: Consensus statement of the American association for emergency psychiatry project BETA psychopharmacology workgroup. *Western Journal of Emergency Medicine, 13*(1), 26-34. https://doi.org/10.5811/westernjem.2011.9.6866

Wu, W. W-K. (2015). Psychosocial correlates of patients being physically restrained within the first 7 days in an acute psychiatric admission ward: Retrospective case record review. *East Asian Archives of Psychiatry, 25*(2), 47-57. Retrieved from http://www.easap.asia/index.php/component/k2/item/269-1502-v25n2-p47

You, J., Ren, Y., Zhang, X., Wu, Z., Xu, S., & Lin, M. P. (2018). Emotional dysregulation and nonsuicidal self-injury: A meta-analytic review. *Neuropsychiatry, 8*(2), 733-748. https://doi.org/10.4172/Neuropsychiatry.1000399

APPENDIX A: UMCIRB APPROVAL

EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board
4N-64 Brody Medical Sciences Building· Mail Stop 682
600 Moye Boulevard · Greenville, NC 27834
Office **252-744-2914** · Fax **252-744-2284** · **rede.ecu.edu/umcirb/**

Notification of Initial Approval: Expedited

From:	Biomedical IRB
To:	Debra Dickson
CC:	Laura Gantt
Date:	11/12/2019
Re:	UMCIRB 19-001265 Weighted Blanket

I am pleased to inform you that your Expedited Application was approved. Approval of the study and any consent form(s) occurred on 11/11/2019. The research study is eligible for review under expedited category # 5,7. The Chairperson (or designee) deemed this study no more than minimal risk.

Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a Final Report application to the UMCIRB prior to the Expected End Date provided in the IRB application. If the study is not completed by this date, an Amendment will need to be submitted to extend the Expected End Date. The Investigator must adhere to all reporting requirements for this study.

Approved consent documents with the IRB approval date stamped on the document should be used to consent participants (consent documents with the IRB approval date stamp are found under the Documents tab in the study workspace).

The approval includes the following items:

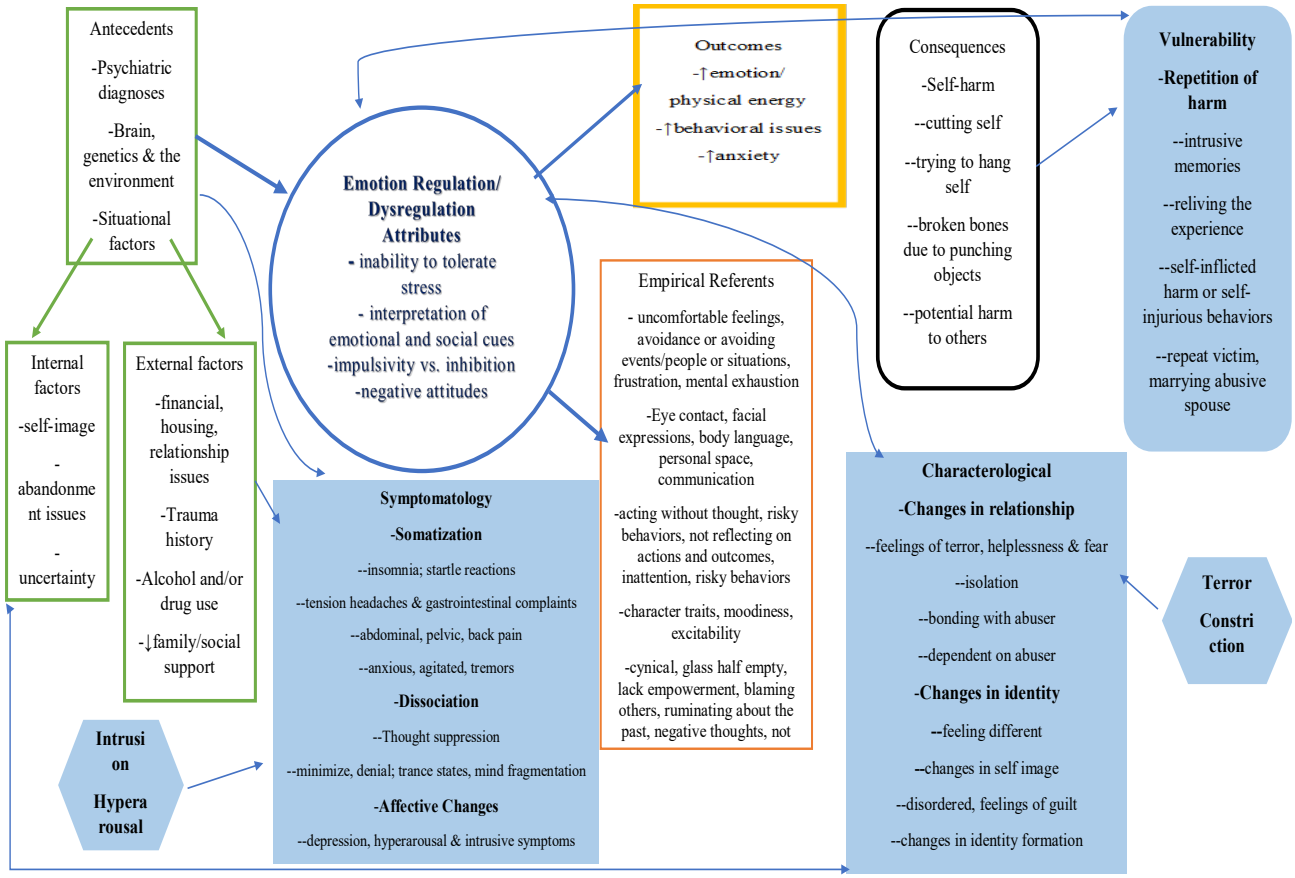
Name	Description
Adolescent/Adult Sensory Profile	Surveys and Questionnaires
Application for Waiver Authorization Form 2019	HIPAA Authorization
Data Collection sheet	Data Collection Sheet
Dissertation chapters 1 to 3	Study Protocol or Grant Application
Exit Questionaire	Surveys and Questionnaires

