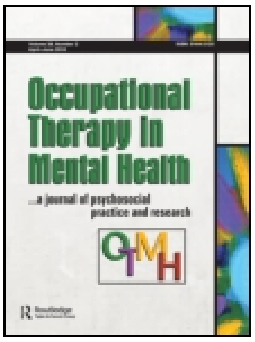

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Evaluating the Safety and Effectiveness of the Weighted Blanket With Adults During an Inpatient Mental Health Hospitalization

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The weighted blanket (WB) is a modality used to self-comfort, rest, sleep, and decrease anxiety. This exploratory, pilot study investigates the safety and effectiveness of the standardized use of the 30-pound WB with 30 adults during an acute inpatient mental health hospitalization. Safety measures include blood pressure, pulse rate, and pulse oximetry monitoring, with and without the 30-pound WB. The State Trait Anxiety Inventory-10 (STAI-10), a self-rating 0–10 anxiety scale, and electrodermal activity (EDA) readings measure effectiveness for anxiety reduction. No statistical differences in vital signs indicate WB safety. The STAI-10 and self-ratings indicate 60% had a significant reduction in anxiety using the WB. EDA readings were inconclusive.

KEYWORDS *anxiety, autonomic nervous system, deep pressure, touch, weighted blanket*

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Color versions of one or more of the figures in the article can be found online at www.tandfonline.com/womh.

BACKGROUND

A weighted blanket (WB) is a therapeutic modality that is used to self-comfort, rest and to reduce anxiety or stress (Champagne, 2010, 2011). The therapeutic use of WBs was first initiated by occupational therapists employing a sensory-based approach, among people with learning and pervasive developmental disabilities (Ayres, 1979; Roley, 2009). More recently, the WB has become increasingly utilized with consumers of mental health services to expand upon the existing humane and therapeutic interventions (Champagne & Stromberg, 2004). This trend parallels the trauma informed care and recovery models, and the mission of the President's New Freedom Commission, toward increasing the holistic therapeutic options available to people with a mental illness (U. S. Department of Health and Human Services, 2003a, 2003b).

The National Association for State Mental Health Program Directors (NASMHPD) also promotes the integration of interventions that are sensory supportive, humane, and trauma-informed across mental health care service delivery (NASMHPD, Medical Directors Council, 1999; National Executive Training Institute [NETI], 2003). Consequently, the skilled use of weighted modalities is being endorsed as part of the national trauma-informed care, seclusion and restraint reduction, and recovery initiatives, as tools that may be used for prevention and crisis intervention purposes (NASMHPD, NETI). Research is limited, however, on the safety and effectiveness of WBs.

From a neurophysiological perspective, sensory processing is one of the purported mechanisms supporting the effectiveness of the WB. Since there is limited literature available on the use of WBs and proposed mechanisms of effectiveness, a review of sensory processing as it has been applied to the use of weighted modalities will be reviewed. According to Miller and Lane (2000),

> Sensory processing is an encompassing term that refers to the way in which the CNS and the peripheral nervous system manage incoming sensory information from the seven peripheral sensory systems. The reception, modulation, and integration of sensory stimuli, including the behavioral responses to sensory input, are all components of sensory processing (p. 1).

Sensory modulation is a component of sensory processing (Miller & Lane, 2000). Miller, Reisman, McIntosh, and Simon (2001) define sensory modulation as,

> the capacity to regulate and organize the degree, intensity, and nature of responses to sensory input in a graded and adaptive manner. This allows the individual to achieve and maintain an optimal range of performance and to adapt to challenges in daily life (p. 57).

Sensory modulation interventions are non-invasive, self-directed therapeutic interventions (activities and modalities), offering specific amounts and types of sensory input for the purposes of fostering organization and self-regulation. More recently, sensory modulation interventions are increasingly offered to people experiencing a variety of mental health symptoms (Champagne, 2003, 2005, 2006, 2010, 2011). According to Hanschu (1998), attention must be paid to the type and amount of sensorimotor input, provided at strategic times, in order to significantly influence alertness, arousal, attention, and an individual's ability to adapt and participate in meaningful life activities. In this way, sensory modulation interventions such as WBs are used to assist individuals in achieving and maintaining an optimal level of nervous system arousal to help support self-regulation and participation in meaningful roles and occupations.

Deep Pressure Touch Stimulation

WBs are a class of sensory processing-related interventions that utilize deep pressure touch simulation (DPTS). Sensory modulation interventions offering DPTS involve the application of a tactile stimulus, providing the feeling of firm pressure, similar to that experienced from a hug, holding, swaddling, or massage (Grandin, 1992). Anecdotal accounts support the hypothesis that when used in an individualized manner, the WB appears to facilitate the ability to feel safe, comforted, and grounded in the world (Champagne, 2010, 2011; Champagne & Stromberg, 2004). Therapists use modalities and activities affording DPTS with clients for the purpose of achieving specific functional, occupational goals. DPTS can be provided through human application (squeezing a person or brushing), or the use of weighted modalities (e.g., WBs, vests, or wraps), elastic garments (e.g., pressure vest), inflatable devices (e.g., inflation vest), or other therapeutic equipment (e.g., squeeze machine, brushing techniques).

