Abstract

Use of a Pressure Vest to Reduce the Physiological Arousal of People with Profound Intellectual and Physical Disabilities During Routine Nail Care

by Rebecca LaChappelle

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This single subject ABAB study explored whether the use of a commercially available deep pressure vest would decrease physiological arousal in a male with profound mental retardation during nail care activities. Psychophysiological responses of electrodermal activity, skin temperature, electromyography, and heart rate were used as indicators of physiological arousal and recorded using the NeXus-10. Visual and statistical analysis revealed that the use of the deep pressure vest did not reduce physiological arousal during nail care.

Use of a Pressure Vest to Reduce the Physiological Arousal of People with Profound Intellectual and Physical Disabilities During Routine Nail Care

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Use of a Pressure Vest to Reduce the Physiological Arousal of People with Profound Intellectual and Physical Disabilities During a Routine Grooming Activity

by

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CHAPTER 1: Introduction

The Center, located in eastern North Carolina, provides services to individuals with mental retardation. The Center is actively participating in research to increase the quality of life of their residents. The idea for my study came about because of a particular resident who is very resistive to nail care activities. During these activities staff, report he displayed signs of anxiety including frowning, negative vocalizations and pulling his hand/finger away from the staff performing nail care. The staff at the Center believe that this anxiety reduced his quality of life and that the associated physiological arousal was detrimental to his health. The staff reported that there were other residents of the Center who appeared anxious during nail care activities. The occupational therapists and staff at the Center expressed a desire to find cost-effective, easy to implement techniques to reduce the residents' observed signs of anxiety, and resultant physiological arousal during these activities. It was essential to find a way to reduce the anxiety during this activity because nail care is an unavoidable and routine self care activity for all residents of the Center.

Occupational therapists find ways to decrease the observed anxiety during the administration of self-care activities in those with severe/profound mental retardation in order to improve daily living skills and quality of life (American Occupational Therapy Association, 2008). An increase in observed anxiety during self-care activities is often an issue with this population yet, these are activities that need to be completed daily for personal health and are therefore unavoidable. Occupational therapists are trained in ways to maximize participation in daily activities for individuals who cannot perform self-care activities for themselves, including individuals with profound mental retardation. One way to maximize participation is to modify the activity in order to minimize resistance to these activities (AOTA, 2008). One modification is to do the activity in association with the application of deep pressure to an individual's body (Edelson, Edelson, Kerr, & Grandin, 1999). The application of deep pressure is a technique associated with sensory integrations (Parham & Mailloux, 2005).

Sensory integration is a theoretical model used by occupational therapists (Kimball, 1999). Occupational therapists and others have noted that some individuals actively seek deep pressure to modulate sensory input resulting in self-regulation of the sensory system and a modification of responses to the environment (Grandin, 1992; Grandin, 1995; Parham & Mailloux, 2005). Deep pressure is used by occupational therapists as a way to calm anxious individuals and to aid in concentration and focus (Fertel-Daly, Bedell, & Hinojosa, 2001)

Temple Grandin, who has a PhD in animal science, is an individual with autism, a frequent lecturer on autism, and a pioneer in the use of deep pressure, explained that deep pressure had a very calming effect on her (1995). Specifically, Grandin (1992) explained that deep pressure can serve to organize the central nervous system and modulate the sensory stimuli, this in turn leads to a temporary decrease in tactile defensiveness resulting in a decrease in physiological arousal. Grandin (1992) lists numerous examples of animals and adults who seek deep pressure stimulation and subsequently experience a calming effect. This is supported with a study done by Kumazawa (1963) who found that deep pressure actually serves to "deactivate" a portion of the brain in rabbits, which led to a decrease in activity. Therefore, there is some support that deep pressure can reduce anxiety and physiological arousal.

Several studies have tried to identify ways to decrease observed anxious behaviors in adults with mental retardation living in large residential facilities. Many of these utilize various mechanisms of deep pressure such as a body sox, weighted blanket, joint compression, or tightly wrapping the individual in a blanket (Doty, 1996; Hollifield, 1996; Oakes, 1998; Rogers, 1994).

Many of these studies have methodological issues such as small sample size, non-compliance by the staff or participant, unforeseeable influences such as illnesses and/or discharge of the research participant. Few of these studies are published and most were completed by students of Eastern Kentucky University in 1990's at the J. Iverson Riddle Center.

My study is different from these studies because it looks specifically at reducing physiological arousal during nail care, an activity of daily living (ADL) that is essential and performed with regularity. Specific to my study, no research has examined the use of a deep pressure vest on an adult with mental retardation during ADLs. My study is important to occupational therapists working with individuals with mental retardation, as it is examining an intervention, which may reduce observed anxiety. The use of a deep pressure vest is also a simple, cost-effective, and easily implemented technique, which may be easily incorporated into the daily routine of an individual.

Because few studies were performed with an adult population with mental retardation, my study will help to fill an existing gap in the research. My study investigated the effectiveness of a deep pressure vest on reducing an observed physiological arousal in a person with severe/profound mental retardation during self-care activities, specifically during nail care.

Definitions

Activities of Daily Living: activities to take care of one's own body and are fundamental to basic survival, well being, and functioning in a social world (AOTA, 2008).

Anxiety: a subjective state of apprehension and unease with accompanying physiological reactions of rapid heartbeat, muscle tension, sweating (Bourne, 2005).

Autonomic Nervous System: “the component of the peripheral nervous system that controls smooth muscle, glands and cardiac muscles… comprises two major division, the sympathetic and the parasympathetic nervous systems” (Cohen, 1999, p.443).

Deep Pressure: a type of tactile sensory stimulation arising from firm touching, holding, hugging, squeezing, stroking or swaddling (Fertel-Daly, Bedell, & Hinojosa, 2001; Grandin, 1992; Krauss, 1987).

Electrodermal Activity (EDA): a measurement of skin conductance of electricity (Dawson, Schell, & Filion 2000).

Heart Rate: the measure of the number of times the heart contracts and completes a cardiac cycle in a minute (Obrist, 1976; Shier, Butler, & Lewis, 1998).

Nail Care: for the purposes of this study nail care is defined as filing the fingernail to reduce length and smooth the edge of the fingernail.

Peripheral Skin Temperature (PST): the measure of the presence of heat of the skin, for this study peripheral skin temperature refers to the temperature of the skin of the first toe.

Physiological Arousal: for the purposes of the study physiological arousal is defined as the bodies physical response to a stressful stimulus.

Sensory Integration: sensory integration is a theory and type of intervention used in occupational therapy that was developed by A. Jean Ayers (1972) (as cited in Kimball, 1999). Sensory integration is described by professionals as the process by which the brain organizes sensory information and prepares the body for an adaptive response (Parham & Mailloux, 2005).

Stress: “a pattern of behavioral and physiological responses to cope with events that match or exceed an organisms abilities” (Gazzanga & Heatherton, 2003 p. 314).

Surface Electromyography (sEMG): surface electromyography is a direct measurement of the electrical charges associated with muscle tension, or contraction (Tassinary & Cacioppo, 2000).

Sympathetic Nervous System: a division of the autonomic nervous system that “helps the body deal with stressful conditions” (Cohen, 1999, p.468).

CHAPTER 2: Review of Literature

Individuals with severe/profound mental retardation often require assistance to perform activities of daily living (ADLs) (American Association on Mental Retardation, 2002; American Psychiatric Association, 2000). Professionals and staff working with these individuals have observed that some individuals display signs of anxiety during ADLs (Atchison, 2007). Because these individuals are often non-verbal, they are unable to express stress, anxiety, or a dislike of activities (American Association of Mental Retardation, 2002; *DSM-IV-TR, 2000*). It may therefore be useful to use psychophysiological indicators of stress to research ways to decrease the anxiety associated with these behaviors. Psychophysiological indicators of stress such as electrodermal activity (EDA), peripheral skin temperature (PST), surface electromyography (sEMG) and heart rate (HR) have been shown to reliably correlate with self-report measures of anxiety in the adult population (Barron & Blair, 1999; Brownley, Hurwitz, & Schneiderman, 2000; Dawson, Schell, & Filion, 2000; Tassinary & Cacioppo, 2000). Deep pressure, a technique used by occupational therapists, has been shown to reduce anxiety in the healthy adult population, children with autism, and animals (Blairs & Slater, 2007; Edelson, Edelson, Kerr, & Grandin, 1998; Grandin, 1992; Krauss, 1987; Kumazawa, 1963). My study will examine the use of deep pressure to reduce psychophysiological indictors of stress in an adult with severe mental retardation.

Self-Care and Individuals with Severe/Profound Mental Retardation

Within professional groups, there is a movement to rename the condition, formerly called mental retardation, to intellectual disability (Schalock et al., 2007). In 2007, the American Association on Mental Retardation (AAMR) changed its name to the American Association on Intellectual and Developmental Disability (AAID), however the change in name will not be reflected in the manual on the disorders published by the AAID until the year 2010 (AAID, 2009). The criterion for diagnosis of intellectual disability is identical to mental retardation reflecting the movement to change only the name. The title of my study reflects this movement, however because the changes have not been reflected in the diagnosis of the participant, my study will continue to use the term mental retardation, and for the purpose of this study this term is considered synonymous with intellectual disability.

Mental retardation is defined as significantly below average IQ, deficits in adaptive functioning and behavior and onset prior to age 18 (American Association on Mental Retardation, 2002; American Psychiatric Association, 2000). Mental retardation is further classified as mild, moderate, severe, and profound *(DSM-IV-TR,* 2000). Profound mental retardation is described as having an IQ score below 20 points and is generally identified in infancy (Atchison, 2007; Davison, Neale, & Kring, 2004). Individuals diagnosed with profound mental retardation likely experience difficulties in communication and self-care skills (American Association of Mental Retardation, 2002; *DSM-IV-TR, 2000*). Because of these limitations, those with profound mental retardation require assistance in order to perform basic ADLs including nail care (Atchison, 2007).

According to Atchison (2007), a professor of occupational therapy, individuals with profound mental retardation often display behavioral signs of anxiety during self-care activities such as fingernail clipping, face washing, bathing, or tooth brushing. In addition, they often resist these activities and appear to dislike these activities when they are performed (Oakes, 1998). In an unpublished study, Oakes documented that the signs of resistance include avoidance, self-injurious behaviors, grimaces, and vocalizations during self-care activities.

In an unpublished research paper, Diceky, Lowerre, Stevenson, and Favell (1994) suggested this dislike of self-care activities was related to tactile defensiveness. Professionals define tactile defensiveness as hypersensitivity or over reactivity to touch in ordinary situations (Parham & Mailloux, 2005; Shangraw, 2007). In the textbook *Occupational Therapy for Children* Parham and Mailloux (2005) explained that individuals who experience tactile defensiveness commonly find the sensations related to self care activities as irritating and respond with anxiety, aggression, fear, or emotional distress.

Another contributing factor to the dislike of activities of daily living may be that these individuals are unable to perform these activities themselves. They therefore require the aid of someone else, thus the unpredictability, and inability to control another person's actions may contribute to heightened indices of anxiety. Parham and Mailloux (2005) support this hypothesis and explain that those with tactile defensiveness regularly display less anxiety when they can control the stimuli. In addition, professionals in the field of psychology explain that when an aversive stimulus is present and people feel as though they have no control over the stimulus, they become upset and experience anxiety (Wortman, Loftus, & Weaver, 1999). Therefore, when a person with profound mental retardation is experiencing nail care, s/he perceives an aversive stimulus over which s/he has no control and this may cause anxiety. Unfortunately, this conclusion cannot be affirmed by someone with severe/profound mental retardation because of his/her lack of verbal communication skills.

Stress and Psychophysiological Responses

It is difficult to gauge emotional responses such as anxiety in individuals with profound mental retardation due to cognitive and communication limitations. Many people with profound mental retardation are non-verbal and therefore verbal communication of emotional experiences is not possible (Atchison, 2007). Professionals agree that individuals with severe/profound mental retardation are unable to comprehend surveys and other assessments to provide a self-report measure of their emotions (Davison, Neale, & Kring, 2004). For this reason, using physiological measurements to infer the emotional experiences of individuals who are non-verbal may be useful.

Many experts in the field of psychophysiology believe the emotional states of a person effects his/her physiological states (Cacioppo, Tassinary, & Berntson, 2000; Wells-Federman et al., 1995). The discipline of psychophysiology studies the connection between a person's physiological state and her/his psychological state (Cacioppo, Tassinary, & Berntson, 2000). The connection is so strong between these two states that individuals use physiological processes to describe psychological states. For example, professionals studying anxiety use the following physiological symptoms: racing heart, sweating, and increased muscle tension to describe anxiety (Davison, et al., 2004; Wortman, Loftus, & Weaver, 1999). They believe that physiological responses such as increased heart rate are detrimental to health. Barron and Blair (1999) explain that the mind body connection becomes obvious when stress activates the sympathetic nervous system, initiating what is known as the "flight or fight" response and resulting in an increased in heart rate, increase in electrodermal activity, an overall increase in muscle tension and a lowering of peripheral skin temperature (Fox, 2006). Experts have concluded that these responses all prepare the body to be able to fight or flee the potentially dangerous situation (Baron & Blair, 1999, Davison, et al., 2004; Wells-Federman et al., 1995).

Wells-Federman et al. (1995) provide more details regarding the stress response in a research article on the implications of the mind body connection in the field of nursing. They explain that when a situation is perceived as stressful, or as a threat, the presence of the stressful event activates a cascade of biochemical events. A very simplified version of the biochemical events is as follows: the cerebral cortex stimulates the hypothalamus which activates the sympathetic nervous system which in turn directly innervates the heart and blood vessels. The autonomic nervous system also activates the release of hormones into the blood stream producing generalized arousal and heightened awareness which are characterized by an increase in muscle tension, heart rate, and sweating (Wells-Federman et al., 1995).

