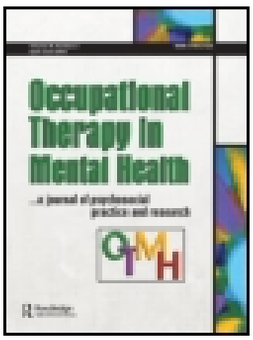

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Exploring the Safety and Therapeutic Effects of Deep Pressure Stimulation Using a Weighted Blanket

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ABSTRACT. This paper presents the results of a concurrent, nested, mixed methods exploratory study on the safety and effectiveness of the use of a 30 lb weighted blanket with a convenience sample of 32 adults. Safety is investigated measuring blood pressure, pulse rate, and pulse oximetry, and effectiveness by electrodermal activity (EDA), the State Trait Anxiety Inventory-10 and an exit survey. The results reveal that

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the use of the 30 lb weighted blanket, in the lying down position, is safe as evidenced by the vital sign metrics. Data obtained on effectiveness reveal 33% demonstrated lowering in EDA when using the weighted blanket, 63% reported lower anxiety after use, and 78% preferred the weighted blanket as a calming modality. The results of this study will be used to form the basis for subsequent research on the therapeutic influence of the weighted blanket with adults during an acute inpatient mental health admission. doi:10.1300/J004v24n01_05

KEYWORDS. Sensory modulation, weighted blanket, deep pressure touch stimulation, skin conductance, electrodermal activity

INTRODUCTION

The weighted blanket is a therapeutic modality used within the scope of occupational therapy practice (Nackley, 2001; Walker & McCormack, 2002). It has been increasingly employed in acute mental health care settings for crisis intervention, preparatory purposes, and as a purposeful activity, which appears to help the consumer nurture, soothe, and care for himself or herself (Champagne & Stromberg, 2004). When used in this way it is considered a sensory modulation treatment tool aiding in the stabilization and recovery process (Champagne, 2005). While there is no published research on the safety or effectiveness of the therapeutic use of the weighted blanket, anecdotal accounts support that when used in an individualized manner, the weighted blanket appears to facilitate the ability to feel safe, comforted, and grounded in the world (Champagne & Stromberg, 2004; Heller, 2002).

The President's Freedom Commission (Department of Health and Human Services, 2003) was initiated to promote a national focus on increasing options in the areas of treatment, education, employment, assistive devices, and universally designed technology for people with mental illness. National and state mental health organizations, such as the National Association for State Mental Health Program Directors (NASMHPD) and the Department of Mental Health (DMH) support this initiative and advocate the use of more humane, person-centered, and sensory supportive options (Huckshorn, 2004; National Executive Training Institute [NETI], 2003). Although it is well established that no one therapeutic tool is helpful to all consumers, the use of the weighted blanket as a

prevention and/or crisis intervention tool, classifies as a primary and secondary crisis prevention approach (NASMHPD, 1999), which may ultimately help to decrease the need for the use of restraint and seclusion (Champagne & Stromberg, 2004; NETI, 2003). Therefore, given the potential of this humane and recovery supportive treatment option and the importance of engaging in evidence-based practice, it is necessary for occupational therapists to begin studying the safety and effectiveness of the use of the weighted blanket.

Further, when requesting the allocation of resources to introduce a novel treatment modality into clinical practice it is necessary to present empirical evidence demonstrating that its use is within one's scope of practice and that it is both safe and effective. This may be achieved through the application of principles from traditional social science and engineering data analysis. Such an analysis will not only lead to a better understanding of the therapeutic effects of deep pressure, but also will lay the foundation for technological advances in the remote sensing of anxiety (Luharuka, Gao, & Krishnamurty, 2003), and the engineering of new and improved modalities offering deep pressure stimulation. To this end, this paper presents the details of the first clinical study exploring both the *safety* and *effectiveness* of the use of a 30 lb weighted blanket, the heaviest available at the time of the study, with a heterogeneous convenience sample of 32 volunteer adults.

Background Information

Deep Pressure Stimulation (DPS)

One of the qualities offered by the weighted blanket is DPS, which is generally referred to as a form of touch pressure applied to the body providing the feeling of a firm hug, holding, swaddling, or massage (Grandin, 1992). Although there is no published research regarding the use of the weighted blanket, there is a growing body of research supporting the use of DPS for varied therapeutic purposes. Interestingly, when using Grandin's Hug Machine, the use of DPS had a calming influence for adults and children with anxiety, autism, and attention difficulties (Edelson, Edelson, Kerr, & Grandin, 1999; Grandin, 1992). Additionally, DPS applied through the use of the weighted vest, for children with pervasive developmental and attention disorders, influenced an increased ability to focus on fine motor tasks (Fertel-Daly, Bedell, & Hinojosa, 2001; Olson & Moulton, 2004a, 2004b; VandenBerg, 2001), and a decrease in self-stimulatory behaviors (Fertel-Daly et al., 2001).

Foam-padded splints to the arms applying firm pressure appeared to help reduce self-stimulatory and self-injurious behaviors in a child with autism (McClure & Holtz-Yotz, 1991). Wrist weights providing DPS influenced a reduction in self-injurious behaviors by 92% in a child with intellectual disabilities (Hanley, Piazza, Keeney, Blakeley-Smith, & Worsdell, 1998). These studies provide support for the use of DPS modalities for a variety of treatment purposes, such as the facilitation of attention, self-control, and a decrease in anxiety. While providing some evidence of the effectiveness of the use of DPS modalities these studies do not specifically explore the use of the weighted blanket or whether the modalities used are safe.