Informed consent with HIPAA	Consent Forms
PROMIS Emotional Distress Anger	Surveys and Questionnaires
PROMIS Emotional Distress Anxiety	Surveys and Questionnaires
Rating form	Surveys and Questionnaires
script for weighted blanket study	Recruitment Documents/Scripts

For research studies where a waiver of HIPAA Authorization has been approved, each of the waiver criteria in 45 CFR 164.512(i)(2)(ii) has been met. Additionally, the elements of PHI to be collected as described in items 1 and 2 of the Application for Waiver of Authorization have been determined to be the minimal necessary for the specified research.

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

APPENDIX B: CONCEPT MAP*



*Concept map for Emotional Dysregulation created during course work for Theory Analysis & Application in Nursing Science. The blue boxes are an adaptation of Judith Herman's trauma theory.

APPENDIX C: WEIGHTED BLANKET: AN ALTERNATIVE INTERVENTION IN INPATIENT PSYCHIATRY RESEARCH PROTOCOL

Obtain IRB approval

Day 1 (is based on recruitment date and not admission date)

Pre-Intervention

1. The PI will recruit participant(s) daily on the adult unit who meet the inclusion criteria
2. Obtain informed consent
3. Participant given the PROMIS Emotional Distress-Anxiety and PROMIS Emotional Distress Anger scales.

4. Participant given visual analog scale (VAS) to rate their anxiety
   a. The PI will ask the participant to rate their anxiety and anger by circling the number on a scale from 0-10 based on how they are currently feeling
5. Based on VAS rating of anxiety:
   a. 0-3: no weighted blanket
   b. 4-6: weighted blanket
   c. Greater than 6: weighted blanket

Intervention

1. VAS 0-3: no weighted blanket group
   a. If the participant has PRN (as needed) anxiolytics (anti-anxiety) medications ordered they can ask the medication nurse for them.
   b. Note: MD does not always order PRN anxiolytics as a standard order. PRN meds are ordered based on needs of the patient.
   c. Use of PRN medications will be tracked starting from date of informed consent until day 5 of admission

2. VAS 4-6 and greater than 6: weighted blanket group
   a. The PI will give the weighted blanket to the participant
   b. Patient will be instructed to:
      i. lie on their back or on their side with the blanket over them from the collar bone down
      ii. not cover their head
      iii. If at any time while wearing the blanket, they feel uncomfortable with it they can remove the blanket.
   c. Weighted blanket will be used for 30 minutes which the PI will keep track of the start and end time.