In order to measure physiological arousal, my study will use measurements of electrodermal activity (EDA), peripheral skin temperature (PST), surface electromyography (sEMG), and heart rate (HR) to answer the proposed research question. Increases in EDA, sEMG, and HR and decreases in PST are associated with an increased anxiety in a healthy adult population (Barron & Blair, 1999; Brownley, Hurwitz, & Schneiderman, 2000; Dawson, Schell, & Filion, 2000; Tassinary & Cacioppo, 2000). Because of the potential differences between the healthy adult population and the population for my study, making an inference from the typical population to the population of persons with profound mental retardation comes with problems. There is no information on the psychophysiology of adults with severe/profound mental retardation.

Psychophysiological Responses

Many times physiological responses are used as an indicator of and support for psychological experiences, hence the term psychophysiological responses. Mullen, Champange, Krishnamurty, Dickson, and Gao (2008) used a self-report measure of anxiety and monitored vital signs in a recent study on the effectiveness of a weighted blanket. The study consisted of 32 healthy adult participants who served as their own control. They concluded that a reduction in anxiety was associated with a reduction in EDA and that EDA could be seen as a quantitative indicator of anxiety. The researchers came to this conclusion since higher anxiety scores on the measure of anxiety corresponded to higher EDA values. The small sample (n=32) limits the generalizability of the results. The sample size however would have little impact on the correlation found within each individual that was found between anxiety and EDA. While the population was different from my study, the results lend support to the use of EDA as an indicator of anxiety.

Wells (2005) published a study regarding cardiovascular responses to stress. The study consisted of 100 healthy adult university students, 58 males, and 42 females. In the study, she concluded that a reduction in psychological stress was associated with a reduction in HR and blood pressure. Measurements of HR and blood pressure were compared after a five-minute relaxation period, after watching a relaxing video of animals and after experiencing a cognitive stressor of reading aloud a complex text. Wells concluded that the measurements of HR and blood pressure differed in each of these conditions with the cognitive stressor condition causing an increase in HR and blood pressure. However, the results of this study should be interpreted cautiously because the control groups had a significantly higher mean HR at baseline than the other groups. The reduction in HR however was shown within the experimental groups and therefore the limitations of this study have a small impact on the conclusion that an increase in psychological stress is associated with an increase in HR and blood pressure.

Edelson, Edelson, Kerr, and Grandin (1998) found a significant association between behavioral and physiological indices of anxiety in their study of 12 children with high anxiety, an autism spectrum disorder, and the use of a hug machine to apply deep pressure. In this study, parents completed an observational survey in which they identified behaviors associated with anxiety. The results of this questionnaire were then compared to the EDA values. Through visual analysis and statistical analysis of the intercorrelations of the variables, they concluded that the behavioral indices of anxiety were correlated with EDA (statistical analysis was found at $p<0.10$ level). This study is limited in sample size (n=12) and the use of the parent questionnaire since it was not a direct measurement of the anxiety or emotion experienced by the participant. The study however lends support to the use of EDA as a measure of anxiety

Psychophysiological Indicators of Stress

According to the literature, there are numerous psychophysiological indicators of stress that could be used to measure physiological arousal. My study limited the number of variables to four and used EDA, PST, sEMG and HR (Cacioppo, Tassinary, & Berntson, 2000). These were chosen because they are frequently used in other published studies and they may be recorded simultaneously using the neXus-10.

Electrodermal Activity

Dawson, Schell, and Filion (2000), professionals in the field of psychophysiology, explain that EDA is a measurement of skin conductance of electricity. When there is an increase in eccerine sweat gland activity the skin becomes a better conductor of electricity. They argue that the sympathetic nervous system activation causes an increase in eccrine gland activity, which in turn increases skin conductance. Dawson, Schell and Filion (2000) argue that EDA may be the most responsive measure of anxiety. Mullen et al. (2008) agree and explain that EDA is a direct measurement of sympathetic nervous system activity therefore EDA is a useful way of quantifying anxiety experiences since the sympathetic nervous system is influenced by anxiety, this connection was supported by their research which was described earlier.

Peripheral Skin Temperature

Barron and Blair (1999), professionals in the field of neuroscience, explain that when the sympathetic nervous system is activated by stress it causes a constriction of the arteries in the skin and veins which subsequently decreases skin temperature. This is supported by Mullen et al. (2008) who explain in their research article that skin temperature is a measure of sympathetic nervous system arousal and it is the sympathetic nervous system that is aroused when a person is anxious.

Surface Electromyography

Surface electromyography is a direct measurement of the electrical charges associated with muscle tension, or contraction (Tassinary & Cacioppo, 2000). Specifically, Tassinary and Cacioppo (2000) have found and reported in their text *Handbook of Psychophysiology* that during anxiety or unpleasant sensory stimuli there is a greater electromyographic activity occurring in the forehead. Wells-Federman et al. (1995), in an article on the mind-body connection, explained that when the stress response is elicited in an individual, there is an increase in muscle tension.

Heart Rate

According to professionals in the field of physiology, heart rate is the measure of the number of times the heart contracts and completes a cardiac cycle in a minute (Shier, Butler & Lewis, 1998). Obrist (1976), an expert in the field of cardiology, has done extensive work with the cardiovascular-behavioral interaction and has found that when an individual is exposed to an aversive stimulus, there is a subsequent increase is heart rate and associated anxiety. This is supported by Fox (2006), a physiologist who explained that when the sympathetic system is activated there is an increase in heart rate, rate of conduction, and strength of cardiac contractions.

EDA, PST, sEMG and HR will be used in my study to determine whether an individual with profound mental retardation may be experiencing physiological stress. Because the individual in this study is non-verbal, I will rely on the physiological monitoring to infer whether the participant is experiencing stress during nail care. Since nail care is an unavoidable activity, it is beneficial to explore techniques that may reduce the stress that accompanies nail care. My study will explore the application of a deep pressure vest to the participant's trunk.

Deep Pressure

Sensory integration is a theory and type of intervention used in occupational therapy that was developed by A. Jean Ayers (1972) (as cited in Kimball, 1999). Sensory integration is described by professionals as the process by which the brain organizes sensory information and prepares the body for an adaptive response (Parham & Mailloux, 2005). Sensory integration includes sensory modulation, which is a process of the central nervous system by which neural messages are received and adjusted so that an appropriate response to the stimuli may be made (Parham & Mailloux, 2005). The use of deep pressure is a sensory integration technique used by professionals. According to sensory integration theory, deep pressure would enable individuals to organize the tactile information that is being received and allow the person to respond to this tactile information in an appropriate manner (Kimball, 1999). The manner in which deep pressure helps to organize this information is unknown.

Research support of sensory integration techniques is limited. Parham et al. (2007) completed a systematic review of 34 research articles to examine the fidelity of sensory integration intervention. These authors suggested that this lack of research support is due in large part to the dynamic and unstructured way in which sensory integration intervention is performed. Even though there is a lack of research to support the use of sensory integration many professionals and experts continue to use the approach (Parham & Mailloux, 2005).

The application of deep pressure appears to calm an individual, however the reason it works is unknown (Fertel-Daly, Bedell, & Hinojosa, 2001). Grandin (1992) hypothesized that deep pressure application can serve to organize the central nervous system and modulate the sensory stimuli, that in turn leads to a temporary decrease in tactile defensiveness, resulting in a decrease in physiological arousal. Kimball (1999) suggested that sensory integration theory supports Grandin's hypothesis.

Deep pressure is the type of tactile sensory stimulation arising from firm touching, holding, hugging, squeezing, stroking or swaddling (Fertel-Daly, Bedell, & Hinojosa, 2001; Grandin, 1992; Krauss, 1987). There are numerous ways to provide deep pressure including a tightly tucked in blanket, tight clothing or garments, a "Hug Machine", the "squeeze machine" (Blairs & Slater, 2007; Edelson, Edelson, Kerr, & Grandin, 1998; Grandin, 1992; Krauss, 1987; Zissermann, 1992). After evaluating the techniques reported in the research I chose a pressure vest made out of neoprene material that was tightly secured around the person's trunk.

Kumazawa's research (1963) is frequently cited to support of the calming effects of deep pressure stimulation. Pressure stimulation was applied to the 43 rabbits by clipping numerous paperclips padded with rubber to the rabbits' skin. Cortical and sub cortical electrodes surgically implanted in the rabbits' brains allowed monitoring of the brain activity. Kumazawa (1963) noted a pattern of brain wave activity that he termed "deactivation" this pattern included high amplitude slow waves and a disappearance of hippocampal waves. The changes in brain wave activity were supported by changes in behavioral states. The researcher noted that when deactivation occurred the rabbits would display relaxed muscle tonus, narrow lid aperture, and constriction of the pupils. Kumazawa (1963) concluded that application of pressure to the skin caused a deactivating effect in rabbits.

Kirsten Kraus (1987), an occupational therapist, conducted a study on the effectiveness of deep pressure on reducing anxiety in 78 healthy college students ranging in age from 18-35 years old. In this study, Krauss used a hug machine apparatus to apply deep pressure for 15 minutes to the majority of the participants' body, specifically from their mid-chest to their calves. The hug machine allowed the participants to have control over the amount and timing of the pressure. Data collection consisted of heart rate monitoring and a self-report questionnaire. The participants were either in the experimental group in which they received deep pressure or in the control group in which they were still in the hug machine but the pressure was not applied. Krauss (1987) found that both the control group and the experimental group experienced a significant decrease in self reported anxiety ($p=0.0001$, $p=0.03$ respectively). Although this did not support her hypothesis that deep pressure would have more of a calming effect than the control group, the researcher concluded that confinement alone may have a calming effect and thus the experimental and control groups both experienced a situation that is calming. Krauss's study is limited because only three participants exhibited high anxiety in the baseline measurement and thus the ability to see a reduction in anxiety was limited. The experiment lacked an adequate control group. In addition, data collection occurred at a relatively low stress times for the participants (late afternoons, weekends, after an exam), which also limited the ability to see a reduction in anxiety.

Edelson, Edelson, Kerr, and Grandin (1998) found some support for deep pressure with a sample of 12 children (9 boys and 3 girls) with high anxiety and an autism spectrum disorder.

They used a hug machine to provide lateral pressure to the participants' entire body while they were supported in a quadruped position. The data collected included EDA and a parent questionnaire on the observation of behavioral indices of anxiety. The participants were divided into a control group and an experimental group with the experimental group receiving 20 minutes of deep pressure stimulation applied by the hug machine. There was a high degree of correlation (0.46-0.65) between the behavioral and physiological measure of anxiety. The physiological measures showed no difference between the control group and the experimental group. However, when the experimental group was divided between those with high baseline anxiety and those with low baseline anxiety, the group with high anxiety did show a decrease in physiological arousal. The authors suggested individuals with a high baseline anxiety may benefit the most from deep pressure intervention. This study was limited due to a small sample size. This study also used a unique device to apply deep pressure, the hug machine. This device may not be readily available to others and therefore even if statistically and clinically significant, the result may not be applicable or feasible to others that do not have the hug machine.

More recently, Blairs and Slater (2007) concluded that deep pressure proved to be a safe and effective way to reduce anxiety and challenging behaviors in an adult with autism. This single-subject case study consisted of an adult male (31 years old) diagnosed with an autism spectrum disorder and moderate learning disabilities who resided in an assessment and treatment facility for people with learning disabilities. The participant frequently exhibited challenging behaviors that required physical restraint and medication. The researchers integrated deep pressure as part of the individual's daily routine. In this study, deep pressure was provided to the individual by tightly tucking the participant between a sheet and his mattress. The participant would lie on his back on his bed with his head supported, a sheet covered his shoulders to his ankles, and the sheet was tucked in tightly under his body. For additional pressure, a second sheet was laid over his torso and tucked in the same way. The participant stayed tucked in for a total of 15 minutes. A staff member was present at his bedside throughout the time in case he indicated that he wanted to get out. The time in physical restraints and number of times medication was administered was compared to pre intervention measurements. In addition, mean monthly heart rate, respiration, temperature, and blood pressure were compared. All of the variables showed a decrease during the intervention phase. The decrease was determined by a visual analysis of the data. The strength of this study would have been improved if the intervention was subsequently removed challenging behaviors requiring restraints returned, however, this would have created ethical problems it would not have been ethical to remove the effective intervention, which would have resulted in an increase in physical restraints and increase in medication. Another difficulty was pragmatic because the use of the tuck in technique severely restricts movement and does not allow the participant to get out of the position by himself and therefore a staff member must be present during the duration of the deep pressure application. It may not be feasible in residential facilities, or other settings, to have a staff member tuck in and sit with a participant without interruption for an extended period.

Another type of deep pressure technique is the use of a weighted blanket. Mullen et al. (2008) explored the safety and effectiveness of using a weighted blanket. The weighted blanket was considered safe if it did not increase participants' anxiety identified as an increase in blood pressure, pulse rate, pulse oximetry and the scores on the State Trait Anxiety Inventory-10. The study consisted of 32 healthy adult participants, 18 males, and 14 females. All participants experienced a length of time with the weighted blanket and without and thus served as their own control. Each participant laid on his/her back in a hospital bed with the curtain divider pulled around him/her seclude him/her from the researchers and monitoring equipment. The weighted blanket (total of 30 lbs.) was placed on him/her by the researcher, and left on the participant for five minutes. Results were graphed and researchers used visual analysis to determine whether any participant's vital signs were outside the normal and accepted range. They concluded that the blanket was safe, meaning that all of the data was within normal ranges. Unfortunately, they did not present the data to show if there was a general decrease when the blanket was applied compared to when it was not applied. The researchers also analyzed whether the weighted blanket produced a calming effect as measured by a reduction in skin conductance, which they argued was a measurement of anxiety. They concluded that in both conditions participants experienced a reduction in skin conductance and explained that this was probably because the participants were lying down in both conditions, as this position tends to reduce anxiety. When analyzing the results from the STAI-10, a self-report measure of anxiety, the researchers found that on average anxiety was lower after using the weighted blanket than when not using the blanket (19 participants showed more of a decrease with the blanket, 8 experienced no change and 3 reported higher anxiety). In addition to the quantitative analysis, a qualitative approach was used by conducting an exit interview with each of the participants. Twenty-five out of 32 participants reported that they felt more relaxed with the blanket than without. In summary, Mullen et al. (2008) concluded that the use of a 30 lb. weighted blanket is safe therapeutic technique and in addition, the participants reported lower anxiety with the use of the weighted blanket.