Despite the increased use of modalities providing DPTS in occupational therapy practice, and the many different types of weighted and pressure modalities available today, a clear understanding of the safety and the therapeutic effects among varied client populations and age ranges is lacking. Currently, the literature available on the safety and effectiveness of the use of DPTS affording modalities primarily focuses on weighted vests, pneumatic/pressurized devices or garments used with varied populations. There is only one research study currently published on the safety and effectiveness of WBs with adults (Mullen, Champagne, Krishnamurty, Dickson, & Gao, 2008). Thus, existing evidence on DPTS as a therapeutic intervention is primarily with DPTS modalities other than the WB, and with populations other than the adults with mental health-related therapeutic needs and goals.

Although the use of deep touch pressure is not yet considered an evidence-based practice (Morrison, 2007), the lack of evidence does not necessarily exclude the use of interventions affording DPTS as an effective therapy. Rather, research is needed to continue to further develop the evidence-base, which will ultimately support caregivers and clients when making treatment decisions. Given the potential of the WB as a humane, sensory, and recovery supportive treatment option, it is necessary to continue studying the safety and effectiveness variables involved in the use of WBs among varied client populations.

Existing research on other DPTS affording modalities (e.g., weighted vests, inflation vests, WBs) supports the anecdotal reports of the effectiveness of WBs with adult consumers of mental health services. For instance, research on weighted and inflation vests demonstrates that skilled use can result in changes in autonomic arousal, a decrease in impulsivity, an increase in attention and the ability to focus on fine motor tasks, and a decrease in self-stimulatory behaviors in children with pervasive developmental and attention disorders (Fertel-Daly, Bedell, & Hinojosa, 2001; Lin, Lee, Chang, & Hong, 2014; Olson & Moulton, 2004a, 2004b; Reynolds, Lane, & Mullen, 2015; VandenBerg, 2001). Additionally, Smith, Press, Koenig, and Kinnealey (2005) showed that 95% of children with ADHD benefited from using sensory modulation-related interventions, including those providing DPTS, along with taking medications. Krauss (1987) examined the influence of DPTS among college students who used a self-controlled mechanical device to self-administer DPTS with a pulley system, by administering qualitative surveys and measuring body temperature to measure anxiety. Although the results of Krauss's study were inconclusive, this study demonstrates the value of the use of psychophysiological and self-report measures when researching the influence of DPTS (Edelson, Edelson, Kerr, & Grandin, 1999; Krauss, 1987).

Edelson et al. (1999) used electrodermal activity (EDA) and the Connors Parent Rating Scale to explore the influence of Grandin's Squeeze Machine on the anxiety levels of children with autism. Although only a marginal reduction in physiological anxiety was observed, a significant decrease in tension (a behavioral measure of anxiety) occurred. The researchers concluded that "deep pressure appears beneficial for children with high levels of anxiety or arousal, and there may be a threshold of anxiety or arousal required for deep pressure to be beneficial" (Edelson et al.). One must approach many of the existing studies with some caution because several use small sample sizes and there are some inconsistencies in the amount, type, and length of time DPTS is used, which may influence study results. Two recent studies on the use of vests affording DTPS used larger sample sizes, each showing positive results with children (Lin et al., 2014) and adults (Reynolds et al., 2015).

WBs are currently being used with children and adults with mental health diagnoses without a basis for understanding whether or not WBs are safe to use (physiologically). Furthermore, given the dynamic nature of human systems, there are many possible reasons why the WB may be perceived by clients or therapists as effective or ineffective. This study seeks to begin to explore initial WB safety and effectiveness outcomes with adults admitted to an acute inpatient psychiatric hospital setting. Due to the complex relationship between neurophysiological and psychological functioning, knowledge from the fields of neuroscience, neuro-occupation, and trauma-informed care is reviewed.

Neurophysiological Mechanisms Supporting Effectiveness

One of the purported mechanisms explaining the effectiveness of WBs involves the influence on the autonomic nervous system. The sympathetic nervous system (SNS), influences an increase in anxiety, tension and the "fight-or-flight" response, and the parasympathetic nervous system (PNS) influences the "rest and digest" and polyvagal responses (Boucsein, 1992; Porges, 1992). Interventions affording DPTS are often recommended by occupational therapists to influence a dampening of the SNS response (often perceived as increased arousal and/or anxiety), for the purposes of enhancing adaptation, emotion regulation, occupational performance, and participation (Edelson et al., 1999; Fertel-Daly et al., 2001; Grandin, 1992; Mullen et al., 2008; Reynolds et al., 2015; VandenBerg, 2001). DPTS is carried by the dorsal column system to higher levels through the reticular formation (RF), thalamus and the sensory processing areas of the parietal lobe (VandenBerg, 2001). Royeen and Lane stated, "Since the RF mediates arousal, the reticular projections of the dorsal column pathway may be related to the efficacy of these inputs in decreasing arousal and producing calming" (1991, p. 115). Therapeutic activities and modalities affording DPTS also send information to the Purkinje cells in the cerebellum, which can influence a dampening of stimulation coming into the RF through neurotransmitters or other avenues of brain chemistry (Vandenberg, 2001).

Studying the PNS more closely, Porges (1992) expanded upon the understanding of the dynamic and significant role of the vagus nerve as a central contributor to the parasympathetic system. The vagus nerve innervates many of the muscles supporting the ability to listen, communicate, and self-regulate (social engagement system). When an individual is fearful, one's vagal tone may increase, influence, and increase in the PNS response. Thus, Porges' work emphasizes that unless an individual feels safe and secure, it is neurophysiologically difficult to communicate and function (e.g., emotionally, cognitively, socially, academically, vocationally). Polyvagal theory helps to substantiate why it is critical to help people to feel safe and secure, in order to foster the ability to participate in meaningful life roles and activities. Such neurophysiological findings help to support the need to create and offer more nurturing types of sensory, trauma informed, and recovery-focused interventions to people with mental health challenges.