Post Intervention

1. All participants will be given the VAS to rate their anxiety and anger after 30 minutes
2. Participants will be provided with exit survey to complete
3. PI will collect data on PRN medication (anxiolytics, antipsychotics) use for the weighted blanket participants
    a. Did the participant receive PRN medication (anxiolytics, antipsychotics) prior to using the weighted blanket?
    b. What time did they receive the PRN medication (anxiolytics, antipsychotics)?
    c. PRN medication (anxiolytics, antipsychotics) use from day of informed consent to day 5 will be collected
4. For the participants who did not receive the weighted blanket, the PI will collect the following PRN medication (anxiolytics, antipsychotics) information:
    a. Did RN document anxiety level before PRN administered?
    b. What was anxiety score?
    c. What was reassessment score for anxiety?
    d. Did the RN document anxiety reassessment score? Or did PI ask the patient their anxiety score?
5. All participants will be given the adolescent/Adult Sensory Profile (A/ASP) by the PI to complete
    a. The participants will be informed that the occupational therapy students will review and help them with completion of the sensory profile (if needed)
    b. The occupational therapy student can answer any questions that the participant has about the sensory profile when they arrive to collect it from them.
    c. The occupational therapy students will collect the A/ASP or sensory profile within 24-48 hours after informed consent has been obtained
6. Review chart for demographic information on all participants
    a. Diagnosis
    b. Age
    c. Gender
    d. Marital status
    e. Weight
    f. Restraint history

Day 2:

1. Occupational therapy students to collect A/ASP if completed

Day 3:

1. Occupational therapy students to collect A/ASP if not collected on the previous day.
    a. .

Day 5 or day before discharge, whichever comes first:

1. All participants will complete the PROMIS Emotional Distress-Anxiety and PROMIS Emotional Distress-Anger scales.

APPENDIX D: VISUAL ANALOG SCALE (VAS) RATING FORM FOR BEHAVIORAL HEALTH STUDY

Date: _____

Before:

Time: _____

_____

0 1 2 3 4 5 6 7 8 9 10

Calm Anxious

Before:

Time: _____

_____

0 1 2 3 4 5 6 7 8 9 10

Calm Angry

Visual Analog Scale (VAS) Rating Form for Behavioral Health Study

Date: _____

After:

Time: _____

_____

0 1 2 3 4 5 6 7 8 9 10

☺ 😐 ☹

Calm Anxious

After:

Time: _____

_____

0 1 2 3 4 5 6 7 8 9 10

☺ 😐 ☹

Calm Angry

1. **Was the weighted blanket used?** ☐Yes ☐No

   a. **If the weighted blanket was used, please answer the following:**
      i. **Did it seem to help?** ☐Yes ☐No
      ii. **Why/why not?** _____
      _____
      _____

   b. **How was the weighted blanket used:**
      ☐Lying under it on the bed ☐Wrapped around entire body lying on the bed

2. **If weighted blanket not used, did you do one of the following for 30 minutes**?
   a. Ask the medication nurse for medication
   b. Journal
   c. Crossword puzzle
   d. Color
   e. Spend time in room
   f. Walk on the unit
   g. Other: _____

Please initial: _____

Study Team Member Comments:

- **Patient rated independently**
- **Study Team assisted with rating: _____**

Study Team Member's signature: _____

APPENDIX E: PROMIS EMOTIONAL DISTRESS ANXIETY

PROMIS Item Bank v1.0 – Emotional Distress – Anxiety – Short Form 8a

Emotional Distress – Anxiety – Short Form 8a

Please respond to each question or statement by marking one box per row.

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
EDANX01	I felt fearful	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX40	I found it hard to focus on anything other than my anxiety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX41	My worries overwhelmed me	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX53	I felt uneasy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX46	I felt nervous	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX07	I felt like I needed help for my anxiety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX05	I felt anxious	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX54	I felt tense	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

APPENDIX F: PROMIS EMOTIONAL DISTRESS ANGER

PROMIS Item Bank v. 1.1 – Emotional Distress - Anger - Short Form 5a

Emotional Distress - Anger – Short Form 5a

Please respond to each item by marking one box per row.