There are published studies that appear to support the use of deep pressure to reduce anxiety in various populations, including healthy adult college students, children with an autism spectrum disorder, and adults with an autism spectrum disorder and learning disabilities (Blairs

& Slater, 2007; Edelson, Edelson, Kerr, & Grandin, 1998; Krauss, 1987; Mullen, 2008). None of the published studies however addressed the effects of using a pressure vest in adults with profound mental retardation during activities of daily living.

Summary

Because individuals with profound mental retardation are unable to communicate their emotional experiences verbally, the use of psychophysiological responses may be an appropriate way to identify the anxiety experienced.

Those with profound mental retardation require assistance during self-care activities, and this assistance results in tactile stimulation often inducing physiological arousal. A simple, cost effective, and efficient method to reduce physiological arousal is therefore needed which could increase the quality of life with these individuals.

Hypothesis

The application of a deep pressure vest during nail care activities will reduce anxiety identified as changes in levels of physiological arousal (decreases in EDA, sEMG, and HR and increase PST)

CHAPTER 3: Methods

Design

My study used a single subject withdrawal (ABAB) design with four weeks in condition A_1 and three weeks in all subsequent conditions. Phase A indicates the baseline phase where nail care occurred without the pressure vest. Phase B indicates the intervention phase where nail care occurred with the pressure vest. The phases were repeated so that a replication of effect could be seen. My study took place at the Center, a state institution for persons with mental retardation. The study was approved by both the Center's Review Board (Appendix A) and East Carolina University UMCIRB (Appendix B). Investigators agreed to follow the reporting procedures for adverse reactions policies of the Center. There were three members of the research team including a student enrolled in the occupational therapy master's program, an occupational therapist employed by the Center, and the director of the thesis study.

Participant

My study included one participant who met specific criteria. Inclusion criteria were: 1) resident at the Center, 2) dependent upon staff during ADLs, 3) a diagnosis of profound mental retardation 4) staff report of resistance to nail care. Exclusion criteria included; 1) a change in psychotropic medications, 2) illnesses that result in behavior change and 3) noncompliance of the participant in use of the deep pressure vest.

The research team member employed at the Center and a residential house manager recruited the participant and obtained written consent (see Appendix C) from the guardian of the participant in the study. The study participant was not deemed capable of consent based upon the conclusions of Center staff and the guardian. The research team member from the Center reviewed the consent document with the guardian, allowed the guardian to ask questions, obtained a signature, and left a copy of the consent form with the guardian. The person supervising the consent process verbally stated, and it was written in the consent form, that participation was voluntary and could be terminated at any point during the research process by the guardian.

Participant Safety

Nail care is a required weekly activity to insure the health of the individual. Before the research project began, the student and Center researchers conducted one trial session with the participant to determine the appropriate size of vest, to mark the placement of the hook and loop closures of the vest and to observe the participant's initial responses to the vest. If the participant's behavior indicated a negative response to the vest (such as increased arm movements, vocalizations or attempts to remove the vest) the trial session would have been terminated and the researchers would have performed a second trial at a later date. The participant did not display any observable adverse reactions to the use of the vest. Once the research study began, if the staff member conducting the nail care identified an observed increase in anxiety with the application of the deep pressure vest, or an extreme and unusual reaction to the nail care routine, the session would have been terminated and the procedures in the participant's Plan/Protocol would have been followed. The participant was compliant with the use of the vest and with the nail care routine throughout the study. If at any point in the study, any sudden adverse events (SAE)/unanticipated problems occurred, they would have been reported to the UMCIRB and the Center's IRB. No SAEs were encountered. The participant's identity was protected with a fictional name throughout the study.

The NeXus-10, the primary research instrument used in the study, is operated using batteries and posed no safety hazards to the participant.

Materials

Psychophysiological responses consisting of electrodermal activity (EDA), peripheral skin temperature (PST), surface electromyography (sEMG), and heart rate (HR) were measured using the NeXus-10 a physiological monitoring unit. The NeXus-10 is a certified medical device that uses BlueTooth wireless communication and is approved for use at the Center. The NeXus-10 is interfaced with BioTrace + Software for data analysis (Stens Corporation, 2006). Information regarding the NeXus-10 can be found in Appendix D. Prior to data collection the researcher associated with the Center provided an hour of training to the student researcher on how to use the NeXus-10 and BioTrace+ software and correct placement of the physiological sensors. Throughout the data collection process the same NeXus-10 and computer were used to record data. All sensors remained the same throughout except for EDA. During pre-baseline measurements, the EDA sensor broke and a replacement was used for the remaining duration of the experiment. The EDA data from this session was not used in analysis. Consultation with the Stens Corporation indicated that the data collected would remain valid and reliable between the pre baseline and the study despite this change in EDA sensor.

A commercially available pressure vest was used to apply deep pressure to the participant's trunk (Appendix E). The vest was constructed of neoprene material and was secured using hook and loop fasteners on the lateral aspect of the participant's trunk and over the shoulders. For every session, a new emery board nail file was used to ensure cleanliness and a consistent texture and grit.

Protocol

The study began with an observation and establishment of pre-baseline measurements for EDA, PST, sEMG, and HR. Pre-baseline measurements were established since there are no known norms for this population. These pre-baseline measurements were used as an indicator of a non-aroused physiological state. Pre-baseline measurements for all dependent variables were taken on five days at the same time of day and in the same room as the nail care activity occurred during the experimental phases. Pre-baseline measurements were established for twenty minutes while the participant was sitting quietly in his room with the NeXus-10 and sensors attached in the same fashion as during the experimental phases. Ambient room temperature was recorded using the NeXus-10 prior to every session.

Once pre-baseline measurements were established, the experimental phases began. All phases took place at the same time of day, in the participant's room, and with the same staff member completing nail care. Due to an unforeseen scheduling conflict of the student research, the data collection day changed from Wednesday to Thursday at the midway point of the data collection process. This meant that the first A and B phases were collected on Wednesdays and the second A and B phases were collected on Thursdays.

During phase A, nail care activities took place without the pressure vest. Ambient room temperature was recorded using the NeXus-10 prior to every session. The subject was transported to his room by the staff member who performed the nail care routine. The staff member remained in the room for the entire duration of the activity. The researchers entered the room; placed the psychophysiological sensors on the participant, and then set up the computer and the NeXus-10. The researchers then waited five minutes for the NeXus-10 readings to stabilize. In every phase, the researchers waited a full five minutes prior to beginning nail care.

The nail care routine remained the same throughout the phases and consisted of the same staff member approaching the participant and filing his nails. A detailed procedure for each session is found in the procedure section. The duration of the session was recorded using the NeXus-10 software. Data was considered to have stabilized when 80% of data fell within 20% of the median value (Dattillo, Gast, Loy, & Malley, 2000) for two of the measurement variables or after five weeks. Once stabilization occurred, the phase ended and the next phase began.

During Phase B, nail care activities took place while using the pressure vest. The procedure was the same as in Phase A with the exception of the application of the deep pressure vest. After application of the vest and an elapsed time of five minutes, the staff member and researcher applied the pressure vest to the participant. The pressure vest was previously fitted to the participant and had hook and loop markers indicating the place at which the vest should be fastened to ensure a consistent application of deep pressure throughout the sessions. After the application of the deep pressure vest, the researchers waited for five minutes to allow the data to stabilize. Then the staff member began nail care. Phase A and Phase B were then repeated providing further support for the effectiveness of the vest resulting in a withdrawal (ABAB) research design.

Procedure

1. Approval was obtained from the institutional review boards prior to beginning this study.
2. The participant was recruited using the inclusion criteria from the Center by the research team member and the staff member at Center. Consent to participate in the study was obtained from the guardian of the participant.
3. The research design was then implemented. The student researcher maintained a research log recording date, place, time, ambient room temperature, persons present, anecdotal

information regarding procedures and reports from staff including any changes in medication or wellness of the participant. Procedure instructions for each session included:

a. Researchers washed hands.

b. Researchers entered room.

c. Researchers turned on computer.

d. Researchers recorded the ambient room temperature using the skin temperature probe.

e. Staff member washed her hands.

f. Staff member brought participant to room.

g. Staff member removed sock of participant's right foot.

h. Researcher explained to participant what was about to happen by saying "I am going to put some things on your toes and forehead".

i. Researcher applied PST sensor using medical tape to participants big toe one inch from the tip.

j. Researcher applied EDA sensors to the inside of the foot 10 cm and 12 cm from the tip of the big toe (Boucsein, 2006).

k. Researcher applied sEMG sensor to participant's forehead approximately one quarter inch above each eyebrow, directly in line with each pupil (Cram & Kasman, 1998).

l. Researcher applied electrocardiogram sensors to the participant's chest. The ground sensor was applied 1" below the left clavicle in line with the nipple, the negative sensor was positioned approximately 1" below the right clavicle in line with the nipple and the positive sensor was positioned on the lateral aspect of the ribs approximately 2" below the left pectoralis muscle (Stens Corporation, 2006).

m. Researchers began recording data using the NeXus-10.

n. Researchers waited five minutes in order to allow data to stabilize.

o. Once the five minutes was over the staff member explained to the participant what was about to happen by saying "I am going to file your fingernails".

p. Phase B ONLY: Pressure vest was applied to the participant by the staff member and researcher. The pressure vest was secured to a pre-determined placement to ensure consistent pressure between sessions.

q. Phase B ONLY: Researchers waited five minutes to allow the data to stabilize.

r. Researchers signaled to staff member with a raised hand to begin nail care.

s. Staff member filed each of the participant's nails beginning with the fifth digit on the right hand and proceeding to the thumb. Staff member then filed the participant's nails on the left hand beginning with the fifth digit and proceeding to the first digit.

t. Throughout this process the researchers marked the data when each step began.

u. Staff member signaled researchers that nail care was complete with a raised hand

v. Researchers stopped collecting data once nail care was complete.

w. Researchers then removed the psychophysiological sensors from the participant's foot, chest, and forehead.

x. Staff member then reapplied sock to the participant's foot and took participant out of the room and to a desired location.

4. Graphed data.

5. Visually inspected and analyzed data.
6. Developed manuscript.

Procedural Reliability

Procedural reliability was tested on a random sample of four of the 13 sessions by a staff member employed by the Center, familiar to the research participant but unaffiliated with the research. The staff member observed the entire session and using the Procedural Reliability Checklist (Appendix F) recorded whether each step was completed and in what order. To determine procedural reliability the number of steps completed correctly was divided by the total number of steps to determine how reliably the researchers followed the protocol across sessions.

Data Analysis

Data was kept in a password locked computer file. Data was analyzed for stability during each phase and for changes in trend and magnitude across the four phases at the completion of the study. Data was considered to have stabilized when 80% of data fell within 20% of the median value (Dattillo et al., 2000) for any two of the measurement variables or after five weeks. Stabilization was only required in two of the four variables since there is no research to indicate what measurements would be most stable or responsive in the population of adults with mental retardation. Once data stabilized, the next phase began.

Visual analysis and statistical analysis were both used when determining whether the hypothesis was supported. Using these methods in conjunction with one another has been advocated in single-subject research (Barlow, Nock, & Hersen, 2009; Morgan & Morgan, 2009). The use of visual analysis in single-subject research has long been accepted as a way to determine whether an intervention was effective (Barlow et al., 2009). However, some critics of this method advocate using statistical analysis in order to reduce the subjectivity that is inherent in visual analysis (Barlow et al., 2009).

Visual Analysis

All dependent variables (EDA, PST, sEMG and HR) were graphed using EXCEL™ 2007 and the methods described by Carr and Burkholder (1998) to determine whether the use of the pressure vest was effective in reducing physiological arousal during nail care. Carr and Burkholder (1998) detail procedures to make single subject graphs with data points that do not touch the lines between, and do not connect across phases (see Appendix G for detailed procedures). The mean of each session was calculated and represented on the graph by a single data point. The proportion for the graphs was 2:3 (ordinate: abscissa) with the ordinate representing the dependent variables and abscissa representing time (Tawney & Gast, 1984). Vertical lines were drawn to indicate phase changes (*Journal of Applied Behavior Analysis*, 1996). A line to indicate the mean of the entire phase was drawn and visual analysis was used to determine whether there was a change in level or trend. The hypothesis would have been supported if the means electrodermal activity, surface electromyography, and heart rate were lower and peripheral skin temperature was higher in the vest conditions when compared to the no vest conditions.

Statistical Analysis

Data was also analyzed using SPSS to determine whether there was a statistically significant difference between the Phases A (no vest) and B (vest), and between all four phases with a p value of less than 0.05 considered statistically significant.

Based on the literature describing physiological measures of stress and anxiety, the hypothesis would be supported if the electrodermal activity, surface electromyography and heart rate values were lower and peripheral skin temperature higher in the pressure vest condition.

CHAPTER 4: Results

Participant

The single participant was a male in his late 40s living at the Center who met all inclusion and exclusion criteria. He was diagnosed with profound mental retardation, epilepsy, microencephaly, spastic quadriplegia and cerebral palsy with a mental age of four months. He currently lives at the Center and has for almost 40 years

Procedural Reliability

To determine procedural reliability the number of steps completed correctly (71) was divided by the total number of steps (72) to determine how reliably the researchers followed the protocol across session The agreement between the procedure and performance was 98.6% indicating that the researchers only missed or incorrectly performed one step. Upon examination of the procedural reliability checklist, the step that was not checked was “researchers will wait for data to stabilize for five minutes”. Upon examination of the data from the NeXus-10 there is a recording of five minutes of data prior to nail care. Procedural reliability data indicated a very high agreement between the procedure and performance ensuring that the procedure was consistent across phases.

Data stabilization

Data stabilization was required in two of the four dependent variables before changing phases. Heart rate and peripheral skin temperature were the two dependent variables that stabilized first and subsequently used to determine a change in phase.

Ambient Room Temperature

Figure one displays the ambient room temperature of each session.