Neuro-Occupation

From a neuro-occupational perspective, the works of Gray, Kennedy, and Zemke (1996), Lazzarini (2004), Padilla and Peyton (1997), and Royeen (2002, 2003) may be used to explore and describe the use of sensory modulation-related occupational therapy interventions, such as the WB. The process of self-organization governs neuroactivity and occupational performance through the process of circular causality, as one experiences and learns from the sensorimotor consequences of one's actions in context and over time (Freeman, 2000). Self-organization refers to the spontaneous formation and adaptation of patterns and pattern change in dynamic systems, such as human beings (Abraham, Abraham, & Shaw, 1990). Freeman asserts that the self-organization of one's actions is the product of context, previous experience, states of arousal and attention, expectancies of responding to stimuli and of one's goals and meanings. In this view, occupation is the neurodynamical process (occupation as means) that gives rise to the engagement in meaningful activity (occupation as ends). The WB might be used as a preparatory, purposeful, or occupation-based intervention to positively influence occupational performance skills and participation (American Occupational Therapy Association, 2014; Champagne, 2010, 2011).

Trauma-Informed Care Interventions

Trauma-informed care is a national mental health initiative promoting a model of care and advocates for the offering of interventions that are empathic, empowering, client-centered, nurturing, sensory supportive and do *not* contribute to re-traumatization (NETI, 2003, 2009; van der Kolk, 2006). Adult studies have demonstrated links between sensory processing, anxiety, and trauma histories among adult consumers of mental health services (Brown, Cromwell, Filion, Dunn, & Tollefson, 2002; Brown & Dunn, 2002; Brown, Tollefson, Dunn, Cromwell, & Filion, 2001; Kinnealey and Fuiek, 1999; Kinnealey, Oliver, & Wilbarger, 1995; Moore & Henry, 2002; Pfeiffer & Kinnealey, 2003). Thus, it is necessary to consider trauma, anxiety and sensory processing symptoms and patterns, as variables affecting occupational performance, health, wellness, and recovery. Trauma experts recommend that interventions with people with trauma histories must first focus on stabilization (Levine, 2005; Luxenberg, Spinazzola, Hidalgo, Hunt, & van der Kolk, 2001). WBs are particularly promising in the area of trauma-informed care because they can be used to help foster self-care, self-nurturance, rest/sleep, and stabilization. The lack of existing evidence supporting the use of WBs with people with mental illness and with trauma histories, and the national initiatives advocating for sensory-based interventions as part of recovery-focused and trauma-informed care, points to the need for research.

Encouraged by initial WB research findings, the authors explored and published the first study on the safety and effectiveness of the use of using a 30-pound WB among a heterogeneous, non-hospitalized volunteer, adult population (Mullen et al., 2008). The results demonstrated that the use of a 30-pound WB was safe among the adult participants based on vital sign readings of pulse oximetry, pulse rate, and blood pressure among the sample population. EDA results indicated that 33% of the participants found the WB to be effective in anxiety reduction. The perceived sense of relaxation for many participants, however, was greater than indicated by the corresponding EDA responses. For example, the State Trait Anxiety Inventory-10 (STAI-10) survey responses showed that over 60% of the participants found the WB to be effective (Speilberger, Gorsuch, & Luchene, 1970). Additionally, the exit survey results showed that 76% of the participants reported that the use of the WB was an effective modality for reducing anxiety.

This article presents the results of an exploratory pilot study with an adult, volunteer sample ($n = 30$) during an acute care inpatient mental health hospitalization using a 30-pound WB. The hypotheses are as follows: (a) the standardized use of the 30-pound WB will be safe to use among adults hospitalized on an acute mental health inpatient unit, as evidenced by vital signs data (heart rate, blood pressure, pulse rate); (b) the standardized use of the 30-pound WB will be effective in decreasing anxiety for some of the participants; and (c) the use of varied measures among a heterogeneous population will yield inconsistencies as well as insights for future studies (Portney & Watkins, 2000).

METHODS

Study Design

To assess the safety and effectiveness of the use of the 30-pound WB, an exploratory, pilot study was employed within a controlled environment. Safety metrics consisted of pulse, blood pressure, and pulse oximetry. A pulse oximeter is a medical device that indirectly measures the oxygen saturation of an individual's arterial blood via the use of a spectrophotoelectric instrument applied to the skin (Harkreader & Hogan, 2004). Efficacy metrics consisted of galvanic skin response (Boucsein, 1992), the STAI-10 questionnaire (Stern, Ray, & Quigley, 2001), and a subjective self-rating 0–10 anxiety scale. Galvanic skin response refers to change in the ability of the skin to conduct electricity, caused by the effect of an emotional stimulus on the operation of the sweat glands (Boucsein). The metrics were then studied to determine if there were any changes in each participant's vital signs, skin conductance, and anxiety levels during the testing period.

To ensure symmetry, a random assignment and cross over design was used to divide the participants into two equal groups, with each person receiving an even or odd code and number designation. The assigned code determined whether the treatment (30-pound WB) was given during the first or second test session. An even code required the use of the treatment during the first testing session, and an odd code required use of the treatment during the second testing session.