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
EDANG03	I was irritated more than people knew ...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG09	I felt angry	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG15	I felt like I was ready to explode	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG30	I was grouchy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG35	I felt annoyed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

27 April 2016

APPENDIX G: ADOLESCENT/ADULT SENSORY PROFILE (A/A SP)

http://www.specialtherapies.com/wp-content/uploads/2015/05/Sensory-Profile-Questionnaire-Adolescent-Adult.pdf

APPENDIX H: INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Study ID:UMCIRB 19-001265 Date Approved: 11/11/2019 Does Not Expire.

Informed Consent to Participate in Research

Information to consider before taking part in research that has no more than minimal risk.

Title of Research Study: "Weighted Blanket: An alternative intervention for an inpatient psychiatric unit"

Principal Investigator: Debra Dickson (Person in Charge of this Study)

Institution, Department or Division ***(As Applicable)***: Vidant Medical Center

Address: 2100 Stantonsburg Road Greenville, NC

Telephone #: 252-847-3074

Study Coordinator ***(If Applicable)***:

Telephone #:

Participant Full Name: _____Date of Birth: _____

Please PRINT clearly

Researchers at East Carolina University (ECU) and Vidant Medical Center study issues related to society, health problems, environmental problems, behavior problems and the human condition. To do this, we need the help of volunteers who are willing to take part in research.

Why am I being invited to take part in this research?

The purpose of this research is to find out if the weighted blanket will be a helpful alternative in decreasing feelings of anxiety, anger, and agitation. The weighted blanket is a comforter-like blanket that has weights (crushed stones) sewn into the blanket and distributed evenly throughout the blanket. The pressure from the weighted blanket is thought to aid with relaxation. You are being invited to take

part in this research because you have been admitted to the inpatient psychiatric unit with a psychiatric illness and may also have feelings of anxiety, feeling upset/ angry and/or agitated. The decision to take part in this research is yours to make. By doing this research, we hope to learn whether the weighted blanket is effective in decreasing anxiety, anger, agitation and feelings of aggression by offering a sense of calmness to the participant.

If you volunteer to take part in this research, you will be one of about __30-60__ people to do so.

Are there reasons I should not take part in this research?

I understand I should not volunteer for this study if I am, under 18 years of age, I have an open wound, I am unable to

control my bladder or my bowels, and I am unable to remove the weighted blanket on my own.

What other choices do I have if I do not take part in this research?

You can choose not to take part in the study. If you do not wish to take part in the study, would you be interested in journaling, coloring or another activity that you can do while on the inpatient psychiatric unit.

Where is the research going to take place and how long will it last?

The research will be conducted at Vidant Medical Center Inpatient Psychiatric Unit (also known as Behavioral health unit). The total amount of time you will be asked to volunteer for this study is about 5 **hours** over the next **5 days**. Most of the time will be during the first day which will be covered in the next question.

What will I be asked to do?

You will be asked to do the following:

While you are a patient on the psychiatric unit, one of the study team will discuss the study with you and that you will be assigned to one of the following: no weighted blanket or the weighted blanket group for 30 minutes. The study team will also review the purpose of the study and explain the pre and post-tests to you. Below is a description of the pre and post-tests and questionnaires that will be completed for this study. The study will begin shortly after you have agreed to take part and signed this consent form.

- Pre and Post visual analog scale to rate anxiety and anger
- PROMIS-Emotional Distress-Anxiety Scale will be given to you to respond to 8 questions before the study begins
- PROMIS-Emotional Distress-Anger Scale will be given to you to respond to 5 questions before study begins
- Exit Survey
- Sensory Profile will be given to you by one of the study team after you have consented to participate in the study and one of the study team will collect this assessment tool either on day 2

or day 3 after you have completed it. If you have questions about this tool, the study team can answer your questions during day 2 or day 3.
- PROMIS-Emotional Distress-Anxiety Scale and PROMIS-Emotional Distress-Anger Scale will be given to you again on day 5 or earlier depending on your discharge date from the hospital.

What might I experience if I take part in the research?