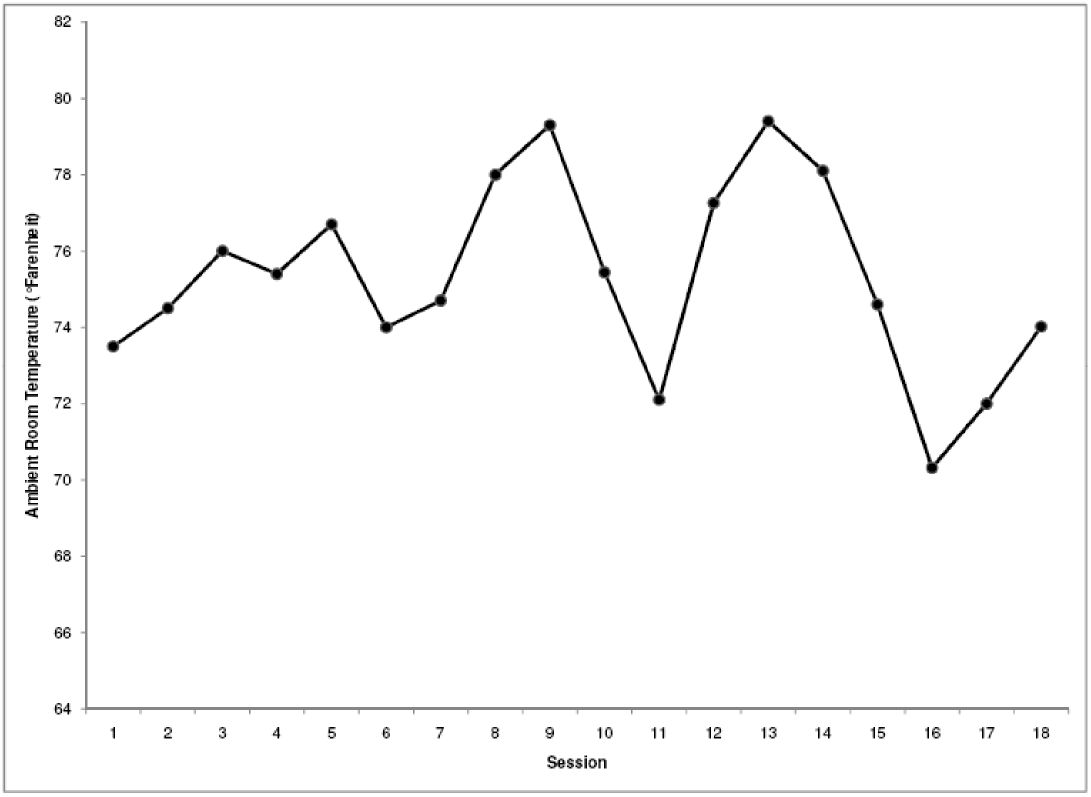

Figure 1. Ambient Room Temperature

Visual Analysis

Data was graphed to allow for visual analysis of the data. A visual inspection of the graphs, created by displaying the means of the dependent variables [electrodermal activity (EDA), peripheral skin temperature (PST), surface electromyography (sEMG), and heart rate (HR)] for each session (Figures, 2, 3, 4, 5) indicated that the means for the phases without the vest was no closer to the pre baseline measurements than the phases with the vest. Figure 1 has only three data points for the pre baseline phase due to sensor failure and two separate sessions. Visual analysis of the figures did not support the hypothesis because the phases with the vest do not appear to be closer to pre baseline measurements than the phases without the vest. Upon independent analysis, the Center and student researchers came to the same conclusion.

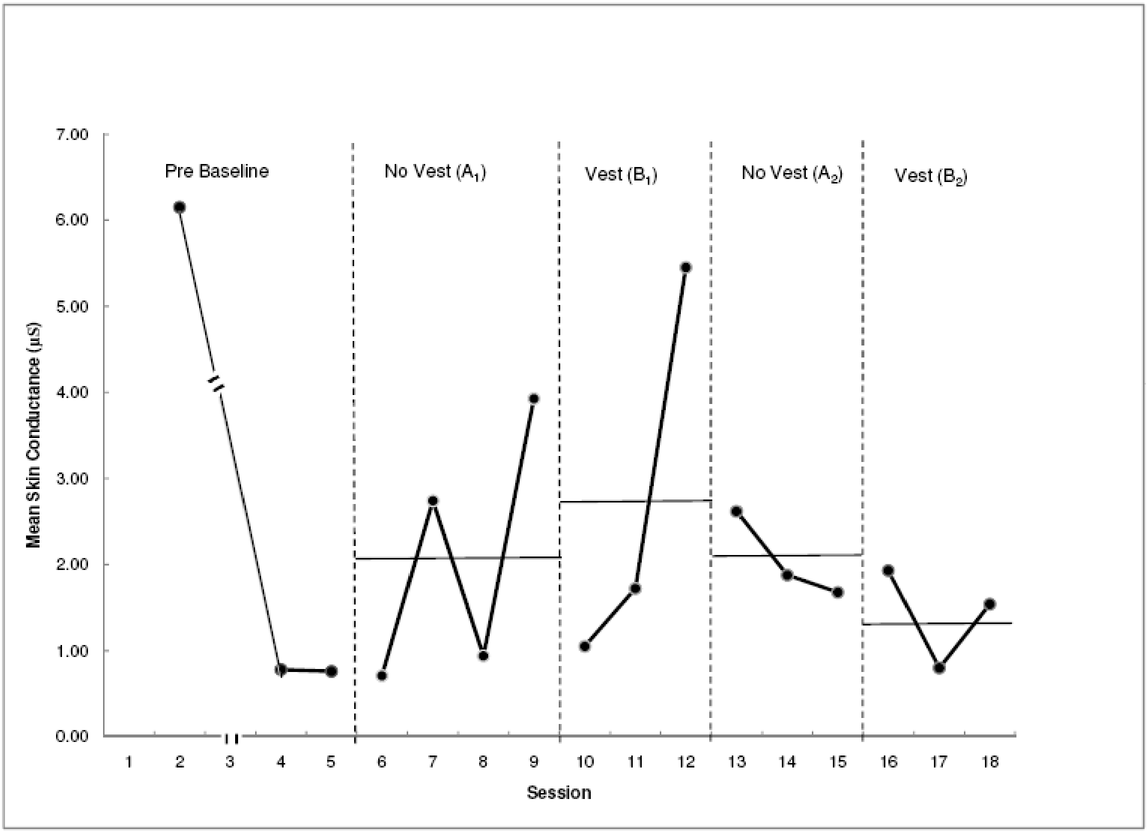

Figure 2. Mean EDA for Each Session

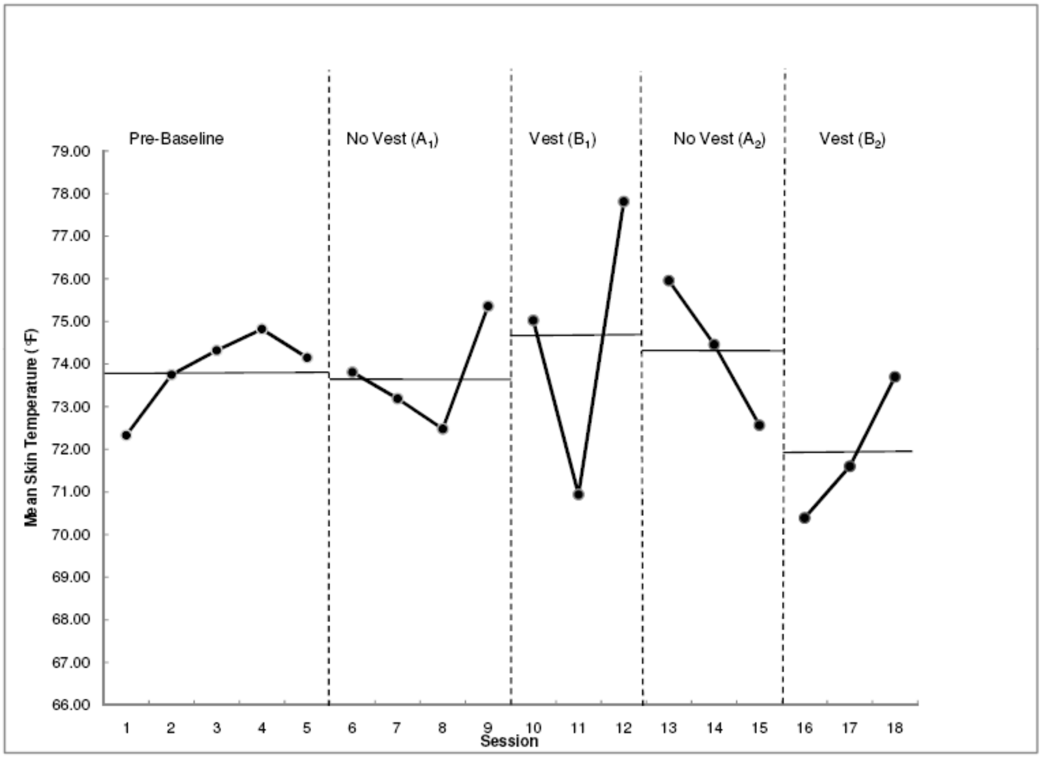

Figure 3. Mean PST for Each Session

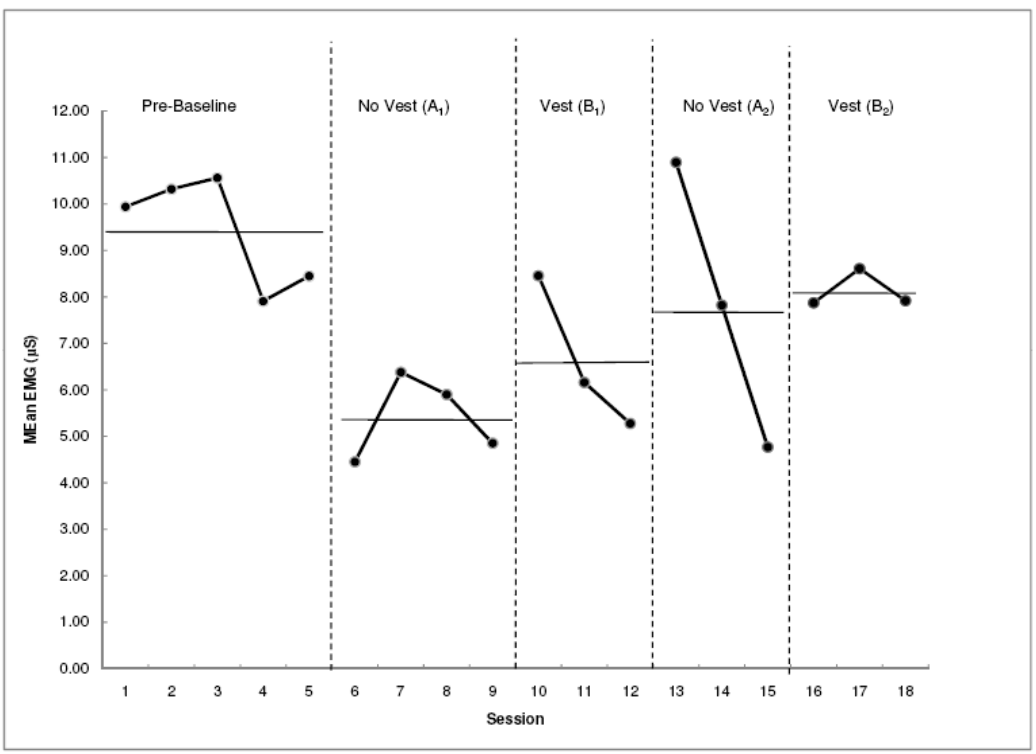

Figure 4. Mean sEMG for Each Session

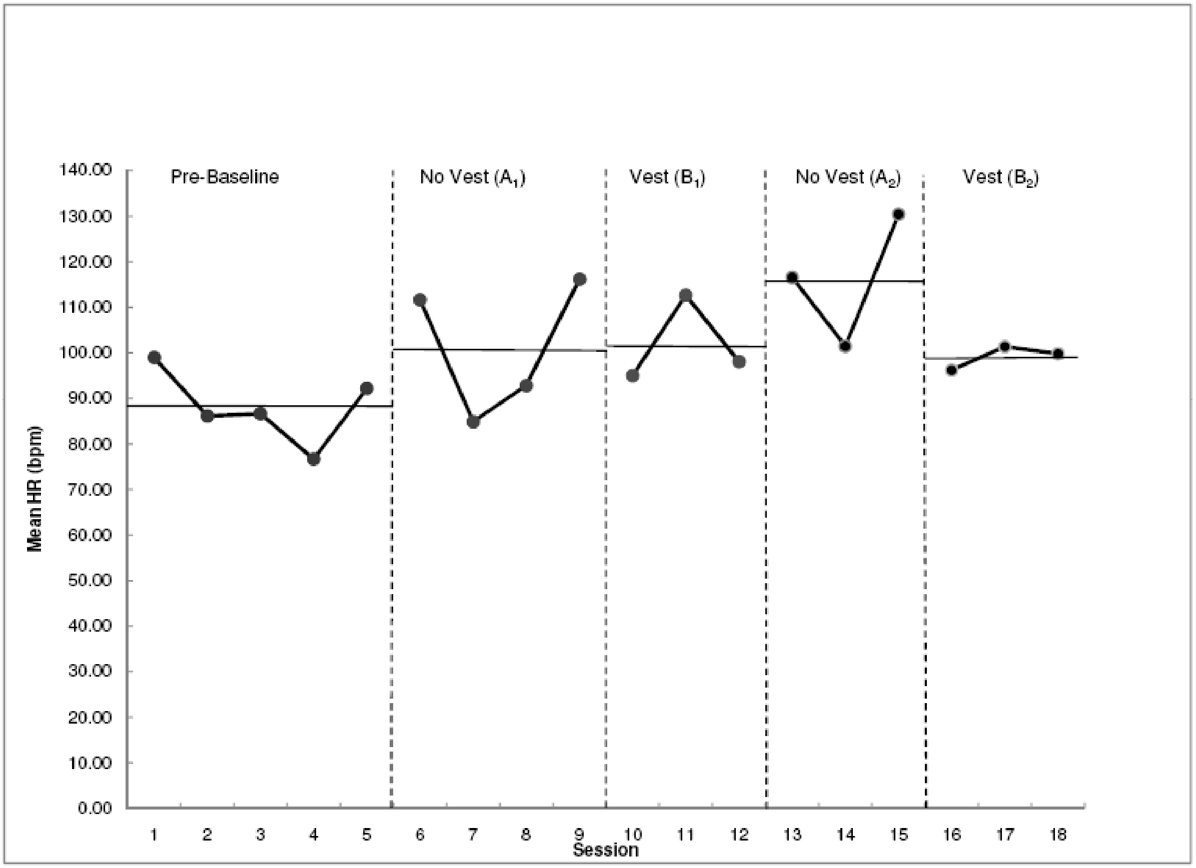

Figure 5. Mean HR for Each Session

For further analysis of the data, the researchers calculated the mean of each phase for each dependent variable (Figures 6, 7, 8, 9). Data means were then graphed using the same procedures and visual analysis used to determine whether the phases with the vest were closer to pre-baseline than those without the vest. Visual analysis of the figures did not support the hypothesis because the phases with the vest did not appear to be closer to pre baseline measurements than the phases with the vest. Upon independent analysis, the Center and student researchers came to the same conclusion. This additional analysis did not provide support for the hypothesis.