Participants

A heterogeneous population was used due to the lack of existing literature identifying adult mental health consumers that might benefit from WB use. Consecutive sampling was used to recruit adults (ages 18–64) willing to volunteer for all portions of the study during an acute inpatient mental health hospitalization. A sample size of 30 participants completed all portions of the study, with an age range of 18–54, a mean age of 30.53 and a standard deviation of 9.68. Eight participants were males and 22 were females, 80% of the participants had a trauma history, and 33% had a history of restraint use in previous hospitalizations. A randomized assignment procedure (even and odd coding method) was used and helped create a cross-over design to address ordering effect (Portney & Watkins, 2000).

Exclusion Criteria

The Allen Cognitive Level Screen (ACL) assesses global cognitive functional ability (Allen, Earhart, & Blue, 1992). An ACL score of 4.8 or greater, and the ability to understand and sign the informed consent document, helped determine the cognitive ability to participate. Exclusion criteria also included having open wounds, moderate to severe physical injuries, illiteracy, and a positive pregnancy test upon admission. Although 40 participants met inclusion criteria, only 30 participants completed all of the steps required for study completion ($n = 30$). Of the 10 participants whose data were not used due to lack of completion, reasons for exclusion included: discharge prior to completion of all steps, anxiety related to the study procedures, and the loss of willingness to participate with no reasons provided.

Setting

A 24-bed locked acute care mental health unit within a community hospital was the study location. Each participant's room and hospital bed was used to conduct all aspects of the study. The room temperatures ranged between 65°F–79°F. The participant's hospital bed and a privacy screen were used to reduce environmental stimulation and to seclude the participants from the monitoring equipment and data collectors during the monitoring activities. The only people allowed in the room included the participant and two data collectors. During the monitoring phase, each participant's door was closed and a sign was placed on the door to inform others that the study was taking place and not to enter.

The Treatment: The WB

The treatment was the use of the 30-pound WB. The WBs used in the study were custom made to weigh 30 pounds by Weighted Wearables (2015, Cozy Comforter), with one side of the blanket offering fleece and the other side a cotton fabric. For standardization purposes, only the fleece side was used against the body of the participant. All persons participated in two test sessions, one session with the treatment (the 30-pound WB), and one control session without the treatment, as previously explained. During the control session no WB was applied.

INSTRUMENTS AND MEASUREMENT TOOLS

Safety Measures

To determine whether the 30-pound WB is physiologically safe for the participants to use, vital sign metrics were compared when using and when not using the WB, considering each individual's vital sign baseline. The vital signs collected included pulse rate, blood pressure, and pulse oximetry (non-invasive measure for identifying oxygen saturation in the blood). Vital signs are used by health care professionals to detect and monitor potential medical issues related to circulation when not within normative ranges. Collecting and comparing vital signs helped to show if the amount of weight from the 30-pound WB was safe to use by adults while in the lying down position, or if it caused any one or more of the vital signs to enter an unsafe region. If vital signs entered into an unsafe region, this would be an indication that the use of a 30-pound WB impaired breathing or blood circulation. Accordingly, the quantitative vital signs were measured using blood pressure, pulse, and pulse oximetry instruments, taking into consideration that blood pressure and pulse rate decrease when sitting or lying down (Harkreader & Hogan, 2004). Each participant's vital signs data, with the treatment and without the treatment, were analyzed. Generally, the participants' vital signs were within the safety range acceptable for this study.

Effectiveness Measures

The previous study by the authors (Mullen et al., 2008) formed the basis for the effectiveness metrics. Accordingly, EDA, the STAI-10 questionnaire and a 0–10 self-report anxiety measure were used to explore effectiveness. EDA is a measure of galvanic skin response, or skin conductivity, which can be used as an indication of one's state of arousal (Boucsein, 1992). EDA has been observed to continuously change over time and is correlated to the activity of the eccrine sweat glands. Located in the dermis, the eccrine sweat glands regulate body temperature by manufacturing and excreting sweat onto the skin's surface (Stern et al., 2001). EDA can be measured through the collection of skin conductance and used as the quantitative indicator of anxiety (Stern et al., 2001). In this study, skin conductance readings were obtained using ProComp + skin conductance sensor from Thought Technology (2015) using a constant-voltage sampling of skin conductance at a rate of 32Hz with an accuracy of ±5%. The development of bias potentials and polarization were minimized through the use of silver chloride cup electrodes. Velcro fasteners were used to secure the electrodes to the volar surfaces of the first and second distal phalanges of the right hand of each participant.

The STAI-10 (Speilberger et al., 1970) is a standardized, self-administered questionnaire that measures perceived anxiety. The STAI-10 uses an ordinal scale, it is used for assessment and research purposes, and validity and reliability have been established. Additionally, a 0–10 self-rating anxiety scale (0 being the most calm one could feel and 10 representing the extreme crisis state) was used to obtain a quantified self-reported measure of perceived anxiety (McDowell, 2006).

PROCEDURE

Permission was received from Dartmouth Hitchcock's Internal Review Board and an informed consent document was thoroughly reviewed and signed by each client willing to participate. On the first day of admission, a standardized procedure was used to identify participants meeting inclusion criteria. After a complete description of the study to the participants, those who were interested were provided with the informed consent document to read and sign. Questions were encouraged and answered before the volunteers signed the informed consent document, as well as during the subsequent monitoring phase. Recognizing that the novelty of the testing experience may influence test responses, the test environment, the equipment and procedures were reviewed with the participants in a standardized manner prior to the start of the monitoring phase.

The monitoring phase was conducted on the second day of admission. The participant's hospital room was first set up by the two data collectors, and the participant was then brought in and encouraged to ask questions related to the monitoring equipment. The participant then had all of the monitoring equipment applied while seated on the hospital bed, and then the equipment was activated by the researchers in a standardized manner. Two researchers were present at all times to ensure consistency and accuracy of testing procedures and data recording.

