Abstract

Comparison of Two Relaxation Techniques to Reduce Physiological Indices of Anxiety in a Person with Mild Mental Retardation

by

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Purpose: Occupational therapists play an important role in improving the occupational performance of persons with mental retardation. Relaxation techniques are a preparatory activity used by occupational therapists to enhance occupational performance. When working with persons who are mentally retarded, one preparatory technique related to anxiety reduction is relaxation strategies. The purpose of this study was to examine the effects of 2 relaxation treatment techniques: paced respiration technique and an object manipulation technique on heart rate as a physiological measure of anxiety, in a person with mild mental retardation. **Methods:** This study used a single subject alternating treatment design consisting of a 14 session treatment phase (paced respiration or object manipulation) followed by a best-treatment phase with 5 sessions. Each session consisted of an acclimation, treatment, and post-treatment period. Staff who worked with the participant on a regular basis were surveyed to ascertain their opinion of the social validity of the best treatment. **Results:** There were no statistically significant differences

in heart rate when comparing the paced respiration to the object manipulation technique. The object manipulation technique was chosen as the best-treatment because it was found to have more of a lasting effect after the treatment was ended. Within each treatment, between the acclimation and the post period, each technique produced a statistically significant difference in heart rate. Staff agreed this research was socially valid.

Discussion: Since both the paced respiration and object manipulation techniques individually reduced heart rate in an individual with mental retardation, both could be used to influence anxiety. Because staff viewed the object manipulation treatment in a positive manner, they may be more likely to implement this type of treatment. Occupational therapists working with individuals with mental retardation may find the use of these two relaxation methods effective as preparatory intervention strategies.

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Chapter One: Introduction

According to the American Occupational Therapy Association (1999), occupational therapists play an important role in helping persons with mental retardation and other cognitive impairments achieve a level of occupational performance that contributes to a quality lifestyle. For many persons with mental retardation, anxiety inhibits occupational performance. One occupational therapy intervention aimed at attenuating the effects of anxiety is metacogntive training where the individual learns to monitor and control cognitive processes that interfere with occupational performance and implement techniques to address those issues. The purpose of this study was to examine the effects of a paced respiration technique versus an object manipulation technique on physiological measures related to anxiety of a person with mild mental retardation, as well as determine whether staff working with an individual with mental retardation feel this research is socially valid.

Over 50% of institutionalized persons with mental retardation have at least one identifiable psychiatric disorder, including depression and anxiety (Singh, Sood, Sonenklar, & Ellis, 1991). Although anxiety disorders are common psychological problems for individuals with mental retardation, they often go undiagnosed and untreated (Glenn, Bihm, & Lammers, 2003). Identification of anxiety disorders in individuals with mental retardation is difficult because individuals may have ineffective communication skills or behavior problems, and professionals may lack standardized assessments specific to diagnosing anxiety in persons with mental retardation (Davis, Atezaz Saeed, & Antonacci, 2008; Esbensen, Rojahn, Aman, & Ruedrich, 2003).

Anxiety is defined as a state of uneasiness, apprehension, and agitation about future uncertainties (Biggs, Kelly, & Toney, 2003). It is a result of nonfunctional views held by the individual that center on perceptions of threat, danger, unpredictability, and uncertainty (Glenn et al., 2003). When a person is anxious, physiological changes occur. Anxiety can be identified by measuring these physiological changes (Brewster & Montgomery, 2005; Lindsay, Baty, Michie, & Richardson, 1989; Suzuki, Kumano, & Sakano, 2002). For example, when one is anxious, muscle tension, heart rate, blood pressure, sweat gland activity, and respiration increase in response to an activation of the sympathetic nervous system (Hoehn-Saric & McLeod, 2000). These measures may be especially helpful in identifying anxiety in people with mental retardation because they often have difficulty effectively verbally expressing their anxiety. Conversely, low respiration rate and electro-dermal activity (EDA) have been found to be indicative of a relaxed state (McCaul, Solomon, & Holmes, 1979).

Self-report measures of anxiety in individuals with mental retardation are limited by the individual's ability to communicate, social skills, intellectual functioning, and capacity to reflect on his/her internal states. Instruments that focus on observable measures of anxiety could provide a more effective way to identify anxiety in persons with mental retardation (Davis et al., 2008; Esbensen et al., 2003). One example of an observable measure was suggested by Romanczyk and Gillis (2006) who advocated the use of psychophysiological recording in the assessment of stress-related arousal and anxiety in children with developmental disorders. Because psychophysiological and brain imaging studies indicate that persons with mental retardation may have abnormal

stress indicated by autonomic system reactivity and brain function, psychophysiological measures may be useful in identifying stress in persons with mental retardation. Furthermore, research suggests that there are physiological stress responses associated with individuals with mental retardation and anxiety (Davis et al., 2008).