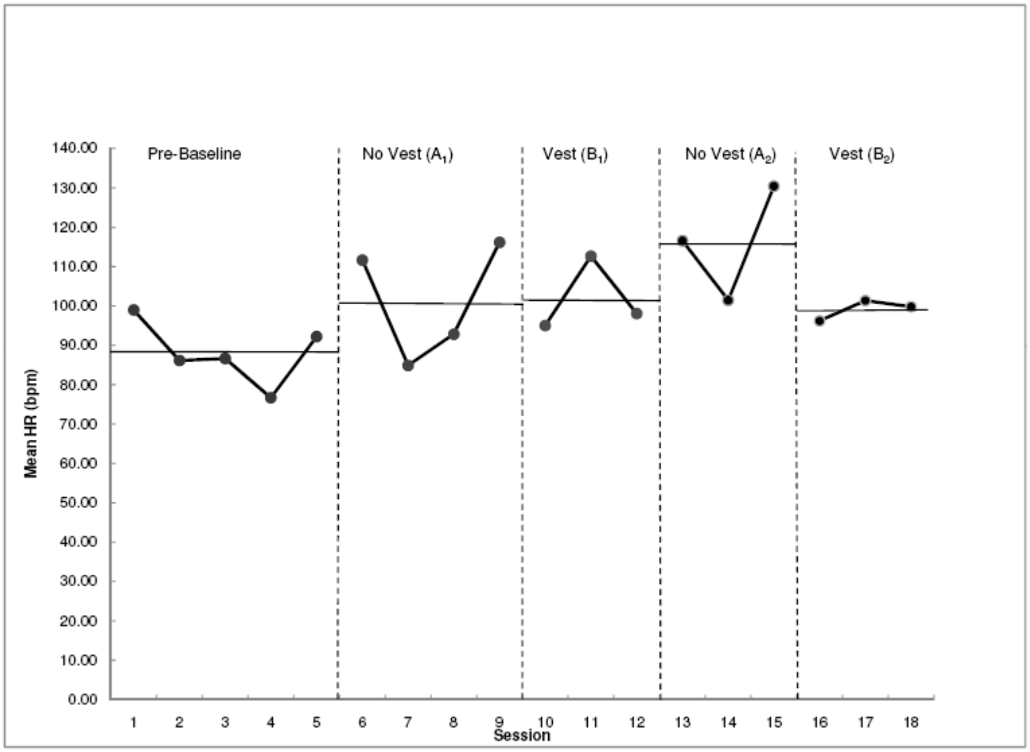

Figure 6. Mean EDA for Each Phase

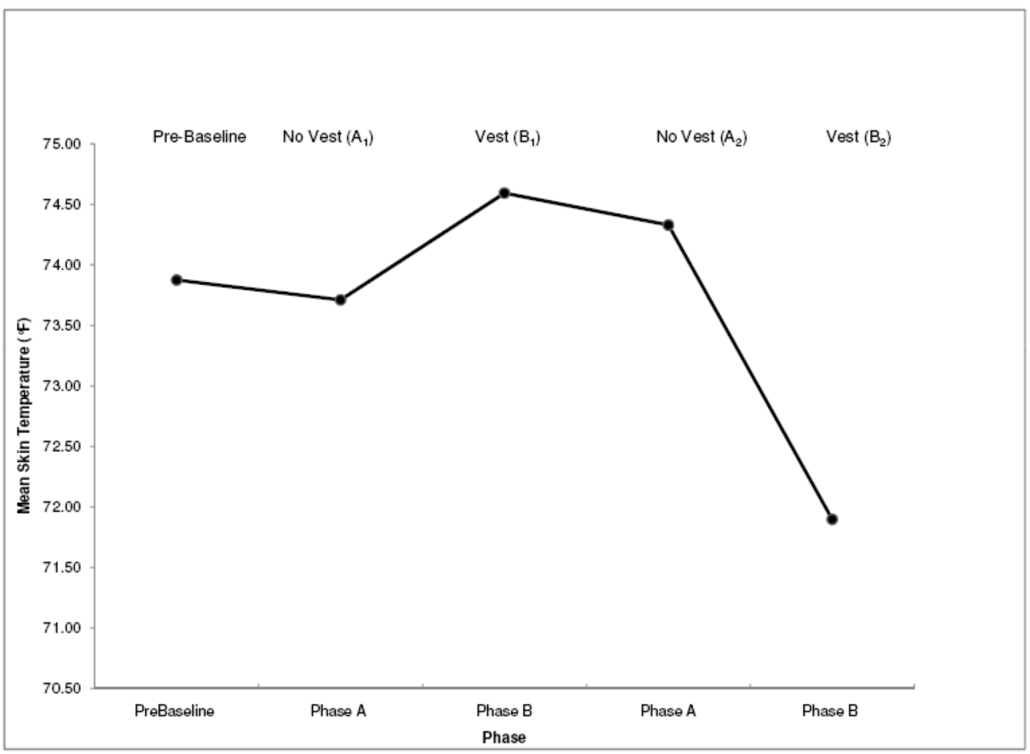

Figure 7. Mean PST for Each Phase

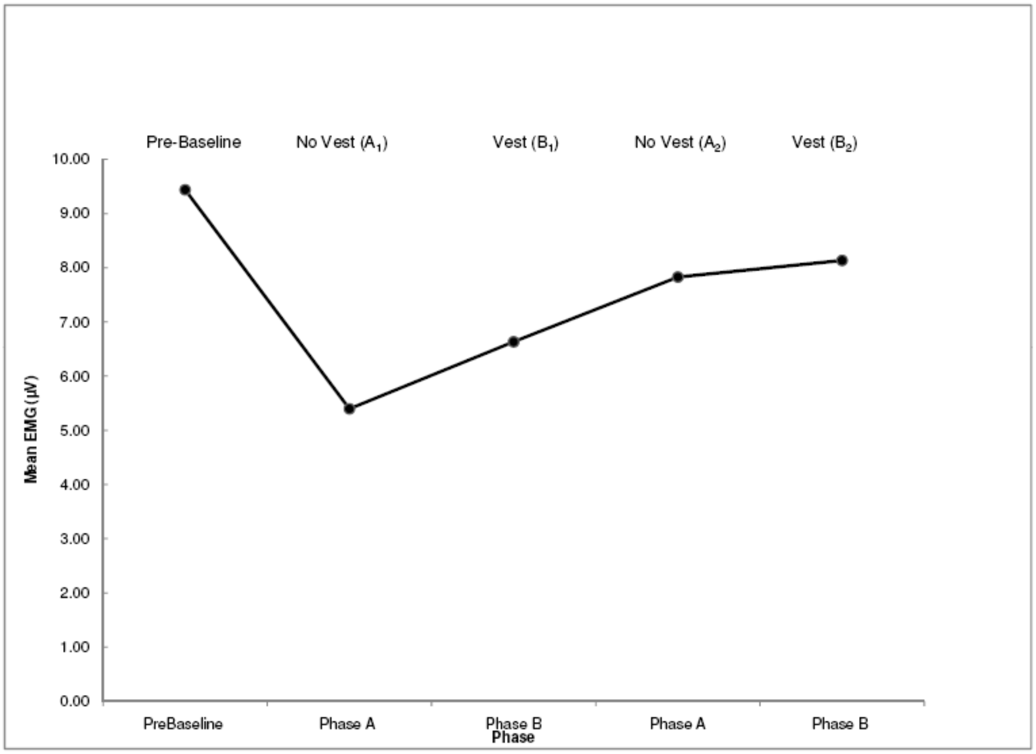

Figure 8. Mean sEMG for Each Phase

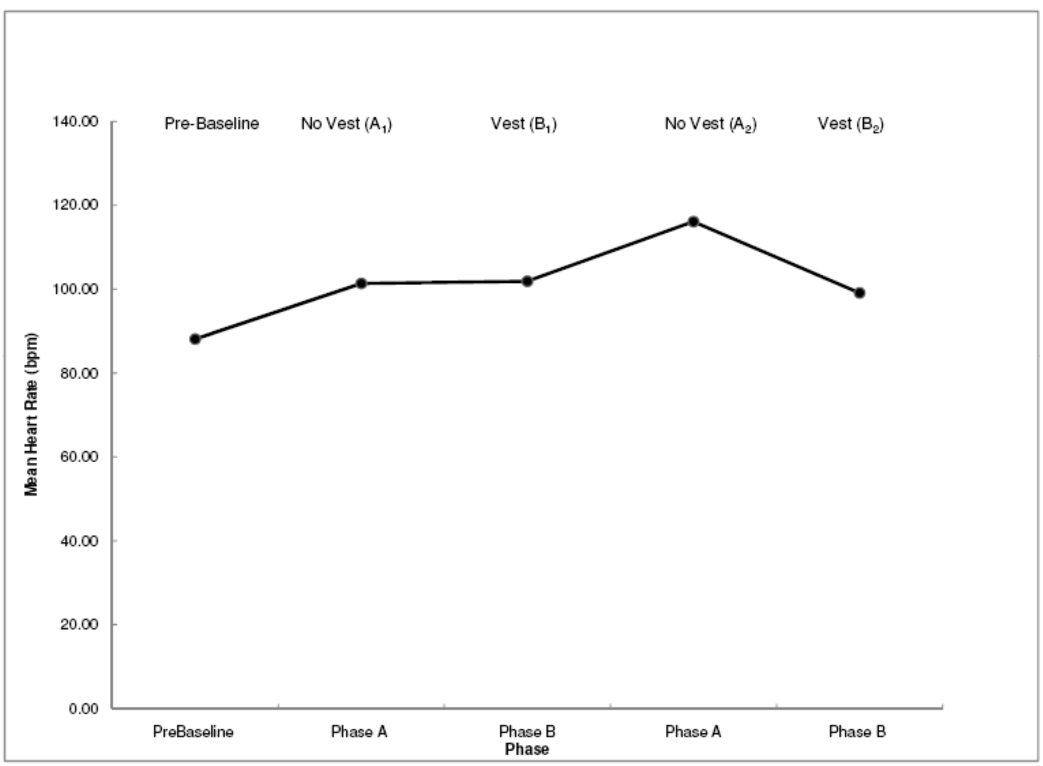

Figure 9. Mean HR for Each Phase

Because there appeared to be a high intersession correlation of the variables, where one day had consistently higher values and another day consistently lower, the change in dependent variables was calculated. The change in three of the dependent variables was calculated by taking the mean value of the variables during nail care and subtracting the mean value during the five-minute acclimation period. The change in mean temperature was calculated by taking the mean during acclimation and subtracting the mean during nail care since we expected the temperature to decrease. If the vest reduced physiological arousal this analysis would reveal that there was less of a change in dependent variables when the vest was in use as compared to when the vest was not in use. The changes in mean dependent variables were graphed and visual analysis was used to determine whether there was less of a change during the phases with the vest than the phases without the vest (Figure 10, 11, 12, 13). Visual analysis revealed that there was not a difference in change of mean dependent variables when compared between phases.

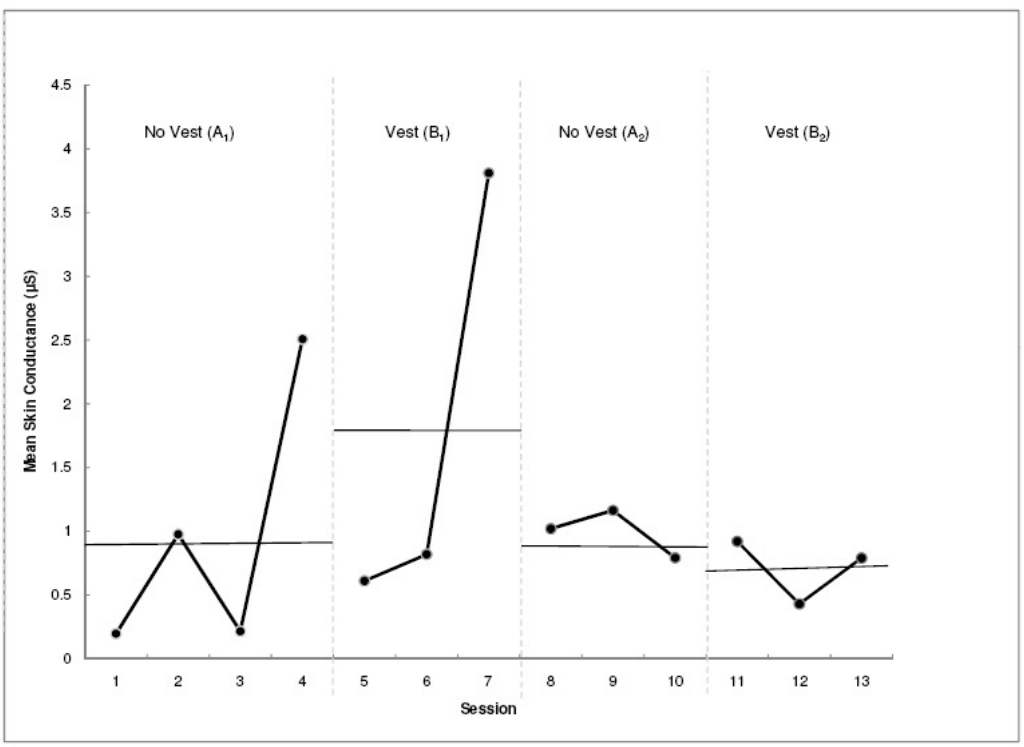

Figure 10. Change in Mean EDA (Nail Care – Baseline)