The STAI-10 was completed prior to lying down, and the 0–10 self-report anxiety rating was also obtained from the participants and recorded by the researchers (Speilberger et al., 1970). Although in practice clients use WBs for a longer period of time, a 5-minute timeframe was used for each monitoring session, which was found to be sufficient by Mullen et al. (2008) to measure a response. The 30-pound WB (Weighted Wearables, 2015, http://www.weightedwearables.com/cozy_comforter.html) was applied during the first of the two 5-minute monitoring sessions if the participant's code was even, with the fleece side against the body. If the participant's code was odd, no WB was applied for the first monitoring session. The participant was shielded from the researchers and the equipment monitors by a standard hospital screen during each session. At the end of the 5-minute monitoring period, the participant's vital signs, the STAI-10 and 0–10 self-rating anxiety scales were all repeated. The monitoring equipment was removed and the participant was instructed to walk up and down the hallway of the unit for 5 minutes to nullify the carry-over effect from lying down and use or non-use of the WB (Mullen et al., 2008). The participant was then retrieved by the researchers and the process was repeated, with no WB for those with even codes and with the application of the WB for those with odd codes. This was a reversal of intervention of the first session, with the even and odd numbers being switched.

Statistical Analysis

For the analysis of the data on safety, vital signs were collected using a pre- and post-test method and compared to adult norms. For the analysis of effectiveness, statistical analysis included the use of *t*-tests to analyze the results, focusing on the differences between the participants when compared to themselves during treatment and control sessions (paired tests), and between groups of participants (pooled tests). To further isolate and fully explicate the effectiveness of the use of the 30-pound WB, the results were also analyzed to study the influences of the ordering effect of the treatment sessions. Finally, a Pearson's correlation analysis was carried out to explore the relationship, if any, between the two survey questionnaires (STAI-10 and self-rating), to study whether the simple and easy-to-use self-rating would be a sufficient indicator of participant's dynamic, self-perceived anxiety states.

RESULTS

Safety

Pulse oximetry, pulse, and BP were monitored before and after each 5-minute test period (both during the treatment and control phases), and pulse rate and pulse oximetry were monitored continually throughout the 5-minute test sessions as well. Table 1 shows the results of the initial and final pulse oximetry data for all participants, as well as the change over the 5-minute monitoring

TABLE 1 Pulse Oximetry Results

Participant number	Without blanket			With blanket		
	Initial O_2	Final (after 5 minutes)	Net change	Initial O_2	Final (after 5 minutes)	Net change
CDH-002	99	99	0	99	97	2
CDH-003	97	97	0	97	98	−1
CDH-004	98	98	0	98	98	0
CDH-005	96	97	−1	96	95	1
CDH-006	96	95	1	96	96	0
CDH-007	97	96	1	97	99	−2
CDH-009	98	97	1	98	97	1
CDH-010	99	99	0	98	99	−1
CDH-011	95	92	3	95	97	−2
CDH-013	99	99	0	99	99	0
CDH-015	96	95	1	96	95	1
CDH-016	96	96	0	97	97	0
CDH-017	99	99	0	99	99	0
CDH-018	99	99	0	99	99	0
CDH-019	98	96	2	98	95	3
CDH-020	99	99	0	99	99	0
CDH-023	98	97	1	98	99	−1
CDH-024	99	98	1	98	97	1
CDH-025	97	95	2	97	95	2
CDH-026	98	97	1	98	97	1
CDH-028	98	97	1	98	97	1
CDH-029	99	99	0	99	99	0
CDH-030	93	92	1	93	95	−2
CDH-032	99	98	1	98	97	1
CDH-034	97	96	1	95	94	1
CDH-035	99	99	0	99	99	0
CDH-037	98	97	1	98	97	1
CDH-038	98	97	1	97	96	1
CDH-039	99	99	0	99	99	0
Maximum	99	99	3	99	99	3
Minimum	93	92	−1	93	94	−2

period. It is clear that none of the participants fell below the normative cut-off value of 90%, designating the safe range for pulse oximetry.

A comparison of the results for both systolic BP (Figure 1) and diastolic BP (Figure 2) and pulse rate (see Figure 3) also show that most of the participants stayed within the normative (safe) ranges, both during the treatment and control phases. For the participants whose values were outside of the normative ranges, the values were similar during both the treatment and control phases, thus indicating that the WB was not the cause of deviation outside of the normative (safe) range. From these results, it is concluded that the use of the 30-pound WB did not cause any adverse influence on physiological safety in terms of blood circulation, as evidenced by the three vital signs data collected, for the entire 30 adult participants.