Measuring Safety and Establishing Guidelines

Safety guidelines established for the use of backpacks have been generalized to the use of the weighted vests and weighted blankets (Olson & Moulton, 2004a; Walker & McCormack, 2002). This includes recommendations according to body weight ratios (5-10%), the distribution of the weight, and wearing schedules. Weighted vests are typically used while in ambulatory and/or seated positions, whereas the weighted blanket is not meant for use while ambulating. Rather, the weighted blanket is used while in a lying down or seated position. Therefore, applying the same backpack safety guidelines to the use of the weighted blanket is unsubstantiated. Further, clinical experience of the authors suggests that for some consumers the use of a weighted blanket that is more than 10% of the person's body weight may be preferred. Hence, there is a need to explore whether the use of the 30 lb weighted blanket has a negative influence on physiological safety and whether there are patterns or preferences according to body weight. Vital signs provide information regarding a person's general health status and are used in this study to begin to assess whether the deep pressure provided from a 30 lb weighted blanket influences adverse changes in the vital signs of the test participants.

Measuring Effectiveness

Mixed research methodology, the use of a combination of quantitative and qualitative approaches, is considered a reliable way to measure the effectiveness of therapeutic interventions (Creswell, 2003). Edelson et al. (1999) used a mixed methods approach to explore the influence of DPS provided by Grandin's Hug Machine on the anxiety levels of children with autism using the Connors Parent Rating Scale and electrodermal activity (EDA). Skin conductance (SC), a measure of EDA, provides a

direct measure of sympathetic activity and has been one of the most widely used quantitative metrics in psychophysiology research (Boucsein, 1992; Cacioppo, Tassinary, & Bernston, 2000). Although only a marginal reduction in anxiety was revealed using SC, a significant decrease in tension (a behavioral measure of anxiety) occurred, and researchers concluded, "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., 1999, p. 151). Krauss (1987) examined the influence of DPS among college students using a self-controlled mechanical device to self-administer DPS with a pulley system, using qualitative surveys and body temperature to monitor anxiety. Temperature is also a measure of sympathetic arousal (Boucsein,1992). Although the results from Krauss' study were found to be inconclusive, these studies demonstrate the value of the use of mixed methodology, including psychophysiological metrics in addition to subjective self-report, when studying the influence of DPS.

Evidence demonstrates that sympathetic arousal is directly linked to emotional and other cognitive processes such as attention, decision-making, and memory (Damasio, Tranel, & Damasio, 1991; Damasio, 1994; Bechara, Tranel, Damasio, & Damasio, 1996; Bechera, Damasio, Tranel, & Damasio, 1997; Cahill, 1997). Further, chronic high levels of sympathetic arousal are hallmarks of anxiety disorders and stress, which are conditions associated with high levels of psychological and physical morbidity (Russek, King, Russek, & Russek, 1990; Steptoe, Cropley, & Joekes, 1999). It has also been demonstrated that treatments influencing the reduction of autonomic arousal often reduce anxiety and distress (Critchley, Melmed, Featherstone, Mathias, & Dolan, 2001). Thus, it is hypothesized that the weighted blanket assists in helping consumers decrease anxiety and levels of distress. Since SC is a direct measure of sympathetic nervous system activity, which is influenced by anxiety, SC is a quantitative measure used to explore effectiveness. The State Trait Anxiety Inventory-10 (STAI-10) and an exit survey are self-rating metrics, also used to explore effectiveness.

METHOD

Experimental Design

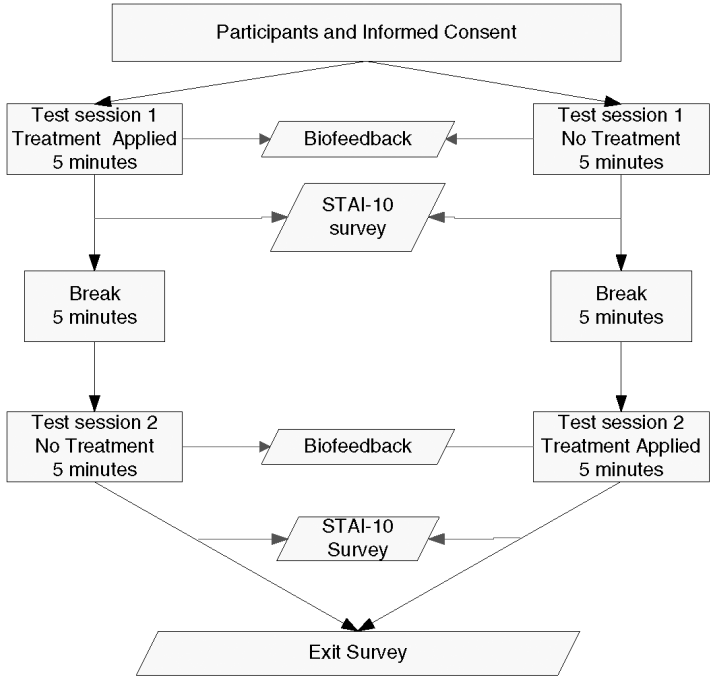
A concurrent, nested, mixed methods design was used to gather quantitative and qualitative data. The qualitative data gathering process was

embedded within the quantitative procedures. Figure 1 shows the experimental design.