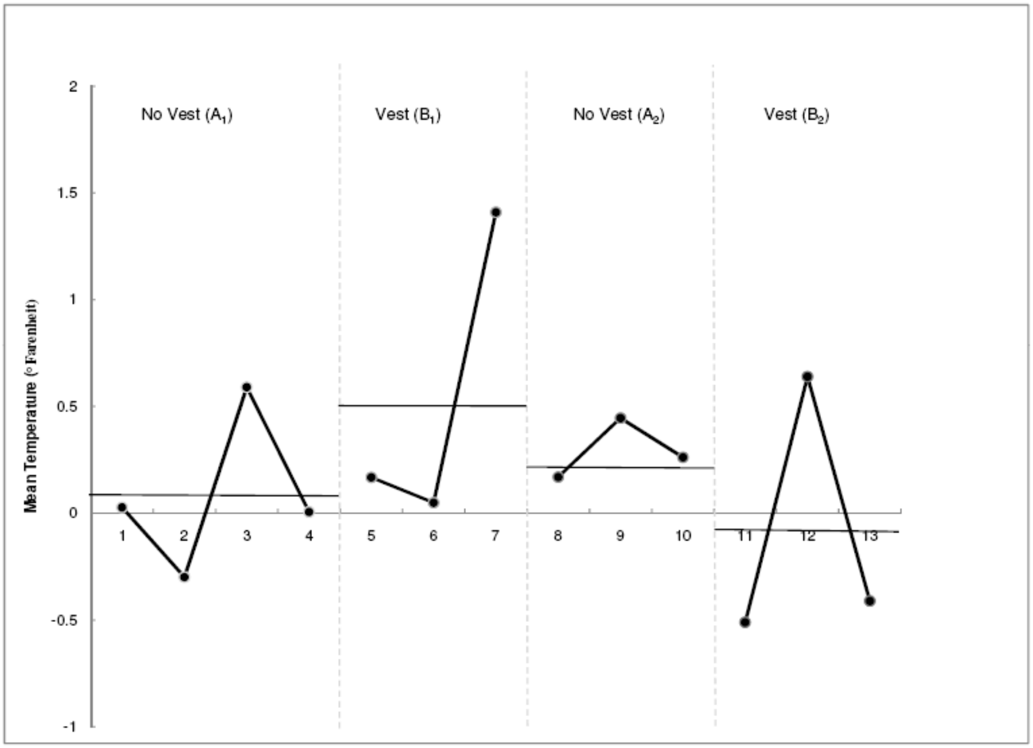

Figure 11. Change in Mean PST (Baseline – Nail Care)

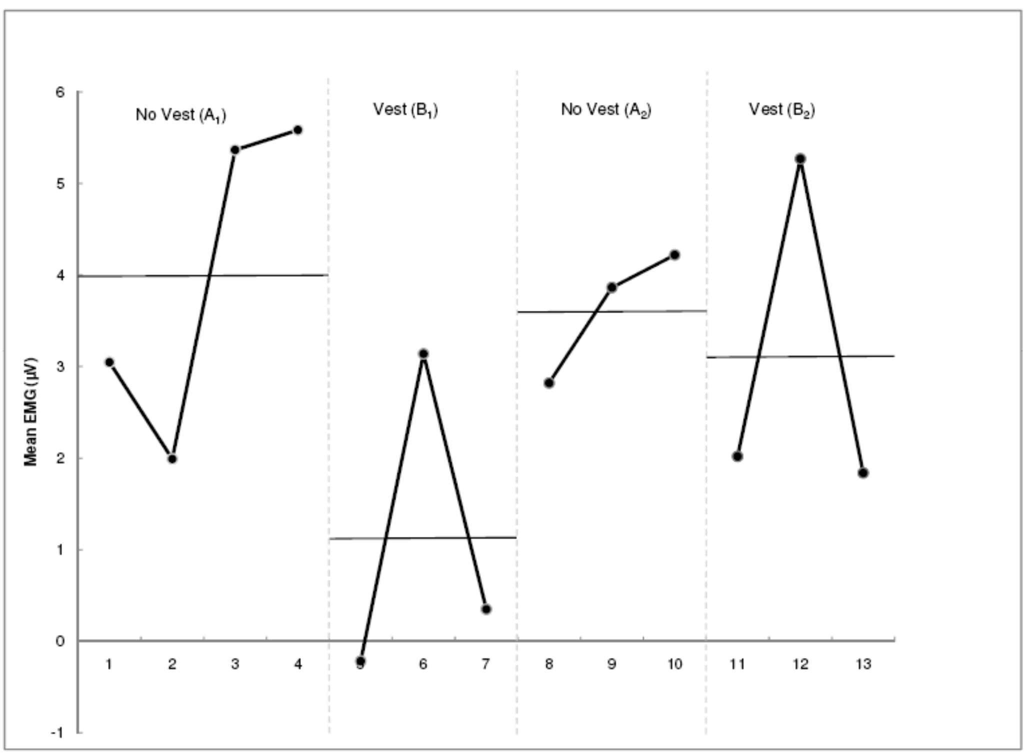

Figure 12. Change in Mean sEMG (Nail Care – Baseline)

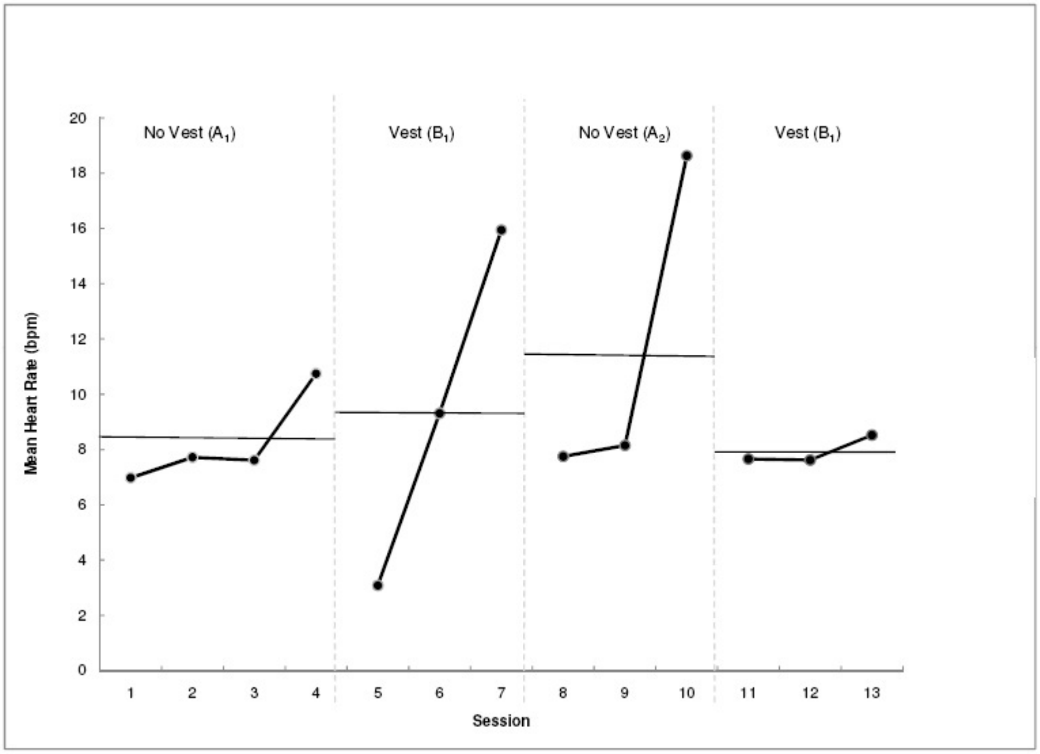

Figure 13. Change in Mean HR (Nail Care – Baseline)

Statistical Analysis

Using SPSS 16.0, independent sample t-tests (equal variance not assumed) and a one way ANOVA were completed to determine whether there was a statistically significant difference between the changes in dependent variables between phases. *T*-tests were calculated to determine whether there was a difference between the mean changes in each variable for the session with the vest when compared to the sessions without the vest. The results of the t-test are shown in Table 1. The t-tests revealed that there was no statistically significant difference in change in three of the dependent variables assuming unequal variances and using a one-tailed test. The *t*-test for sEMG was statistically significance but this needs to be interpreted cautiously as visual analysis of Figure 12 shows a large variability and there does not appear to be a consistent decrease in change of electromyography.

Table 1. *Independent Sample T-test Results of the Difference of Dependent Variables Between Vest and No Vest Conditions During Nail Care*

	t	df	*p*-value
Change in Mean EDA	-0.416	7.99	0.344
Change in Mean Temp.	-0.169	6.46	0.436
Change in Mean sEMG	1.864	8.54	0.049
Change in Mean HR	0.418	10.68	0.342

In addition, a one-way ANOVA was run to determine whether there was a difference between any of the phases. Results of the ANOVA are in Table 2 showing that none of the comparisons is statistically significant.

Table 2. *ANOVA of Dependent Variables Between Vest and No Vest Conditions During Nail Care*

	df	F	*p*-value
Change in Mean EDA (Between Groups)	3	0.534	0.670
Change in Mean Temp (Between Groups)	3	0.866	0.493
Change in Mean EMG (Between Groups)	3	1.99	0.186
Change in Mean Hr (Between Groups)	3	0.438	0.732

To determine whether there was an effect of using the vest, the dependent variables were compared during baseline to time when the vest was on but nail care was not being done. All calculations were done by taking the mean during acclimation and subtracting the mean during the time the vest was on. A paired samples test was completed and shown in Table 3. Skin conductance and skin temperature were statistically significant, but these results must be interpreted cautiously as there is a high variability in the data as evidenced by the visual analysis of the graphs.

Table 3. *Paired Sample T-test Between Vest and No Vest Conditions Without Nail Care*

	df	*p*-value
EDA_BL- EDA_V	5	0.056
Temp_BL-Temp_V	5	0.042
EMG_BL-EMG_V	5	0.399
HR_BL-HR_v	5	0.487

CHAPTER 5: Discussion

The results from my study did not support the hypothesis that the pressure vest was effective in reducing anxiety and physiological arousal than without the vest. When the pressure vest was applied, the participant's physiological data did not approach pre baseline measurements. In addition, there was no difference in the change in dependent variables [electrodermal activity (EDA), peripheral skin temperature (PST), surface electromyography (sEMG), and heart rate (HR)] when the vest was in use (Phases B_1, and B_2) compared to when the vest was not in use (Phases A_1, A_2). This was supported through visual and statistical analysis of the data. It is important to note that although the vest did not reduce physiological arousal, it also did not increase physiological arousal. Instead, there seems to be little relationship between the physiological data and the presence of the vest.

These results are in contrast to other studies that have found that deep pressure is effective in reducing anxiety and positively impacting physiological arousal (Blairs & Slater, 2007; Edelson, Edelson, Kerr, & Grandin, 1998; Krauss, 1987; Mullen et al., 2008). One study published by Zissermann (1992) found that deep pressure applied with the use of an anti-burn scar pressure garment to a child age eight with severe developmental delay and autism actually increased self-stimulating behaviors. Zissermann's study therefore demonstrated that deep pressure did not serve to reduce arousal and disruptive behaviors.

Limitations

My study has a number of limitations. First, there were compelling reasons to use one individual but this limits the conclusions that can be drawn from the data. Therefore, even though this particular individual did not show a reduction in physiological indices of anxiety, it cannot be assumed that no individuals will show a reduction in anxiety. There is some research to support the idea that not all individuals will benefit from deep pressure, therefore there is a chance that the participant in this study was not a candidate for the use of deep pressure (Edelson et al. 1998). In her book about her life with autism, Grandin (1995) predicts that those experiencing a high level of anxiety will benefit most from deep pressure. In a study on the effects of the "Hug Machine" on children with autism Edelson, Edelson et al. (1998) found that those children with a high level of anxiety or arousal benefitted the most from deep pressure. It therefore may be possible that the participant in this study has a generally low level of arousal or anxiety and therefore may experience less of a benefit from the use of deep pressure.

Another limitation was the use of a deep pressure vest. The vest applied deep pressure only to the participants' trunk area and over the shoulders. The vest was chosen for two reasons; to allow access to the hands for nail-care, and so that movement was not restricted and the vest could not be considered a physical restraint. Unfortunately, many of the published research studies that demonstrated the effectiveness of deep pressure involve deep pressure to a larger portion of the participants' body (Blairs & Slater, 2007; Edelson et al. 1998; Krauss, 1987; Mullen et al., 2008). Blairs and Slater (2007) demonstrated that deep pressure applied from the shoulder to the ankles with a tightly tucked in sheet was effective. Edelson et al. (1998) used a specially designed "Hug Machine" that provided deep pressure to the participant's lateral parts of the body from the neck to the ankles. Krauss (1987) also used a special device different from Edelson et al which was termed a "Hug'm". The "Hug'm" applied pressure from the midchest to the calves of the individuals using air mattress and a pulley system to close around the participant. Finally Mullen et al. (2008) used a weighted blanket that measured 56 inches x 76 inches. These dimensions suggested that a large portion of the participants' body could be covered.

The number of days that data was collected created a limitation. Data collection occurred one day a week because that was the frequency of nail care. Changes in phases were determined by data stabilization. Stabilization occurred when 80% of data fell within 20% of the median value (Dattillo et al., 2000) for two of the measurement variables or after five weeks. Unfortunately, data stabilization consistently occurred in only two of the four variables, HR and PST. These two variables had a larger value and therefore the 20% range is much larger for these variables. Had stabilization been required in all four of the variables more days for each phase would have been required. The additional days may have indicated that there was a difference between the conditions.