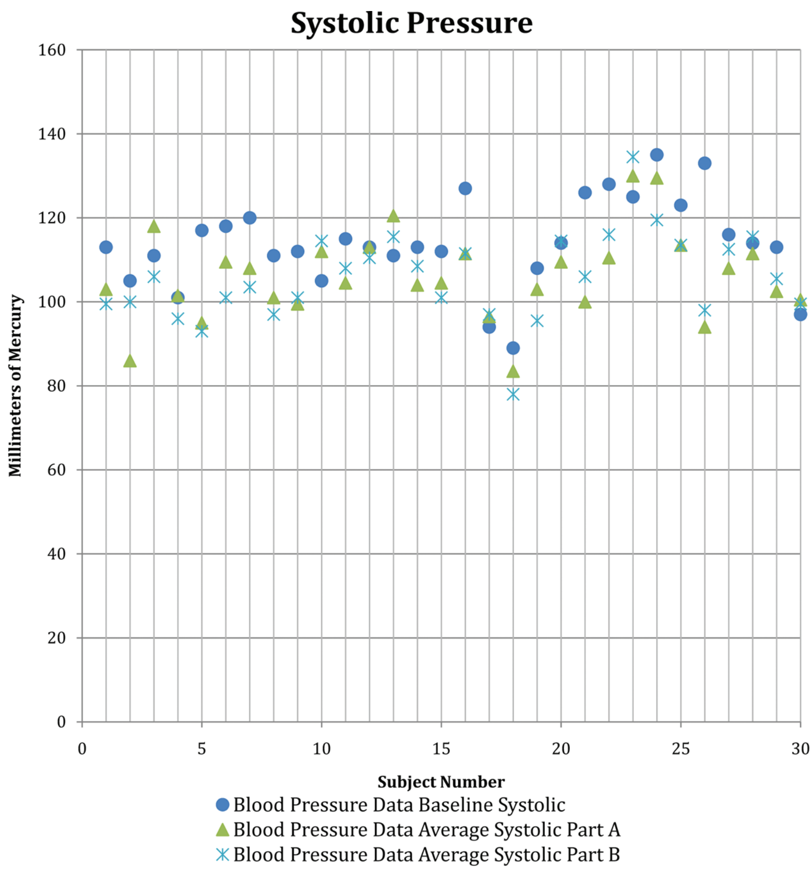

FIGURE 1 Blood pressure comparison with and without the WB.

Effectiveness

EDA

Analysis of the EDA data did not show any conclusive evidence or significance. For example, it was found that even though the participants were in an acute mental health care setting, by the day of the monitoring (day two of admission), participants' EDA levels were relatively low and similar to those of the adult, non-hospitalized participants in the first study (Mullen et al., 2008). This may be due to the added influence of medications provided to the participants in this study, which can affect EDA. Furthermore, the first study outlines some of the difficulties associated with the analysis of low skin conductance results, and the effect of a skin conductance floor (Mullen et al., 2008). For these reasons, the effectiveness results will focus on the analysis and results of the survey-based anxiety metrics from the STAI-10 and 0–10 self-rating anxiety scales.

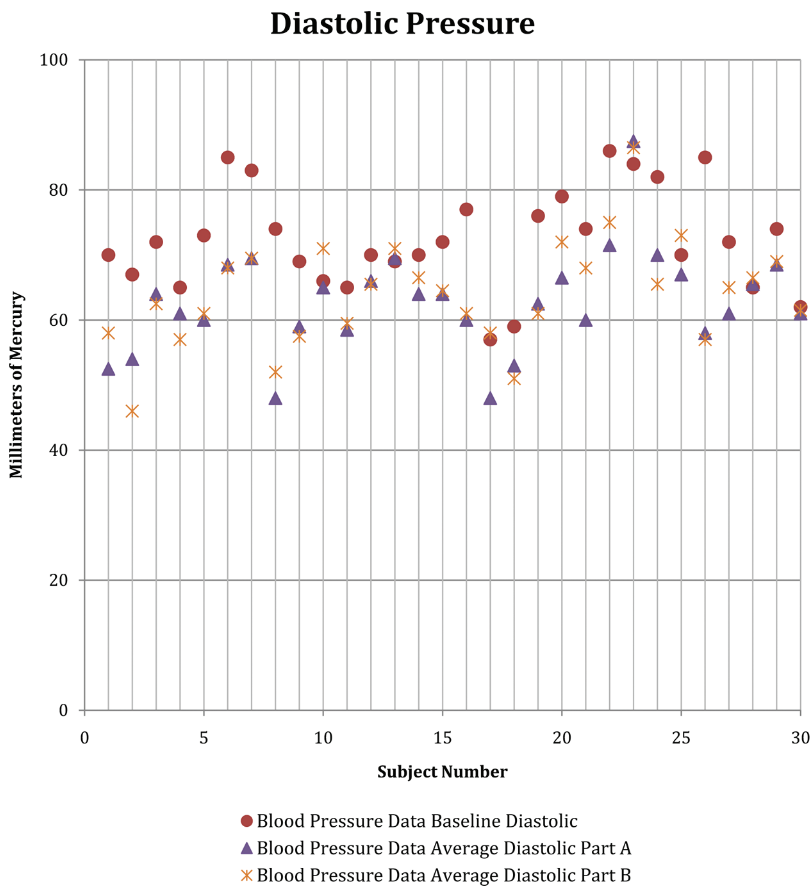

FIGURE 2 Blood pressure comparison with and without the WB.

STAI-10 and 0–10 Self-Rating Anxiety Scales

Table 2 shows the statistical results from STAI-10 and the 0–10 self-rating anxiety data. The results are first shown for all participants, as well as for each group. Group 1 is the set of participants to whom the treatment was applied for the first 5-minute monitoring phase, and group two is the set of participants for whom the treatment was applied during the second monitoring phase. Overall, the results of the questionnaires appear to indicate that the data have relatively high variances. The high variances can be attributed to the relatively small sample size ($n = 30$) and the use of a heterogeneous population.