Sample

A convenience sample of 34 people including 20 males and 14 females participated in the study. Testing was interrupted for two participants; therefore, the data for these two participants were not included in the statistical analysis or results. Consequently, the final sample size of the study was n = 32. The age range was 18-58, with a mean of 31 and a standard deviation of 11.7. The population was skewed toward younger people because a large number of the volunteers were undergraduate and graduate students. The lowest body weight of the participants was 112 lb and the maximum was 234 lb with a mean of 165 lb and a standard deviation of 27.8 lb. Inclusion criteria required consenting, non-hospitalized, volunteer adults with no apparent medical conditions or physical

FIGURE 1. Experimental design overview.



injuries between the ages of 18 and 64. Because this was an exploratory study, a diverse group of people participated. It is understood however, that age, sex, weight, and race may have varying influences on psychophysiological processes and responses.

Using random assignment and a cross over design the participants were divided into two groups, each person receiving an even or odd code and number designation. All persons participated in two-test sessions, one session with the treatment (the 30 lb weighted blanket) and one session without the treatment. The code the person was assigned determined whether the treatment was given during the first or second testing session. An even code required the use of the treatment (30 lb weighted blanket) during the first testing session, an odd code required use of the treatment during the second testing session. Before any testing or data collection occurred age, sex, and weight were recorded and all participants signed an informed consent document. The informed consent document explained potential risks or harm that could arise from being a participant in the experiment, provided a general summary of the instruments to be used, and also the procedures that would take place throughout the course of the experiment. Before starting the experiment, the participants were each individually introduced to the test environment, room, and equipment, and the procedures of the experiment were thoroughly explained. Questions were encouraged and answered before the volunteers were asked to sign the consent form. Being fully informed helps to reduce uncertainty regarding the testing procedures; otherwise, the novelty of the experience may influence the test responses.

Setting

The study was conducted at the nursing resource room at Skinner Hall at the University of Massachusetts-Amherst (UMASS). Two nursing resource rooms were set up to replicate a hospital-like setting, which was determined to best afford a relatively controlled environment, allowing for comparisons to be made in future studies conducted in an acute mental health care hospital setting. Hospital beds with pull curtains were used to seclude participants from the monitoring equipment and most of the stimulation of the rest of the room. During the experiment, the resource room door was locked, a sign was placed on the door to inform the public that an experiment was taking place, and only the participant and data collector were allowed in the room. Before the data collection phase of the test session, the curtain was closed around the bed; the data and all the equipment connected to the sensors were behind

the curtain and out of view of the participant. The room temperatures ranged between 72° and 75° Fahrenheit.

Procedures

Grandin (1992) reported the need to use 5 minutes of sustained DPS to produce a calming influence with children. Anecdotally, the authors have noticed that the influence is often observable within minutes of use with adolescent-, adult-, and geriatric-populations in acute care mental health settings. For the purposes of this initial exploratory study, 5-minute time frames with and without the treatment were used. The participants were given a 5-minute break between testing sessions where they were required to complete a STAI-10 survey and leave the testing area. The data collection equipment was set to have no alarms or noises and remained quiet throughout the monitoring phases. All participants were tested in the lying down position. Blood pressure was monitored on the right upper extremity and all pulse oximetry, pulse rate, and SC data were collected from the right hand. To ensure the consistency of procedures and data collection throughout the experiment for all participants, data collectors used a standardized data-recording protocol document and practice sessions.

Instruments

The Treatment: The Weighted Blanket

One 30 lb weighted blanket was located at each of the two experiment stations. The weighted blankets used in this study were 56 inches × 76 inches in size and each blanket weighed 5 lb in itself (with all of the weights removed). The blankets were each set up to contain five additional (removable) 5 lb sleeves of nylon material filled with popcorn seed, each running the length of the blanket and securely buttoned into place. Velcro secured each of the openings around the edge of the blanket. The additional five weighted sleeves served to provide an additional 25 lb of weight in an evenly distributed manner throughout the blanket. Thus, each blanket weighed a total of 30 lb. The blankets used in this study were purchased from *Weighted Wearables* and ordered specifically to be consistent in make/style, materials used, and weight. This was carefully specified and subsequently verified by the researchers.

Quantitative Measure of Safety: Vital Signs

For the purposes of this initial study exploring safety, the following vital sign metrics were used: pulse oximetry, pulse rate, and blood pressure. Each participant's vital signs, data with the blanket and without the blanket, were compared for each vital sign measured in order to determine if the blanket influenced a change in vital signs. Table 1 shows the safe ranges of the vital signs for adult populations, when in an upright position (Barkauskas, Baumann, & Darling-Fisher, 2002). There are no standardized vital sign parameters available for the lying down position; thus, the information in Table 1 was used as a general guideline. It is well established however that blood pressure and pulse rate decreases when someone is lying down (Barkauskas et al., 2002).