We do not know of any risks (the chance of harm) associated with this research. Any risks that may occur with this research are no more than what you would experience in everyday life. We do not know if you will receive help from taking part in this study. There may not be any personal benefit to you, but the information gained by doing this research may help others in the future. A potential discomfort may be like the shields used in dental offices and x-rays. The difference is the weighted blanket weights are evenly distributed throughout the blanket. The blanket is large enough to fit on a twin-size bed and the person may have five pounds spread evenly across the chest and abdomen, five pounds spread evenly across the hips and thighs. The remaining five pounds would be evenly distributed over the lower legs. The material for the weighted blanket is cotton and the participant may feel an increase in warmth which would be like a comforter or bedspread that is used at home.

Will I be paid for taking part in this research?

We will not be able to pay you for the time you volunteer while being in this study.

Will it cost me to take part in this research?

It will not cost you any money to be part of the research.

Who will know that I took part in this research and learn personal information about me?

ECU and the people and organizations listed below may know that you took part in this research and may see information about you that is normally kept private. With your permission, these people may use your private/confidential information to do this research:

- The University & Medical Center Institutional Review Board (UMCIRB) and its staff have responsibility for overseeing your welfare during this research and may need to see research records that identify you.

- If you are a patient at ECU or Vidant, a copy of the first page of this form will be placed in your medical records.
- Persons Designated by Vidant Health who monitor research.

UMCIRB HIPAA Privacy Authorization

East Carolina University (ECU)/Vidant Medical Center (VMC): Research Participant Authorization to Use and Disclose Protected Health Information for Research

For use only with the research consent form for UMCIRB#: 19-001265
Principal Investigator: Debra Dickson

When taking part in research, protected health information (PHI) is collected, used, and shared with others who are involved in the research. Federal laws require that researchers and health care providers protect your PHI. Also, federal laws require that we get your permission to use collected PHI for the research. This permission is called authorization.

In order to complete the research project in which you have decided to take part, the research team needs to collect and use some of your PHI as described below.

What types of protected health information (PHI) about me will be used or disclosed?

(Select all that apply.)

ECU Health Care Component:

[☐] ECU Physicians
[☐] School of Dental Medicine
[☐] Speech, Language, and Hearing Clinic
[☐] Human Performance Lab
[☐] Physical Therapy
[☐] Student Health
[☐] Other ECU Health Entity

(please list):

Vidant Health Entity:

[☐] Entire Vidant Health system
[☒] Vidant Medical Center
[☐] Other Vidant Health Entity

(please list):

Type of ECU Records:

[☐] Medical/clinic records
[☐] Billing records
[☐] Lab, Pathology and/or Radiology results results
[☐] Mental Health records

Type of Vidant Records:

[☒] Medical/clinic records
[☐] Billing records
[☐] Lab, Pathology and/or Radiology
[☒] Mental Health records

[☐] PHI previously collected for research

[☐] Records generated during this study

[☐] Other:

[☐] PHI previously collected for research

[☐] Records generated during this study

[☒] Other: Axis 1 and Axis 2 Diagnosis

Who will use or disclose my PHI?

[☒]Principal Investigator

[☒]Other members of the research team

[☐]Other providers involved in your care during research procedures, outpatient/inpatient stays during which research is being performed, or physician office visits during which research is being performed.

Who will receive my PHI?

[☐] Sponsor or other funding source to provide oversight for entire research project

[☒] Research investigators to conduct and oversee the research project

[☒] Principle Investigator and research team members to participate in the various research activities

[☐] FDA or other regulatory agencies to provide regulatory oversight

[☒] UMCIRB to provide continuing review of the research project

[☒] Institutional officials in connection with duties for monitoring research activity

[☐] Other providers involved in your care during research procedures, outpatient/inpatient stays during which research is being performed, or physician office visits during which research is being performed.

[☐] Researchers at other sites—List sites:

[☐] Data and Safety Monitoring Board and its staff

[☐] Contract Research Organization and its staff

[☐] Other

We will share only the PHI listed above with the individuals/agencies listed above. If we need to share other PHI or if we need to send PHI to other individuals/agencies not listed above, we will ask for your permission in writing again

How my PHI may be released to others:

ECU and VMC are required under law to protect your PHI. However, those individuals or agencies who receive your PHI may not be required by the Federal privacy laws to protect it and may share your PHI with others without your permission, if permitted by the laws governing them.