Throughout the study, a two-tailed *t*-test was used with a level of significance set a priori at p value $= 0.05$. The overall results show that there is no statistical difference between the treatment and control situations from STAI-10 data ($p = 0.164$), while there is a significant improvement identified in the 0–10 self-rating data ($p = 0.002$). Further analysis of STAI-10 data from each group corroborated the overall population data for group 1 ($p = 0.226$) and

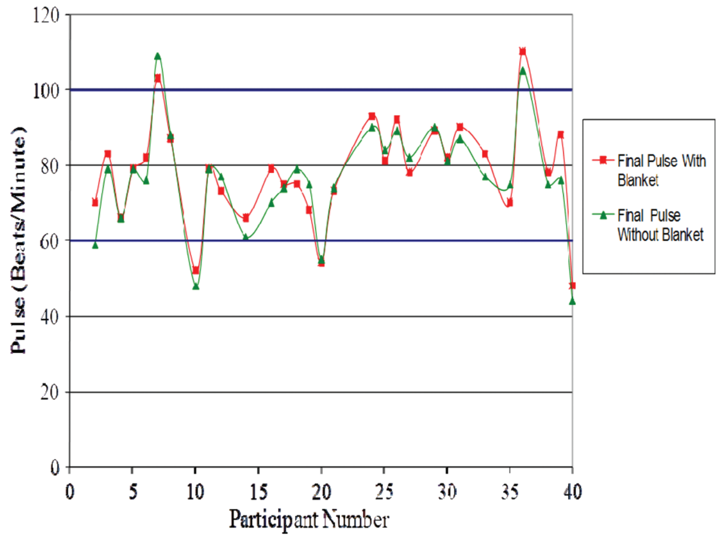

FIGURE 3 Pulse rate results.

TABLE 2 30-Pound WB Effectiveness

	All participants			
	STAI-10		Self-rating	
Effectiveness	Treatment	Control	Treatment	Control
Mean	16.97	19.10	1.00	0.05
Variance	34.79	33.82	2.62	2.14
Observations (n)	30	30	30	30
t-Statistic	−1.41		2.38	
P	0.164		0.020	
t-Critical two-tail	2.001		2.002	
Effectiveness	Group 1			
Paired t-test	STAI-10		Self-rating	
	Treatment	Control	Treatment	Control
Mean	17.71	20.79	1.29	−0.39
Variance	41.45	31.41	2.68	1.47
Observations (n)	14	14	14	14
t-Statistic	−1.27		3.78	
p-Value	0.226		0.002	
t-Critical two-tail	2.160		2.160	
Effectiveness	Group 2			
Paired t-test	STAI-10		Self-rating	
	Treatment	Control	Treatment	Control
Mean	16.31	17.63	0.75	0.44
Variance (n)	30.36	33.18	2.60	2.53
Observations	16	16	16	16
t-Statistic	−0.57		0.55	
p-Value	0.576		0.590	
t-Critical two-tail	2.131		2.131	

for group 2 ($p = 0.576$). Repeating the analysis with the results from the 0–10 self-rating data, however, it was found that there was a statistical improvement for group 1 ($p = 0.002$) but no statistical difference for group 2 ($p = 0.590$).

To further explore the effectiveness of 30-pound WB, additional analysis was performed to identify groups within the heterogeneous population that may have benefited from the use of the treatment. For this purpose, the participants were identified as having (1) a positive effect (when there is a positive change after the use of WB), (2) no effect (when there is no change), and (3) negative effect (when there is a negative change after the use of WB). Table 3 shows the results of this categorization for the STAI-10. Here, 60% of the participants (18 out of 30) had a positive effect when using the 30-pound WB and 40% reported a negative experience. A similar analysis was carried out using the 0–10 self-rating data. For this analysis, the net difference between the pre-treatment and post-treatment was studied to identify the population with a positive effect (see Table 3). Here, 66.7% had a positive experience when using the 30-pound WB, with 20% indicating no change, and 13% experiencing a negative effect. These results appear to indicate that the 30-pound WB could be an effective anxiety reducing intervention in certain segments of the adult acute inpatient mental health population. This inference provides direction for future studies demonstrating the potential value of identifying a more focused homogenous population.

Ordering effect

A concern in a study of this nature is to isolate and document any ordering effect due to a possible residual effect of using the treatment in the first testing session. The ordering effect was analyzed using a standard pooled *t*-test. A two-tailed *t*-test with a level of significance set a priori at $p = 0.05$ was used. The pooled *t*-test results are shown in Table 4. The results clearly indicate that there is no statistical difference between group 1 and group 2 from the STAI-10 and the 0–10 self-rating data, therefore, it can be concluded that there was no ordering effect.

Correlation between STAI-10 and 0–10 self-rating scales

This study also looked into the potential correlation in the results from the two anxiety self-rating questionnaires. Correlation analysis can provide further insight into whether both are needed for assessing the participants'

TABLE 3 Categorization Based on STAI-10 and Self-Rating Results

	Change in STAI-10 from control to treatment	Change in self-rating from pre-treatment to post-treatment
Positive effect	18 (60.00%)	20 (66.67%)
No change	0	6
Negative effect	12	4

TABLE 4 Ordering Effect From STAI-10 and Self-Rating Data

	STAI-10 treatment		STAI-10 control	
	Group 1	Group 2	Group 1	Group 2
Mean	17.71	16.31	20.79	17.63
Variance	41.45	30.36	31.41	33.18
Observations	14	16	14	16
t-Statistic	0.636		1.521	
p-Value	0.530		0.139	
t-Critical two-tail	2.056		2.048	
Pooled *t*-test	Self-rank treatment		Self-rank cntrol	
	Group 1	Group 2	Group 1	Group 2
Mean	1.29	0.73	−0.25	0.4
Variance	2.68	2.78	1.57	2.68
Observations	14	15	14	15
t-Statistic	0.900		−1.204	
p-Value	*0.376*		*0.239*	
t-Critical two-tail	2.051		2.055	

perceived anxiety state. For this purpose, a Pearson correlation using the SPSS software program was employed to investigate if there was a statistical correlation between the STAI-10 and self-rating 0–10 anxiety measures. Using an a priori level of significance of 0.01, strong significant correlation was found when comparing the STAI-10 scores, the self-rating data for the treatment situation (0.834), and for the control situation (0.552). While these results are preliminary and in need of further research, the results suggest that it may be sufficient to use either the STAI-10 or the 0–10 self-rating survey for assessing the participants' perceived, dynamic state of anxiety.