Vital signs were obtained using a GE 4000 vital signs machine (Model # DSH04490805GA). Pulse oximetry (SpO_2) is a measure of the amount of oxygen concentration in the blood. It is measured by placing a probe onto a person's finger. The SpO_2 reading is also known as the oxygen saturation level and is recorded as a percentage. The normal SpO_2 range is from 90 to 100% in adult populations (Barkauskas et al., 2002). Pulse rate indicates the number of times the heart beats per minute. The anatomy and physiology of the blood pressure "is the interaction of the cardiac output and peripheral resistance and is dependent on the velocity of the arterial blood, intravascular volume, and the elasticity of the arterial walls" (Barkauskas et al., 2002, p. 175). There are normal variations that can occur with a person's blood pressure. Typically the first reading is higher than others and at least one to three minutes should be left between readings for accuracy. An average of readings over time affords the best indication of an individual's baseline blood pressure (Barkauskas et al., 2002).

TABLE 1. Vital Signs Parameters

Age	Temperature	Pulse per/min	Respirations per/min	Oximetry Spo_2	BP Systolic (mm Hg)	BP Diastolic (mm Hg)
Adult	98.6 +/− 1	60 to 100 (Mean 75)	12 to 20	90 to 100%	100 to 130	60 to 85

Adapted from: Harkreader, H. and Hogan, M. A. (2004), and Barkauskas, Baumann, and Darling-Fisher (2002).

Quantitative Measure of Effectiveness: Electrodermal Activity (EDA)

The effectiveness of the 30 lb weighted blanket is measured using EDA, the STAI-10, and an exit survey. EDA continuously changes over time and influences the increased or decreased activity of the eccrine sweat glands, and is measured through the collection of SC (Stern, Ray, & Quigley, 2001). Hence, for the purposes of this study, SC is used as the quantitative indicator of anxiety. Skin Conductance (SC) is obtained using the ProComp+ SC sensor from *Thought Technology*, using a constant-voltage sampling of SC at a rate of 32 hz with an accuracy of ± 5%. Silver chloride cup electrodes were used to minimize the development of bias potentials and polarization. The electrodes were secured to the volar surfaces of the first and second distal phalanges of the right hand of each participant, using Velcro fasteners. Since the results will be compared, 10% accuracy is used as the significance level, because, when comparing the control group to the treatment group, it is possible that one of the readings may have an error of +5% and the other by −5%.

RESULTS

Vital Signs Analysis and Interpretation

For the purposes of this study, a negative influence in vital sign measures concludes that the use of the 30 lb weighted blanket is unsafe for the participant. When the vital sign measures remain within the participant's normal range it is concluded that the treatment is generally safe. Not taken into consideration during this initial exploration of the safety of the use of the 30 lb weighted blanket include additional safety factors related to medical conditions not experienced by the participants (e.g., fractured bones, open wounds, circulatory disorders, pregnancy).

The safety results, as evidenced by the three vital signs metrics used, are shown in the following sections. The ending values are analyzed closely because the end of the 5-minute test sessions shows the accumulated influence of the blanket use. The recorded values of the vital signs data during the sessions without the blanket were used as a baseline. The baseline data were compared to the data collected when the blanket was used to determine if the blanket is the cause of the participant being within an unsafe range. A baseline is necessary since some of the

participants may naturally be outside of the safe ranges at their baseline or because of some other unknown contributing variable.

Pulse Oximetry (SPO_2)

Only 20 of the 32 participants were included in the pulse oximetry analysis because of sensor attachment problems during data collection. Table 2 shows the initial and final SPO_2 measurements for 20 participants with complete sets of data collected, both with and without the blanket. None of the participants shown in Table 2 have a final oxygen level below 90%. Thus, there is no evidence to show that the weighted blanket causes any adverse affects to the amount of oxygen in the blood.

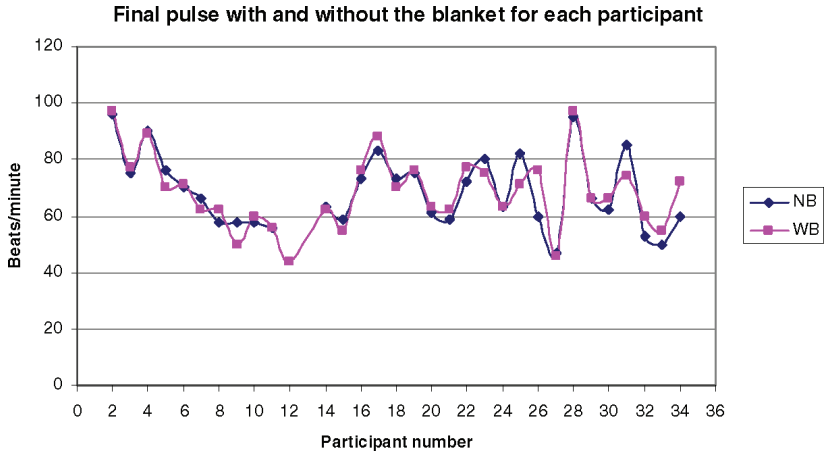
Pulse Rate

As shown in Figure 2, none of the participants have a final pulse rate greater than 100 beats per minute with or without the blanket. There are seven participants whose pulse rates are under 60 beats per minute, with and/or without the blanket. Of the participants with a pulse rate below