Another limitation was the amount of time the vest was used. The vest was applied and left on for five minutes; nail care then began and lasted from 8-12 minutes resulting in 13-17 minutes of total time the vest was in use. Research reports indicate the amount of time required to produce a calming effect ranges from five minutes to twenty minutes (Blairs & Slater, 2007; Edelson et al. 1998; Krauss, 1987; Mullen et al., 2008). It may be possible therefore, that the vest was not left on for the optimal amount of time to produce a calming effect.

The sequence in which the vest was used may have been a limitation. The vest was applied prior to nail care and remained in place during the activity. No other research has combined an anxiety producing situation and deep pressure. The research studies that have indicated deep pressure to be calming have all used deep pressure by itself while the participant was in a supine, or quadruped position (Blairs & Slater, 2007; Edelson et al., 1998; Krauss, 1987; Mullen et al., 2008). Perhaps the deep pressure would have produced more of a calming effect after the nail care activity was completed.

Another limitation was that there may not have been a consistent amount of pressure applied between the phases. The vest was marked and secured at the same spot each time; however, the thickness of the clothing the participant wore varied. Some days the participant wore only a t-shirt and others a bulky sweater. The days that the clothing was bulky, more pressure was applied, conversely when the clothing was thinner less pressure was applied. Perhaps a more consistent pressure would have improved the results.

Unfortunately, there is limited research on the use of psychophysiological responses with persons who have profound mental retardation. Therefore, it is unclear whether this was an appropriate measure to use to determine whether the individual is experiencing stress or anxiety. My study assumed that the physiological responses of the individual correlated with the psychological responses. This may not be an appropriate assumption for this population, unfortunately, there are limited research studies to support or refute this assumption. Similarly, there was limited information or guidelines on the appropriate placement of sensors for this population. My study used guidelines that were developed for the normal healthy adult population and it is unclear whether these are the same for the severe profound mental retardation population (Boucesin, 1992; Cram & Kasman, 1998; Stens Corporation, 2006)

My study only examined the physiological responses of the individual. It may be possible that although the physiological data did not support a reduction in anxiety, the participant may have experienced a reduction in anxiety, or the staff member completing the nail care may have noticed a change in the participants' behaviors.

Recommendations for Future Research

This study did not support the use of a deep pressure vest to reduce anxiety in an individual with profound mental retardation during nail-care. More research on deep pressure and its use in those with profound mental retardation is indicated. Future research should improve upon the limitations previously discussed. Researchers should consider a withdrawal (AB) design because two phases could allow more time for stabilization of data. In addition, because of the limited amount of research regarding the use of deep pressure in those with mental retardation a less stringent research design would be appropriate until there is a base of support. In addition, requiring data stabilization in four of the four variables may decrease the variability in the results. Increasing the amount of exposure to deep pressure by increasing the portion of the body to which deep pressure was applied, or using deep pressure after an aversive event may increase the magnitude of effect size.

Future research should explore the optimal amount of pressure to produce a calming effect, the characteristics of clients that may benefit from deep pressure, and the best way to apply deep pressure. My study did not support the use of deep pressure to reduce physiological arousal but future research should examine whether a vest could more quickly return an aroused person to a non-aroused state.

In addition, more research evaluating the effect of occupational therapy intervention in those with severe/profound mental retardation needs to be done. There are few published research studies in the occupational therapy literature addressing interventions with this population.

Implications for Occupational Therapy

Research on the use of deep pressure is very important for the field of occupational therapy. If the application of deep pressure is to be used as a technique by occupational therapists, there needs to be a base of evidence that supports this type of intervention. The American Occupational Therapy Association (2008) explains that the evaluation and interventions used with clients be based on knowledge, theories, evidence, and skills of the therapists. The use of evidence is particularly important in light of the AOTA's Centennial vision that occupational therapy be science driven and evidence based (AOTA, 2007). More research should examine deep pressure and the ways in which it is most effective so that occupational therapists can best treat their clients.

Impact of Research on Me

I did this project because of my interest in working with individuals with profound mental retardation. Having worked in a group home setting providing care to individuals with mental retardation, I realized how important it was for occupational therapists to provide interventions in this type of setting. As a manager of a group home, I found it upsetting when I had to perform hygiene activities with the individuals and they resisted and demonstrated behaviors of anxiety. By doing this study, I was hoping to find a simple way to reduce anxiety and resultant physiological arousal to increase the quality of life of an individual with mental retardation.

I think the most important thing that I learned from doing this study was that even if you do not achieve the results you expected and hoped for, there is still value in completing the research. It will be beneficial to the staff at the Center to know that this particular individual does not benefit from deep pressure provided by a vest. They will be able to explore other interventions that may be more beneficial to the participant. Although I did not see the results I hoped for by completing this project, I learned the valuable skills of time management, organization, and patience.

Completing this thesis has made me more aware of the amount of research that is available to occupational therapists. This particular topic demonstrated to me the lack of research to support an intervention. However, I also saw the amount of research in occupational therapy and other fields that is published on a wide range of topics that would be relevant to practicing occupational therapists. I think by completing this thesis, I am more aware of finding evidence to support interventions and best practices for my clients.

References

American Association on Intellectual and Developmental Disabilities. (2009). Definition of intellectual disability. Retrieved March 5, 2009 from www.aamr.org.

American Association on Mental Retardation. (2002). *Mental Retardation: Definition, classification and systems of supports.* (10th ed.). Washington, DC: Author.

American Occupational Therapy Association. (2008). Occupational therapy practice framework: Domain and process (2nd ed.) *American Journal of Occupational Therapy, 62,* 625-683.

American Occupational Therapy Association. (2007). AOTA's Centennial vision and executive summary. A*merican Journal of Occupational Therapy, 61(6),* 613-614.

American Psychiatric Association. (2000). *Diagnostic and statistical manual of mental disorders (4th ed. Text revision).* Washington, DC: Author.

Atchison, B.J. (2007). Mental retardation. In B.J. Atchison & D.K. Dirrette (Eds.). *Conditions in occupational therapy: Effect on occupational performance* (3rd ed. pp. 51-66). Baltimore: Lippincott, Williams, & Wilkins.

Barlow, D.H., Nock, M.K., & Hersen, M. (2009). *Single case experimental designs: Strategies for studying behavior change.* Boston: Pearson.

Barron, K.W., & Blair, R.W. (1999). Motor 3: The autonomic nervous system. In H. Cohen, (ed.) *Neuroscience for rehabilitation* (2nd ed. pp. 277-302). Baltimore: Lippincott, Williams, & Wilkins.

Brownley, K.A., Hurwitz, B.E., & Schneiderman, N. (2000). Cardiovascular psychophysiology. In J.T. Cacioppo, L.G., Tassinary, G.G. Berntson (Eds.) *Handbook of psychophysiology.* (2nd ed. pp224-264). New York: Cambridge University Press.

Blairs, S., & Slater, S. (2007). The clinical application of deep touch pressure with a man with autism presenting with severe anxiety and challenging behavior. *British Journal of Learning Disabilities, 35,* 214-220.

Boucsein, W. (1992). *Electrodermal activity*. New York: Plenum Press.

Bourne, E.J. (2005). *The anxiety and phobia workbook. (4th ed).* Oakland CA: New Harbinger Publications Inc.

Cacioppo, J.T., Tassinary, L.G., & Berntson, G.G. (2000). Psychophysiological science. In J.T. Cacioppo, L.G. Tassinary, G.G. Berntson. (Eds.), *Handbook of psychophysiology.* (2nd ed. pp 3-23). New York: Cambridge University Press.

Carr, J.E., & Burkholder, E.O. (1998). Creating single-subject design graphs with Microsoft EXCEL™. *Journal of Applied Behavior Analysis. 31,* 245-251.

Cohen, H. (1999). *Neuroscience for rehabilitation (2nd ed.)* Philadelphia: Lippincott, Williams, & Wilkins.

Cram, J.R. , & Kasman, G.S. (1998). *Introduction to surface electromyography.* Gaithersburg, MD: Aspen Publishers

Davison, G.C., Neale, J.M., & Kring, A.M. (2004). *Abnormal psychology*. Danvers, MA: John Wiley & Sons Inc.

Dattilo, J., Gast, D.L., Loy, D.P., & Malley, S. (2000). Use of single-subject research designs in therapeutic recreation. *Therapeutic Recreation Journal 34,* 253-270.

Dawson, M.E., Schell, A.M., & Filion, D.L. (2000) The electrodermal system. In J.T. Cacioppo, L.G., Tassinary, & G.G. Berntson. (Eds.) *Handbook of psychophysiology.* (2nd ed. pp 200-223). New York: Cambridge University Press.

Dickey, B.J., Lowerre, A., Stevenson, J., & Favell, J. (1994). Decreasing tactile defensiveness in developmentally disabled adults. Unpublished final grant report to the North Carolina foundation for mental health research.

Doty, G.K. (1996). The effect of a weighted blanket on hyperactivity of an adult with profound mental retardation. Unpublished manuscript, Eastern Kentucky University.

Edelson, S.M., Edelson, M.G., Kerr, D.C.R., & Grandin, T. (1998). Behavioral and physiological effects of deep pressure on children with autism: A pilot study evaluating the efficacy of Grandin's Hug Machine. *American Journal of Occupational Therapy, 53,* 145-152.

Feretel-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. *American Journal of Occupational Therapy, 55,* 629-640.

Fox, S.I. (2006). *Human physiology*. New York: McGraw Hill.

Gazzanga, M.S., & Heatherton, T.F. (2003). *Psychological science.* New York: W.W. Norton & Company Inc.

Grandin, T. (1992). Calming effects of deep pressure in patients with autistic disorder, college students and animals. *Journal of child and adolescent pharmacology, 2,* 63-72.

Grandin, T. (1995). *Thinking in pictures: My life with autism*. New York: Vintage Books.

Hollifield, L.R. (1996). Implementation of the body sox and its effect on self-injurious behavior. Unpublished manuscript, Eastern Kentucky University.

Journal of Applied Behavior Analysis. (1996). Manuscript preparation checklist. *Journal of Applied Behavior Analysis, 29,* 115.

Krauss, K.E. (1987). The effects of deep pressure touch on anxiety. *American Journal of Occupational Therapy. 41(6),* 366-373.

Kumazawa, T. (1963). “Deactivation” of the rabbit’s brain by pressure application to the skin. *Electroencephalography and Clinical Neurophysiology, 15, 650-671.*

Kimball, J.G. (1999) Sensory integration frame of reference: Postulates regarding change and application to practice. In P. Kramer & J. Hinojosa (Eds.). *Frames of reference for pediatric occupational therapy* (2nd ed. pp. 119-159). Baltimore: Lippincott, Williams, & Wilkins.

Morgan, D.L., & Morgan, R.K., (2009). *Single-case research methods for the behavioral and health sciences*. Los Angeles: Sage.

Mullen, B., Champange, 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.

Oakes, S. (1998). Heat, massage and weighted blanket as modalities to facilitate relaxation for an individual with profound mental retardation. Unpublished manuscript, Eastern Kentucky University.

Obrist, P.A. (1976). Presidential address 1975: The cardiovascular-behavioral interaction as it appears today. *Psychophysiology, 13(2), 95-106.*

Parham, L.D., Cohn, E.S., Spitzer, S., Koomar, J.A., Miller, L. J., Burke, J.P., et al. (2007). Fidelity in sensory integration intervention research. *American Journal of Occupational Therapy, 61,* 216-227.

Parham, L.D., & Mailloux, Z. (2005). Sensory integration. In J. Case-Smith (Ed.) *Occupational therapy for children* (5th ed. pp.356-409). St. Louis, MO: Elsevier Mosby.

Rogers, J. (1994). The effect of a weighted blanket on an adult with mental retardation. Unpublished manuscript, Eastern Kentucky University.

Schalock, R.L., Luckasson, R.A., & Shogren, K.A. (2007). The renaming of mental retardation: Understanding the change to the term intellectual disability. *Intellectual and Developmental Disabilities, 45(2),* 116-124.

Shangraw, K. (2007). Autism spectrum disorders. In B.J. Atchison & D.K. Dirrette (Eds.). *Conditions in occupational therapy: Effect on occupational performance* (3rd ed. pp. 23-50). Baltimore: Lippincott, Williams, & Wilkins.

Shier, D., Butler, J., & Lewis, R. (1998). *Essential of human anatomy and physiology (6th ed).* Boston: McGraw- Hill Publishers.

Stens Corporation. (2006). NeXus-10. Retrieved April 28, 2008 from www.stens-biofeedback.com.

Tassinary, L.G. & Cacioppo, J.T. (2000). The skeletomotor system: Surface electromyography. In J.T. Cacioppo, L.G., Tassinary, & G.G. Berntson. (eds.) *Handbook of psychophysiology.* (2nd ed. pp 163-199). New York: Cambridge University Press.

Tawney, J.W., & Gast, D.L. (1984). *Single-subject research in special education.* Columbus, OH: Merrill.

Wardell, D.W., & Engerbreston, J. (2000). Biological correlated of reiki touch healing. *Journal of Advanced Nursing, 33(4),* 439-445.

Wells, D.L. (2005). The effect of videotapes of animals on cardiovascular responses to stress. *Stress and Health, 21,* 209-213.

Wells-Federmann, C.L., Stuart, E.M., Deckro, J.P., Mandle, C.L., Baim, M., & Medich, C. (1995). The mind-body connection: The psychophysiology of many traditional nursing interventions. *Clinical Nurse Specialist, 9(1), 59-65.*

Wolery, M., & Harris, S.R. (1982). Interpreting results of single-subject research designs. *Physical Therapy, 62*(4), 445-452.

Wortman, C., Loftus, E., & Weaver, C. (1999). *Psychology.* (5th ed.) Boston: McGraw-Hill College.

Zissermann, L. (1992). The effects of deep pressure on self-stimulating behaviors in a child with autism and other disorders. *American Journal of Occupational Therapy, 46,* 547-551.