What if I do not sign this form?

You will not be eligible to participate in this study if you do not sign this Authorization form.

How may I revoke (take back) my authorization?

You have the right to stop sharing your PHI. To revoke (or take back) your authorization, you must give the Principal Investigator your request to revoke (or take back) your authorization in writing. If you request that we stop collecting your PHI for the study, you may be removed from the study. If you are removed from the study, it will not affect your ability to receive standard medical care or affect payment, health plan enrollment or benefit eligibility. PHI collected for the research study prior to revoking (or taking back) your Authorization will continue to be used for the purposes of the research study. Also, the FDA (if involved with your study) can look at your PHI related to the study even if you withdraw this authorization.

Restrictions on access to my PHI:

You will not be able to see your PHI in your medical record related to this study until the study is complete. If it is necessary for your care, your PHI will be provided to you or your physician.

How long may the PHI about me be used or disclosed for this study?

Research information continues to be looked at after the study is finished so it is difficult to say when use of your PHI will stop. There is not an expiration date for this authorization to use and disclose your PHI for this study. If you have questions about the sharing of PHI related to this research study, call the principal investigator Debra Dickson at phone number 252-847-3074. Also, you may telephone the University and Medical Center Institutional Review Board at 252-744-2914. In addition, if you have concerns about confidentiality and privacy rights, you may phone the Privacy Officer at 888-777-2617.

How will you keep the information you collect about me secure? How long will you keep it?

Your name will be kept confidential and will not appear with any of the data. All paper documents for this

study will be coded and kept locked in a secure cabinet by the principal investigator. Any electronic data

collected will be stored on a secure pirate drive that only the principal investigator has access to. Data is kept securely for a minimum of six years after study completion.

What if I decide I don't want to continue in this research?

You can stop at any time after it has already started. There will be no consequences if you stop and you will not be criticized. You will not lose any benefits that you normally receive.

Who should I contact if I have questions?

The people conducting this study will be able to answer any questions concerning this research, now or in the future.

You may contact Debra Dickson, the Principal Investigator at **252-847-3074** (days, between **9am to 5pm, Monday to**

Friday).

If you have questions about your rights as someone taking part in research, you may call the Office of Research Integrity & Compliance (ORIC) at phone number 252-744-2914 (days, 8:00 am-5:00 pm) or **you may also call the Vidant Health Center for Research and Grants at 252-847-1177.** If you would like to report a complaint or

concern about this research study, you may call the Director of the ORIC, at 252-744-1971 **and the Vidant Health**

Risk Management Office at 252-413-4473.

Is there anything else I should know?

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

I have decided I want to take part in this research. What should I do now?

The person obtaining informed consent will ask you to read the following and if you agree, you should sign this form:

- I have read (or had read to me) all of the above information.
- I have had an opportunity to ask questions about things in this research I did not understand and have received satisfactory answers.
- I know that I can stop taking part in this study at any time.
- By signing this informed consent form, I am not giving up any of my rights.
- I have been given a copy of this consent document, and it is mine to keep.

To authorize the use and disclosure of your PHI for this study in the way that has been described in this form, please sign below and date when you signed this form. A signed copy of this Authorization will be given to you for your records.

Name of Participant (print) **Signature** **Date**

Person Obtaining Informed Consent: I have conducted the initial informed consent process. I have orally reviewed the contents of the consent document with the person who has signed above and answered all of the person's questions about the research.

Person Obtaining Consent (PRINT) **Signature** **Date**

APPENDIX I: EXIT SURVEY FOR INPATIENT BEHAVIORAL HEALTH STUDY

First Name: _____ Date: _____

1. Have you ever used relaxation techniques or coping strategies to calm yourself or decrease your anxiety when upset in the past?
    a. Yes
    b. No