TABLE 2. Pulse Oximetry Results

	Without Blanket			With Blanket		
	%O2			%O2		
Participant #	Initial O2	min 5	Change Initial-Final	Initial O2	min 5	Change Initial-Final
3	96	95	1	96	95	1
4	98	97	1	97	97	0
7	98	98	0	98	99	-1
14	95	95	0	98	96	2
16	97	95	2	95	96	-1
18	95	91	4	90	91	-1
19	97	95	2	95	95	0
20	97	97	0	96	97	-1
21	97	99	-2	98	97	1
24	97	96	1	96	96	0
25	98	96	2	96	96	0
26	99	95	4	96	97	-1
27	100	97	3	99	99	0
28	99	99	0	99	99	0
29	98	98	0	96	97	-1
30	96	96	0	95	96	-1
31	96	96	0	95	96	-1
32	93	96	-3	95	96	-1
33	97	96	1	95	96	-1
34	96	97	-1	97	98	-1
Min	93	91	-3	90	91	-1
Max	100	99	4	99	99	2

FIGURE 2. Pulse rate results: Each participant's pulse rate after 5 minutes of testing with the weighted blanket (squares) and without the blanket (diamonds).



60 beats per minute, only one person's pulse rate with the blanket is below his/her control value without the blanket. This suggests that those participants may normally have a pulse rate outside the general safe range and that the weighted blanket was not the cause of the pulse rate being out of the safe range.

Blood Pressure (BP)

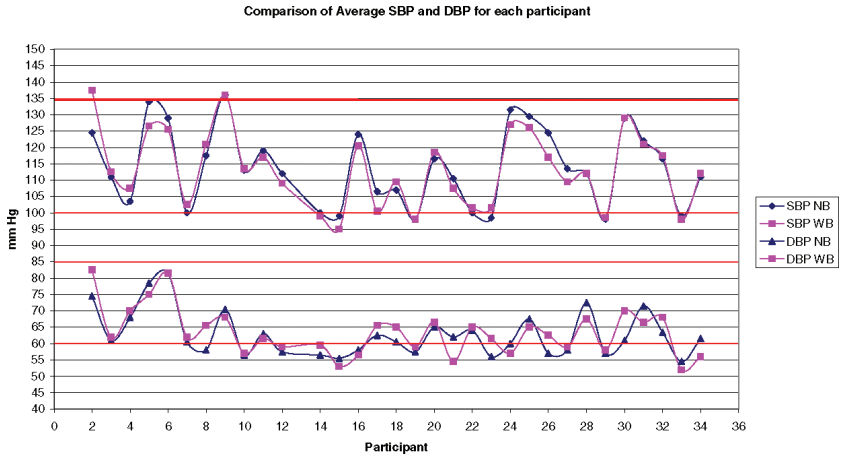
The volunteer's initial and final BP is averaged to account for the variation in BP as discussed in the introduction. On average, all participants are found to be at the low end of the safe range. Only one participant has an average BP, in either of the 5-minute test sessions, in the high end of the safe range. Participant #2 has a high BP average. Upon further examination of this participant's data, however, 3 of the 4 readings were on the low end of the safe range. Only the first BP reading was high and out of the safe range. Participant #2 had the blanket applied during the first test session; the BP right *before* the blanket application was 150/89. BP dropped to 121/76 by the end of the test session and was 124/77 and 125/72 for the beginning and end of the second test session, respectively. Since the blanket was applied during the first session and the BP was high *before* the blanket was applied, the high BP could have been a result of

anxiety caused by participating in the experiment. Thus, the conclusion should not be made that the blanket caused participant #2 to have an average BP out of the safe BP range over the test session.

Figure 3 shows the average systolic and diastolic BP for each person with and without the blanket. The bold horizontal lines denote the safe range over the course of the study. This figure shows that all but participant #2 were inside the safe range for the BP guidelines for systolic blood pressure. The majority of the participants were toward the lower end of the safe range for the average diastolic BP.

In sum, it can be concluded that the data from the three different vital sign measures collected show that the use of the 30 lb weighted blanket did not cause the participants to move into an unsafe physiological range. All 20 participants stayed above 90% for SPO_2, all 32 participant's pulse rates stayed below 100 beats per minute and only one participant's pulse rate with the blanket was below his/her control value without the blanket. Only one person was out of the safe range for systolic BP, which could be attributed to anxiety from participating in the experiment, and not to the blanket. No participant was outside of the safe range for diastolic BP. The data give no evidence to indicate that the use of the 30 lb weighted blanket is unsafe.

FIGURE 3. Average diastolic and systolic blood pressure for each participant with the blanket (squares) and without (diamonds) the blanket.