DISCUSSION OF RESULTS

The purpose of this exploratory, pilot study was to investigate the safety and effectiveness of the standardized use of the 30-pound WB with a volunteer consecutive sampling of 30 adults during an acute inpatient mental health hospitalization. Blood pressure, pulse rate, and pulse oximetry monitoring with and without the 30-pound WB were used as safety indicators. To study effectiveness, multiple measures were used. Skin conductance and EDA readings were measured to examine the participants' state of arousal and anxiety. Similarly, STAI-10 and self-rating exit questionnaires were used to study the participants' perceived reduction in anxiety after the use of the WB (Speilberger et al., 1970). This study builds upon the authors' prior research on the use and benefits of WBs with adults (Mullen et al., 2008). This is the first study, however, to explore the WB's safety and effectiveness with adults with mental illness.

Exploration into the safety of the use of the WB was focused on the standardized use of the 30-pound WB, one of the heaviest on the market at the time of the study, to identify whether there would be a negative impact on vital signs (blood pressure, pulse rate, pulse oximetry) with an adult inpatient mental health population. The results demonstrate no adverse effects on vital signs with the use of the 30-pound WB using a similar methodology as in WB study 1 (Mullen et al., 2008). Ultimately, the adult population in the first published WB study (Mullen et al., 2008), had strikingly similar effectiveness and safety results, as those revealed in the present study. It was found that 33% of this population had a history of restraint use, none of the study participants experienced restraint or seclusion throughout the hospitalization.

The STAI -10 and 0–10 anxiety self-rating results demonstrate that for 60% of the participants, the use of the 30-pound WB was effective in anxiety reduction. Interestingly, the STAI-10 results from study 1 revealed the same effectiveness outcomes for anxiety reduction (Mullen et al., 2008). Together, these results indicate that regardless of diagnosis, a WB appears to provide a calming effect for a significant segment of the participants. Though the initial results are encouraging, the findings should also be interpreted with caution due to its exploratory nature. Therefore, while these results cannot be generalized to all populations, this study supports previously published evidence and provides a methodology for studying the WB from which to build upon in future research.

Limitations

One limitation of the study is the use of a diagnostically heterogeneous adult sample. Additionally, other potential influences include that all participants were allowed the use of medications for mental health symptoms and all became more familiar with the hospital environment after a 24-hour period; both of these variables often influence a decrease in anxiety for many people. Low anxiety levels were demonstrated by the low baseline EDA measurements evidenced with most of the participants. In fact, the EDA data was not used as a quantitative effectiveness measure, because the participant's anxiety levels remained too low for it to be a useful metric, similar to the EDA methodology issues outlined in study 1 (Mullen et al., 2008). Other physiological metrics, more sensitive to assessing calming are warranted in future studies.

The main hypotheses of the study are that the standardized use of the 30-pound WB is safe to use with an acute, inpatient, adult mental health population and that its use will be effective in decreasing anxiety for some participants. To explore the specific hypotheses of this study, a standardized protocol was used (5-minute timeframe, the amount of weight, weight placement, and fabric type used against the person [fleece side down for all participants]). The WB is typically used, however, in a client-centered manner. In occupational therapy practice, WB use is individualized to provide the amount of weight, weight distribution, and timeframe that is most preferred by the client, safe, and effective. For example, the amount of weight, fabric type used against the body, time of day it is used, and the amount of time it is used for, is determined collaboratively in practice. All of these factors play a role in the perceived effectiveness of the use of the WB.

The use of a standardized protocol was also necessary for the purposes of this study, due to the need to explore the safety of the use of the 30-pound WB in a quantitative manner. This standardized protocol, however, may not have been the most optimal for studying effectiveness outcomes, given that the WB is used in a client-centered manner practice (individualized manner). Additionally, having two researchers in the room during the monitoring phase, while useful in helping to establish internal validity, may have also influenced the results (may have been more calming for some or more anxiety producing for others).

CONCLUSION

This study verifies the previous results of the authors, which indicated that the use of a WB was safe for 100% and effective for 60% of the adult participants. These findings provide an initial basis for further examination of the safety and effectiveness variables involved with the use of WBs in the treatment of adults with mental illness. More sensitive and compressive metrics are needed to better capture the complex neurophysiological responses. Measurement systems are also needed to further understand the neuroscience, neuro-occupational, and trauma-care correlations involved in the use of WBs. Future studies exploring the effectiveness and use patterns, employing a client-centered methodology, will help to create evidence-based WB practice guidelines that inherently promote client-centeredness. Such a methodology may also be used to help identify WB variables that clients identify as effective or ineffective, and the impact on occupational skills, performance outcomes and recovery among varied populations. Finally, although one-third of the participants had a history of the use of restraint and seclusion, none of those participants required the use of restraint and seclusion during the study. Thus, future studies exploring the correlations between WB use as a preparatory method, for restraint reduction and stabilization purposes, is warranted.

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