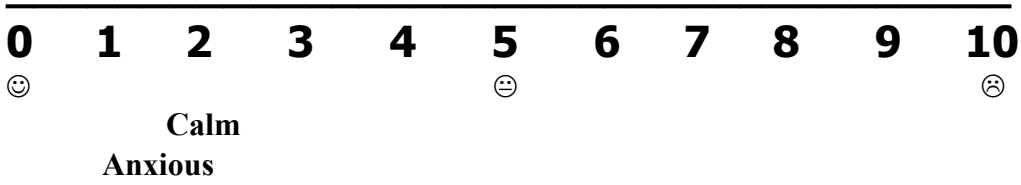
2. If yes to #1, what techniques did you use? _____

3. Do you use medication to manage your feelings of anxiety, anger or aggression?
    a. Yes
    b. No

4. How do the relaxation techniques or coping strategies compare with the use of medication?

If you used the weighted blanket during the study, please answer the following:

5. Was the weighted blanket helpful to calm you down?



6. How would you describe the amount of weight of the blanket?
    a. Not enough
    b. Good
    c. Too much

7. How would you describe the warmth of the blanket?
    a. Too hot
    b. Comfortable
    c. Too cool

8. How would you describe the feel of the fabric?
    a. Soft
    b. Smooth
    c. Rough
    d. Uncomfortable

9. Any other comments about the weighted blanket? _____

Appendix J: **BH study (Check items that have been completed):**

Informed Consent Form Completed ☐ Date_____

Admission Date to unit ☐_____

Vital Signs from EHR ☐ on admission_____

-----Before intervention _____

After intervention _____

Weight ☐ _____ Gender ☐ ___ Race ☐ _____

☐ Age_____ ☐ Marital Status _____

☐ Diagnosis _____

☐ Trauma History _____

PROMIS-Anxiety: Pre (Day 1) ☐ Date_____

PROMIS Anger: Pre (Day 1) ☐ Date_____

Visual Analog Rating Form Completed on Day 1 ☐ Date_____

Sensory Profile given to participant ☐ Date_____

PRN Meds from EHR ☐ prior to Weighted Blanket (date/time)

_____

Weighted Blanket (WB) group: (Include date/time)

-Did the participant receive PRN medication (anxiolytics, antipsychotics) prior to using the weighted blanket?

-What time did they receive the PRN medication (anxiolytics, antipsychotics)?
-PRN medication (anxiolytics, antipsychotics) use from day of informed consent to day 5

_____

_____

_____

Non- Weighted Blanket (WB) group: Pre-Intervention (Include date/time)
Did RN document anxiety level before PRN administered? _____
What was anxiety score? _____
What was reassessment score for anxiety? _____
Did the RN document anxiety reassessment score? _____
Or did PI ask the patient their anxiety score? _____

Exit Questionnaire ☐ Date_____

PROMIS-Anxiety: Post (Day 5 or before discharge) ☐ Date____

PROMIS Anger: Post (Day 5 or before discharge) ☐ Date_____

Sensory Profile completed and given to OT students ☐ Date_____

Was patient restrained during their time in the ED? Yes ☐ No ☐ Hx of restraints or seclusion? Yes ☐ No ☐

Restraints or seclusion occur during 1st 24 hours? Yes ☐ No ☐

If yes, when and how long? _____

APPENDIX J: SAMPLE EXCEL SPREADSHEET

ID#	Axis 1 Diagnosis	Axis 2 Diagnosis	Gender: 1= Male, 2= Female, 3=Transgender	Age 1=18-23 2=24-29 3=30-35 4=36-41 5=42-47 6=48-53 7=54-59 8=60-65 9=66+	Weight 1=45.4-56.7 kg 2=57.2-68 kg 3= 68.5-79.4 kg 4= 79.8-90.7 5=91.2-102.1 6= 102.5-113.4 7= 113.9+ kg	Race 1=Caucasian, 2=African American, 3=Hispanic, 4=other	Restraint: 1=Yes, 2= No	Initial Blood Pressure (BP) and Pulse (P)	Post Study Blood Pressure (BP) and Pulse (P)	Pre-PROMIS Anxiety Score	Pre-PROMIS Anger Score	Post-PROMIS Anxiety Score	Post-PROMIS Anger Score	Sensory Profile Results	How long WB worn: 0= No Blanket, 1=30 minutes
VMCBH-001															
VMCBH-002															
VMCBH-003															
VMCBH-004															
VMCBH-005															
VMCBH-006															
VMCBH-007															
VMCBH-008															
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