EDA Data Analysis and Interpretation

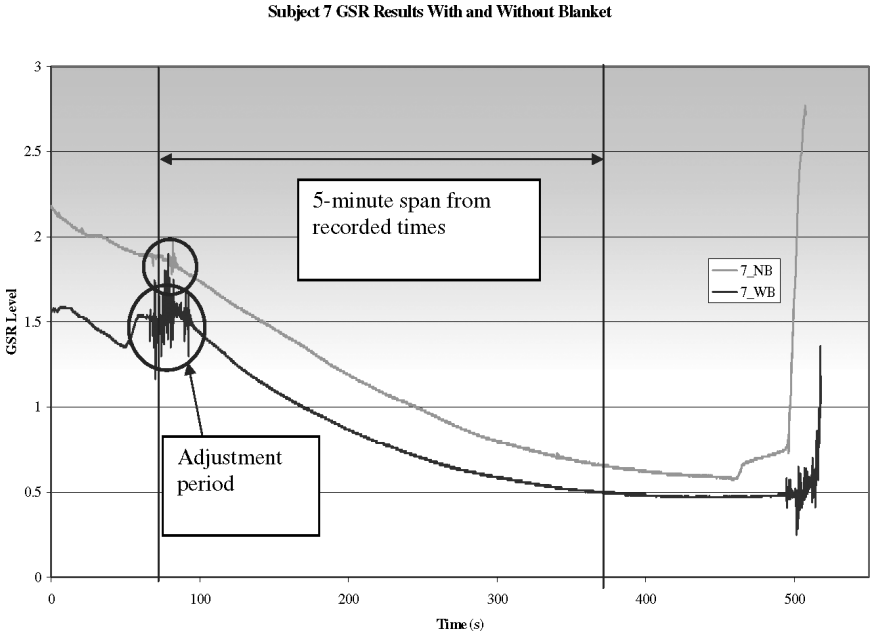
Data interpretation is a critical step in the scientific study of the time series data gathered using SC. It requires a standardization procedure that ensures the integrity of information contained in the raw data in a consistent and uniform manner. Accordingly, this study introduces one such procedure to address the lag time effects related to sensor amplification, the uncertainty associated with the response starting and ending times, and the influence of external factors such as the curtain is closing and opening affecting the responses. Specifically, to overcome the inherent drawbacks by using the raw data, the SC recordings were extended in this study to both before and after the actual test duration of 5 minutes. Additionally, the actual start time was identified as the time at which there was a noticeable drop in the SC reading caused by movement before the person was considered to be settled into the rest position, and the corresponding SC reading at this start time was taken as the average of the data up to that time. Figure 4 shows a sample time-series data and the identification of the resulting 5-minute actual test session for further data analysis.

Skin Conductance (SC) Results

Two of the 32 participants were dropped from the anxiety data analysis because of problems with the SC sensor during their test sessions. Table 3 shows the mean values for the whole sample, the blanket first sample, and the blanket second sample, as well as the standard deviation. The percent change in the SC data is examined to study if there is a difference between using the blanket and not using the blanket. This percent change acts as the indicator of how much change occurs over the 5 minute period, taking into account different starting values by normalizing the data. The average percent changes in Table 3 show that regardless of blanket order or test session, SC values decrease significantly over time indicating that the lying down position influences a reduction in anxiety. When examining each person's response, 27 of the 30 participants have a decrease in SC over both of the 5 minute test sessions.

Table 4 shows the comparison of percent change in SC between participants over a period of 5 minutes. To compare the participants' responses, the percent change with the blanket is subtracted from the percent change without the blanket for each person. If the resulting number is negative then the person had a larger percent change in SC without the blanket than with the blanket. Ten of the 30 participants

FIGURE 4. Example of the GSR level data with the landmarks of participants' adjustment period and curtain close time, and the 5-minute time span of testing window.



demonstrated a significantly larger drop in SC when using the blanket than when not using the blanket. Four of the 30 participants showed an increase in SC with the blanket compared to when not using the blanket and 16 participants had no significant difference between the two test sessions.

Table 5 shows the results from performing a Student's T-test assuming unequal variance comparing "with the blanket" to "without the blanket" sample populations. T-tests were also used to compare the blanket applied to the first group to the blanket being applied to the second group. The results from the statistical analysis show that there is no significant difference between using the blanket and not using the blanket, and therefore, no difference between the orders in which the blanket was applied, with an alpha of 0.05.

A z-test is also conducted for the entire sample because of the necessary assumption of having more than 30 participants to assume normality. The results shown in Table 6 reveal a statistically significant result

TABLE 3. Average and Standard Deviation of the SC Data for the Whole Population

With Blanket Treatment						
	All Participants		Blanket Applied 1st Sample		Blanket Applied 2nd Sample	
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Initial	4.33	5.22	4.38	3.89	4.65	6.62
Final	2.65	4.21	2.47	2.46	3.07	5.70
Percent Change	38.73	20.00	43.59	18.90	33.94	21.65
No Blanket Treatment						
	All Participants		Blanket Applied 1st Sample		Blanket Applied 2nd Sample	
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Initial	4.36	4.53	4.25	3.57	4.76	5.63
Final	2.79	3.53	2.54	1.95	3.31	3.28
Percent Change	35.88	22.20	41.45	23.70	30.86	21.24

when comparing "with the blanket" and "without the blanket," having an alpha of 0.05. This verifies that there is no difference due to ordering.