APPENDIX A: Approval of North Carolina Department of Health and Human Services

North Carolina Department of Health and Human Services
Division of Mental Health, Developmental Disabilities and Substance Abuse Services
Caswell Developmental Center
2415 West Vernon Avenue, Kinston, North Carolina 28504-3321
Courier 01-21-04

Michael F. Easley, Governor
Dempsey Benton, Secretary
Michael S. Lancaster, M.D. and
Leza Wainwright, Directors

Beverly Vinson, Center Director
Office (252) 208-4222
Fax (252) 208-4238

September 10, 2008

Skip O'Neal, M.S.
Occupational Therapist II OTR/L
Caswell Developmental Center
2415 West Vernon Avenue
Kinston, NC 28504

Dear Skip:

This letter acknowledges that your research proposal, "Use of a Pressure Vest to Reduce the Physiological Arousal of People with Profound Intellectual and Physical Disabilities During a Routine Grooming Activity" was approved by the Research Committee on September 10, 2008.

This approval was for a one year period of time and was given to the research proposal, informed consent draft document and the draft of the Authorization to Disclose Health Information for Research with the revisions you have agreed to complete and submit to the committee. The implementation date for beginning your research will be set by me upon the receipt of approval from the University and Medical Center Institutional Review Board at East Carolina University. Any changes required by the ECU IRB to the above documents must be reported.

Your project was approved by the full review of the Research Review Committee as minimal risk research. Please keep me informed of any issues, problems related to the approved project. A quarterly report will be required as long as the research is ongoing. A final repot is required at the conclusion of the research.

Thank you for your research efforts and I look forward to your results.

Sincerely,

Frank Wells

Frank Wells, Ph.D.
Director of Psychology
Research Committee Chair

cc: Diane Fleetwood, Director of Occupation Therapy
Selene Knight, Research Committee Secretary

An Equal Employment Opportunity/Affirmative Action Employer

APPENDIX B: Approval of University and Medical Center Institutional Review Board

EAST CAROLINA UNIVERSITY

University and Medical Center Institutional Review Board
East Carolina University
Ed Warren Life Sciences Building • 600 Moye Boulevard • LSB 104 • Greenville, NC 27834
Office **252-744-2914** • Fax **252-744-2284** • **www.ecu.edu/irb**
Chair and Director of Biomedical IRB: L. Wiley Nifong, MD
Chair and Director of Behavioral and Social Science IRB: Susan L. McCammon, PhD

TO: Beth Velde, PhD, Dept of Occupational Therapy, ECU—3206 LAHN Building

FROM: UMCIRB lcl

DATE: October 9, 2008

RE: Full Committee Approval of a Study

TITLE: "Use of a Pressure Vest to Reduce the Physiological Arousal of People with Profound Intellectual and Physical Disabilities During a Routine Grooming Activity"

UMCIRB # 08-0511

The above referenced research study was initially reviewed by the convened University and Medical Center Institutional Review Board (UMCIRB) on **9.10.08.** The research study underwent a review and approval of requested modifications on **10.8.08** by the convened UMCIRB. The UMCIRB deemed this **unfunded** study **more than minimal risk** requiring a continuing review in **12 months**. 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 continuing review/closure application to the UMCIRB prior to the date of study expiration. The investigator must adhere to all reporting requirements for this study.

The above referenced research study has been given approval for the period of **10.8.08** to **10.7.09.** The approval includes the following items:

- Internal Processing Form (Received 9.17.08)
- Informed Consent (dated 9.12.08)

The following UMCIRB members were recused for reasons of potential for Conflict of Interest on this research study:
None

NOTE: The following UMCIRB members with a potential Conflict of Interest did not attend this IRB meeting:
None

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.

APPENDIX C: Informed Consent

INFORMED CONSENT

Title of Research Study: Use of a pressure vest to reduce the physiological arousal of people with profound intellectual and physical disabilities during a routine grooming activity.
Principal Investigator: Skip O'Neal, MS, OTR/L; Beth Velde, PhD, OTR/L
Institution: East Carolina University and Caswell Developmental Center
Address: Department of Occupational Therapy, 3206 Health Sciences Building, East Carolina University, Greenville, NC 27858
Telephone #: Beth Velde - (252) 744-6196
Skip O'Neal - (252) 208-4056
This consent form may contain words that you do not understand. You should ask the study coordinator to explain any words or information in this consent form that you do not understand.

Introduction:
You have been asked to provide consent for ______________ to participate in a research study being conducted by Beth Velde, PhD, OTR/L, Skip O'Neal, MS, OTR/L, Rebecca LaChappelle, OTS. Dr. Velde is a professor at East Carolina University (ECU) Department of Occupational Therapy, Skip O'Neal is a staff occupational therapist at Caswell Developmental Center, and Rebecca LaChappelle is working towards her master's degree in the ECU Occupational Therapy program. The study will include recording information in the home environment for five days then 20 weeks of nail care.

PURPOSE AND PROCEDURES

The purpose of this single participant research study is to examine the use of a deep pressure vest in reducing physiological arousal during nail care. Some people with profound mental retardation (PMR) demonstrate dislike of particular routine daily activities such as having their fingernails clipped and filed. While they are engaged in these activities, the physiological stress responses of people with PMR can be measured with specialized equipment that measures muscle tension, the skin temperature of the hand or foot, the amount of sweating on the hand or foot, and heart rate. This means that monitoring certain involuntary body functions can give us some idea of how much stress a person is experiencing. The researchers hypothesize that the stress response of a person with PMR will be lower during nail filing/clipping when he/she is provided with deep pressure sensory stimulation. Deep pressure sensory input is often reported to be calming and relaxing. Deep pressure sensory stimulation is experienced when firm, even pressure is applied to the body. In this study, deep pressure sensory input will be provided through the application of the pressure vest pictured below:

This commercially available pressure vest is made of stretchy front and back panels that attach to each other with Velcro closures. The vest is composed of a soft, breathable material and should not be uncomfortable. Vests like this one are used in many places with people who respond positively to deep pressure. In the event ______________ demonstrates a negative response to the vest, the session will be terminated. Before the research project begins the investigators will conduct a trial session with the participant to determine the appropriate size of vest to be used and to observe the participant's initial responses to the vest. The size of vest used with each participant will be determined based on the circumference of the participant's waist and length of his/her torso. During the research project, the vest and sensors will be applied 10 minutes before nail care begins to allow _________ time to get use to it. The vest and sensors will be removed after nail care is completed.

Physiological responses (electrodermal activity, peripheral skin temperature, and heart rate) will be measured using the NeXus 10 a physiological monitoring unit. The NeXus-10 is a small portable unit which sends the measured information to a nearby computer. The computer records the electrodermal activity, peripheral skin temperature and heart rate so that they can be reviewed and analyzed. The NeXus-10 is pictured below

This unit is small, about 8 inches in width wires with small sensors on their ends are plugged into the unit. A mildly adhesive medical tape will be used to attach the sensors to ___________'s body. The sensors will be attached on the toes and upper forehead. Once the sensors are attached, a caregiver familiar with ______ will perform routine nail care activities, such as clipping, filing and cleaning. __________'s electrodermal activity, peripheral skin temperature, EMG (muscle tension) , and heart rate responses to these sessions will be monitored during the session. The session is expected to last 5 to 15 minutes. Sessions will be conducted in __________'s home, where nail care activities are usually performed. After all sessions have been completed, the investigators will analyze the data from all sessions to determine if _________ showed a decrease in physiological arousal when the deep pressure vest was applied as compared to sessions without the vest.

Nail care will be provided by a caregiver familiar with _________ and trained on __________'s Behavior Plan and/or Necessary Care Protocol. If strong resistance to nail care is encountered, the session will be terminated and the procedures in the Plan/Protocol will be followed.

POTENTIAL RISKS AND DISCOMFORTS

There are no known risks for the research participant. A familiar caregiver will be present at all times. The activity that will be observed is necessary grooming that ______ receives weekly. To preserve privacy, nail care activities will be observed that do not require removal of clothing, except a sock. Because ________ has demonstrated discomfort in nail care activities they will be done as close as possible to the time they typically occur to avoid repeating the experience.

POTENTIAL BENEFITS

If the deep pressure vest is shown to be effective in reducing physiological arousal, the vest may be used during nail care and other anxiety inducing events.

SUBJECT PRIVACY AND CONFIDENTIALITY OF RECORDS

No forms of digital or electronic recordings of _________'s image will be used in this study. Physiological data recorded by the computer will be identified using a fictitious name. If a manuscript or presentation results for the research, a fictitious name will be used in any written or verbal documentation to assure confidentiality. Any presentation or publication of the study will not reveal the identity of the participants.

Skip O'Neal, an employee of Caswell Developmental Center, will be the only investigator accessing _________'s records. After all data has been gathered and analyzed, the information will be entered into _________'s permanent records at Caswell. Information not entered into _________'s permanent records will be destroyed.

COSTS OF PARTICIPATION & COMPENSATION

By participating in this research study, you will not incur any costs and you will not receive any monetary compensation for your participation in this study.

VOLUNTARY PARTICIPATION

Participating in this study is voluntary. If you decide that ___________ should not be in this study after it has already started, you may stop the participation of _______ at any time without losing benefits normally received. You may stop participation at any time you choose without penalty, loss of benefits, or without causing a problem with medical care at the Caswell Developmental Center

PERSONS TO CONTACT WITH QUESTIONS

The investigators will be available to answer any questions concerning this research, now or in the future. You may contact the investigators, Dr. Beth Velde or Skip O'Neal at phone numbers (252) 744-6196/ (252) 208-4056 (days) or (252) 975-6857/ (252) 527-3211 (nights and weekends). If you have questions about the rights of a research subject, you may call the Chair of the University and Medical Center Institutional Review Board at phone number 252-744-2914 (days). If you would like to report objections to this research study, you may call the ECU Director of Research Compliance at phone number 252-328-9473

CONSENT TO PARTICIPATE

Title of research study: Use of a pressure vest to reduce the physiological arousal of people with profound intellectual and physical disabilities during a routine grooming activity.

I have read all of the above information, asked questions and have received satisfactory answers in areas I did not understand. (A copy of this signed and dated consent form will be given to the person signing this form as the participant or as the participant's authorized representative.)

____

Participant's Name **(PRINT)** **Signature** **Date** **Time**

If applicable:

____

Guardian's Name **(PRINT)** **Signature** **Date** **Time**

PERSON ADMINISTERING CONSENT: I have conducted the consent process and orally reviewed the contents of the consent document. I believe the participant understands the research.

____

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

____

Principal Investigator's **(PRINT)** **Signature** **Date**

APPENDIX D: NeXus-10

The NeXus-10 is a 10-channel Physiological Monitoring and Feedback platform that utilizes BlueTooth Wireless Communication and Flash Memory (SD) Technologies. NeXus-10 provides data acquisition up to 2048 samples per second.

The NeXus-10 supports a wide and expanding series of physiological sensors that offer high precision and numerous modalities NeXus-10 can measure 4 fast electrophysiological signals at high speed up to 2048 samples/sec. In addition, it can record another 6 auxiliary sensors in different combinations.

The NeXus-10 is a small portable unit, which sends the measured information to a nearby computer. The computer records the electrodermal activity, peripheral skin temperature, electromyography, and heart rate so that they can be reviewed and analyzed. The NeXus-10 is pictured below

Note: NeXus-10 is certified as a medical device class IIa. (EU)

* Retrieved from http://www.mindmedia.nl/english/nexus10.php on April 24, 2008

APPENDIX E: Deep Pressure Vest

This commercially available pressure vest is made of stretchy front and back panels that attach to each other with hook and loop closures. The vest is composed of a soft, breathable material and should not be uncomfortable. Vests like this one are used in many places with people who respond positively to deep pressure. The size of vest used with the participant will be determined based on the circumference of the participant's waist and length of his/her torso.

APPENDIX F: Procedural Reliability Checklist

<u>Procedural Reliability Checklist</u>

Check each step if completed leave blank if not completed. Note if steps were completed out of order by signaling with an arrow. E.g. if the second step occurs before the first draw and arrow from the second step up to the first step

_____ Staff member will bring participant to room

_____ Staff member will remove shoe and sock of participant's right foot

_____ Researcher will explain to participant what is going to happen "**I am going to put some things on your toes and forehead"**

_____ Researcher will apply **temperature** sensor using medical tape to participants big toe (right foot)

_____ Researcher will apply **skin conductance** sensors to the inside of the participants foot 10 cm and 12 cm from the tip of the big toe (right foot)

_____ Secure wires with tape so they don't tickle the bottom of the foot

_____ Clean participants forehead with an alcohol swab

_____ Apply **electromyography** sensor to participants forehead (red on right) directly above the eyebrows

_____ Clean areas where EKG sensors will be secured using an alcohol swab

_____ Apply ground to participants left side 1 inch under the clavicle

_____ Apply **EKG sensors** (use number two leads).

_____ Researchers will begin recording data using the NeXus-10 and the computer

_____ Researchers will wait for data to stabilize or five minutes.

_____ PHASE B ONLY Researchers and staff member will apply pressure vest

_____ PHASE B ONLY Researchers will wait for data to stabilize or five minutes.

_____ The staff member will explain to the participant. “I am going to file your fingernails”

_____ Researcher will signal to staff member with a raised hand to begin nail care.

_____ Staff member will use a nail file to file each nail beginning at the pinkie finger on the right hand

proceeding to the thumb, then the pinkie on the left proceeding to the thumb

_____ Staff member will signal researchers with a raised hand when the nail care is complete

APPENDIX G: Procedures for Entering Data and Creating Single Subject Graphs using Excel

1. Enter data for the first phase into the first column

2. Enter data on the next line in the column to the right of the previous column for each new phase creating a staggering of data

3. Select the cells containing the data and click on the chart wizard icon

4. Select the line graph in the standard types window

5. The string of coordinates will appear; check to make sure they are the correct range

6. A preview window will appear and you can alter the features of the graph such as legend, gridlines and titles.

7. Select where you would like the graph to appear, either in spreadsheet or as separate sheet

8. Click on the text-bow icon, create an area over a phase, and type in phase label

9. Repeat step 8 as necessary

10. Click on the line tool

11. Click and drag to make a vertical line between phases from the x axis to the top of the graph, repeat as necessary

12. Double click on the vertical line. The Patterns menu will appear. Select different styles and weights for the vertical line.

Carr, J.E., & Burkholder, E.O. (1998). Creating single-subject design graphs with Microsoft Excel™. *Journal of applied behavior analysis. 31,* 245-251.