STAI-10 Analysis and Interpretation

The STAI-10, a subscale of the State Trait Anxiety Inventory, is a standardized quantitative (closed-ended) 10 question survey used to measure anxiety (Speilberger, Gorsuch, & Luchene, 1970). Data collected from the STAI-10 were analyzed to show each participant's self-rated perception of anxiety with and without the treatment. The results were also used in comparison with SC data for further SC validation. Since the STAI-10 data was to be directly compared to the SC data, the two participants who did not have SC results were not included in the analysis. Using the STAI-10 results and comparing the scores obtained, after using and not using the blanket, shows whether the use of the 30 lb weighted blanket influences a larger decrease in self-perceived anxiety ratings. STAI-10 scores and exit survey responses help to determine whether

TABLE 4. Each Participant's Percentage SC Change with and Without the Blanket

Participant #	WB Percentage Change	NB Percentage Change	Difference (WB-2NB)
3	36.67	28.71	7.96
5	20.68	23.02	−2.34
7	66.67	64.02	2.65
9	24.06	33.33	−9.28
11	55.33	46.70	8.63
15	48.35	44.19	4.17
17	44.32	−1.10	45.42
19	66.40	48.05	18.35
21	14.66	13.92	0.75
23	59.62	85.31	−25.68
25	49.22	25.02	24.21
27	64.33	33.72	30.61
29	30.77	25.00	5.77
31	29.65	45.31	−15.66
33	−7.89	17.24	−25.14
2	28.47	7.06	21.41
4	48.54	33.33	15.21
6	67.57	11.68	55.89
8	22.01	30.13	−8.12
10	50.00	42.07	7.93
12	12.31	44.99	−32.68
14	50.49	−25.17	75.66
16	27.71	22.92	4.79
18	6.67	5.26	1.40
20	42.52	39.06	3.46
22	56.17	45.46	10.63
24	59.17	43.43	15.74
28	66.05	61.85	4.20
30	43.37	47.98	−4.61
34	55.46	63.34	−7.88

TABLE 5. Statistical Results from the Student's T-test Comparison

	All Participants			Blanket 1st Sample Compared to Blanket 2nd Sample	
				With Blanket	No Blanket
t Stat	1.426	z Stat	1.401	0.302	−0.479
P(T ≤ t) one-tail	0.080	P(Z ≤ z) one-tail	0.081	0.383	0.318
t Critical one-tail	1.672	z Critical one-tail	1.645	1.701	1.701
P(T ≤ t) two-tail	0.159	P(Z ≤ z) two-tail	0.161	0.765	0.636
t Critical two-tail	2.002	z Critical two-tail	1.960	2.048	2.048

TABLE 6. Statistical Comparison of All Participants with the Blanket and Without the Blanket

	All Participants			Blanket 1st Sample Compared to Blanket 2nd Sample	
				With Blanket	No Blanket
t Stat	−3.102	z Stat	−2.721	−0.474	0.329
P(T ≤ t) one-tail	0.002	P(Z ≤ z) one-tail	0.003	0.320	0.372
t Critical one-tail	1.699	z Critical one-tail	1.645	1.725	1.701
P(T ≤ t) two-tail	0.004	P(Z ≤ z) two-tail	0.007	0.641	0.744
t Critical two-tail	2.045	z Critical two-tail	1.960	2.086	2.048

EDA alone is a metric that correlates with the subjective ratings of the blanket's influence. Table 7 shows the average STAI-10 scores for the participants. Higher scores correspond to higher anxiety ratings. On average the participants scored lower after using the blanket than without the blanket. For the participants having the blanket applied first, the mean STAI-10 score was 12.5 compared to a mean score of 15.7 without the blanket in the second session. For the sample population having the blanket applied second, the mean score was, 13.2 with the blanket and 15.3 without the blanket.

These results show that at least 33% of the sample using the blanket had a significantly greater drop in SC or anxiety than without using

TABLE 7. Average STAI-10 Data for All Participants with the Blanket and Without the Blanket

STAI-10	All Participants	Blanket 1st Sample	Blanket 2nd Sample
		Mean	
Blanket Applied	12.87	12.53	13.20
No Blanket Applied	15.50	15.73	15.27
NB-WB	2.63	3.20	2.07

the blanket, and 53% of the sample experienced no difference when comparing the blanket condition and the no-blanket condition. It was hypothesized that only a portion of the tested participants would respond to the blanket with a reduction in anxiety, particularly given that it was a low anxiety population as evidenced by the initial STAI-10 questionnaire results. Grandin (1992) specifically indicated that there might need to be a threshold anxiety before DPS will be effective. Also, given that the population is non-acute and, by lying down for 5 minutes anxiety levels dropped greatly, it may be possible that participants reached their steady (minimum anxiety) dynamic state or baseline SC so that the blanket could not reduce SC levels much further.

From the STAI-10 survey data collected, there were 19 participants whose anxiety decreased more with the blanket, 8 participants experienced no change, and 3 had higher anxiety with the blanket than without. Comparing the STAI-10 data to the SC data in Table 8, it seems that SC accurately indicated the participant's perceived change in anxiety when the use of the blanket resulted in higher anxiety than without the blanket. This raises the question as to why the SC data did not match the STAI-10 survey data. Since the SC measurements indicated when the anxiety of the participant was higher with the blanket and not for when the anxiety was lower with the blanket suggests that by lying down for 5 minutes the participants reach their baseline SC even though anxiety continues to decrease. For some participants using the blanket, the blanket influences an activating response and raises the SC above baseline so the effects could be seen.

Exit Survey Analysis and Interpretation

In addition to STAI-10 data, the exit survey questions were analyzed to explore each participant's responses regarding the use of the weighted

TABLE 8. Statistical Comparison of the Group with the Blanket and Without the Blanket

STAI-10	Skin Conductance			
	Greater Change With Blanket	Greater Change Without Blanket	No Change	Total
Greater change with blanket	7	3	9	19
Greater change w/o blanket	1	1	1	3
No change	2	–	6	8
Total	10	4	16	30

blanket, personal preferences, and whether the self-reports matched the STAI-10 and SC results. When asked, "when did you feel more relaxed, when using the blanket or when not using the blanket?" 25 of the 32 participants (78%) reported that they felt more relaxed with the blanket than without the blanket.

The exit survey included the question, "how did the amount of weight feel?" with three choices to choose from: too much, not enough (I would like it heavier), and good. Table 9 explores if there is a relationship between body weight and preference for a 30 lb weighted blanket. Only one person reported that the 30 lb weighted blanket was "too much," and, given the variability of body weight among the participants, body weight did not appear to significantly influence the person's preference regarding the 30 lb weighted blanket.

Additionally, the participants were asked to rank their preferences according to four of the qualities afforded by the weighted blanket using a Likert scale [ranking very effective (1) through very ineffective (5)]. These qualities include: the warmth of the blanket (temperature), the weight of the blanket (30 lb/deep pressure), the feel of the fabric (tactile), and that it was voluntarily used (not forced upon the participant). Table 10 shows the varied responses.

Finally, to the question "any other comments about the SC or weighted blanket?" Ten participants commented on the use of the blanket, and all were positive comments. When comparing the SC data for these ten particular participants, four had a larger percent change in SC with the blanket, four had a larger percent change in SC without the blanket, and two had no change.

TABLE 9. Deep Pressure Stimulation (DPS) Self-Report

DPS of the 30 lb. Weighted Blanket	Number of Responses	Body Weight Ranges
"Not enough"	5	112 -234 lbs.
"Good"	26	114 -206 lbs.
"Too much"	1	174 lbs.

TABLE 10. Weighted Blanket Qualities: Participant's Self-Ratings

Weighted Blanket Qualities Participant's Rankings	Very Effective (1)	(2)	(3)	(4)	Very Ineffective (5)
Warmth (Temperature)	12	15	3	1	1
Weight (Deep pressure)	13	15	2	2	0
Feeling of the fabric (Tactile)	11	11	7	2	1
Voluntarily used (Not forced upon you)	10	13	7	1	1

DISCUSSION

Limitations

There are several limitations in this study. One limitation is that only a 5-minute time frame was used in each of the test sessions; therefore, results cannot be generalized to the use of the 30 lb weighted blanket for longer time periods. Second, since one of the primary purposes of the study was to research safety, participants were all required to use the full 30 lb. When using the weighted blanket in clinical practice it is part of the protocol to individualize the amount of weight used and the preferred weight placement. Hence, different results may be obtained with the individualization of the amount of weight used. Third, the pulse oximetry and SC sensors did not stay in place for all of the participants; therefore, not all participants' pulse oximetry, pulse rate, and SC data were obtained. Fourth, there may be a difference in the results if the group without the blanket used a thin sheet rather than no sheet or blanket at all. Fifth, there is an absence of well-established mathematical models to characterize SC data without the use of other physiological measures such as respiration, though general guidelines have been put forward

using parameters such as number of SC peaks and their corresponding values (Boucsein, 1992). Thus, it is possible that the development and subsequent use of empirical models, through additional dynamic and statistical analysis of data, may provide more insight into the influence of the use of the weighted blanket. A final limitation includes the use of a low-to-no anxiety population, while according to Edelson et al. (1999), a threshold of arousal or anxiety may be necessary to influence SC changes when using modalities providing DPS. The low anxiety contributed to the physiological signal to seemingly reach a floor during the 5-minute test sessions.

Implications and Recommendations

This paper presents the results of a first exploratory study on the safety and effectiveness of the use of a 30 lb weighted blanket among a heterogeneous, non-hospitalized volunteer sample. A general protocol using quantitative and qualitative metrics was piloted to determine whether it would be useful in future studies on the safety and effectiveness of the weighted blanket. This research group will conduct these studies with both an adult population during an acute inpatient mental health hospitalization and a non-acute, volunteer adult population subjected to a high anxiety task.

The results of this study demonstrate that the use of a 30 lb weighted blanket did not adversely influence pulse oximetry, pulse rate, or blood pressure. Further, using SC as an anxiety metric, 33% of the participants were found to exhibit a greater reduction in anxiety with the weighted blanket than without the blanket. Observations however, reveal that there appear to be differences in the results. The corresponding STAI-10 survey responses showed that 63% of the participants rated their anxiety lower with the use of the weighted blanket. Furthermore, according to the exit survey, 78% reported a lower anxiety after using the blanket than when not using the blanket. Thus, the results indicate that the use of the 30 lb weighted blanket has a calming influence for some adults.

For many participants, the perceived sense of relaxation is greater than indicated by SC measures. This may be a result of some of the participants' reaching a SC floor as a sole result of lying down for 5 minutes. Further research comparing additional psychophysiological metrics more sensitive to changes in anxiety, in conjunction with SC, may enhance the ability to more accurately measure anxiety through the use of quantitative measures. Future studies looking at correlations among SC, DPS, age, sex, race, sensory tendencies, consumer preferences, and

diagnostic factors is recommended to continue exploring the safety and effectiveness of the therapeutic use of the weighted blanket. Research is needed to explore other aspects of safety, such as the use of the weighted blanket with people with different medical conditions. Additionally, future research may afford the ability to gain knowledge of how to engineer new technologies in the remote sensing of anxiety, and new DPS devices specific to people's unique needs and preferences.

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