According to the *Occupational Therapy Practice Framework: Domain and Process, 2nd Edition* (American Occupational Therapy Association, 2008), restful activities support "healthy active engagement in other areas of occupation…[and] include identifying the need to relax; reducing involvement in taxing physiological, mental, or social activities; and engaging in relaxation or other endeavors that restore energy, calm, and renewed interest in engagement" (p. 632). Occupational therapists can help teach people to perform these restful activities, such as specific relaxation techniques. Several authors report success in teaching such techniques to persons with mild, moderate and severe mental retardation to reduce anxiety and/or aggressive behaviors (Lindsay et al., 1989; McCaul et al., 1979; To & Chan, 2000). Many relaxation techniques use some variation of paced respiration, which slows the respiration rate and has been shown to reduce anxiety in persons with anxiety disorders, high anxiety alcohol-dependent patients, and typical college students (Clark & Hirschman, 1990; McCaul et al., 1979; National Health Committee, 1998; Roth, 2005; Schwartz & Andrasik, 2003). Other research has focused on physical techniques to promote relaxation in individuals with mental retardation, such as using muscle tension and release (Chapman, Shedlack, & France, 2006; Lindsay et al., 1989; To & Chan, 2000; Waller, Kent, & Johnson, 2007).

The purpose of this study was to examine the effects of a paced respiration technique versus an object manipulation technique on physiological measures related to anxiety of a person with mild mental retardation. If either the paced respiration or object manipulation techniques impact physiological measures of anxiety, then future research can explore whether these techniques can be used to reduce anxiety in daily life, thereby enhancing quality of life. Because any intervention must be deemed effective by those who might utilize it, staff members at the residential facility where the individual resides were surveyed concerning the social validity of the use of these relaxation techniques within this population.

Definitions

In order for the reader to understand the terms used in this thesis, this section includes the key words and phrases pertinent to the purpose of the thesis and its methodology.

Deep breathing: breathing slowly, inhaling through the mouth, holding for a set count and then exhaling through the nose (Brewster & Montgomery, 2005).

Guided imagery: the use of verbal instruction for relaxation and breathing techniques as well as descriptions of pleasing images (León-Pizarro et al., 2007).

Incentive: something that incites or tends to incite to action or greater effort, as a reward offered for increased productivity (incentive, n.d.). This study will be using a small monetary incentive to encourage participation throughout the study. Researcher experience has shown this method to be effective at maintaining participant compliance.

Mental retardation: "Mental retardation is characterized by significant limitations both in intellectual functioning and in adaptive behavior as expressed in conceptual, social, and practical adaptive skills. This disability originates before the age of 18" (American Association on Mental Retardation, 2002, p. 197).

Object manipulation: for the purposes of this study, using one hand to squeeze a foam ball that fits in the palm of the hand.

Paced respiration: pattern of inhaling and exhaling at a predetermined rate (Schwartz & Andrasik, 2003).

Physiological state: the internal state of the body such as heart rate, skin temperature, electro dermal activity (sweat production), electromyography (EMG), and respiration rate.

Progressive relaxation: tensing one muscle group at a time above normal levels, and then releasing that tension (Lindsay et al., 1989).

Qigong: "a general term for a large variety of traditional Chinese energy exercises. There is no consistent definition of *qigong* in the academic field, but *qigong* is generally considered as 'a self-training method or process through *qi* (vital energy) and *yi* (consciousness or intention) cultivation to achieve the optimal state of both body and mind'" (Hui, Wan, Chan, & Yung, 2006, p 374).

Social Validity: "refers to the social significance of the intervention goals, the social acceptability of intervention procedures, and the social importance of effects produced by the intervention" (Lane, Kalberg, & Menzies, 2009, p. 95).

Technique: a systematic procedure by which a task is accomplished (“technique”, n.d.).

Chapter Two: Review of the Literature

This literature review includes five sections. The first section provides an overview of quality of life for persons with mental retardation and discusses how anxiety impacts quality of life. The second section details the dilemmas of interpreting the value of interventions when working with persons who are mentally retarded and describes how social validation may help to interpret the value of interventions. The third section discusses anxiety research and physiological measures used to evaluate anxiety. The fourth section outlines research about the effectiveness of relaxation techniques. The final section provides a justification for the current study.

Quality of Life and Anxiety

One outcome of successful occupational therapy is increased quality of life (American Occupational Therapy Association, 2008). According to the American Occupational Therapy Association (2008), quality of life results from engaging in occupations that positively contributes to a person's a state of physical, mental, and social well-being. While each individual is unique in what makes his or her life satisfying, research shows that optimal functioning and life satisfaction often result from having interests and self-efficacy, being autonomous, self-accepting, having a life purpose, and having a good fit between personal and environmental factors (Crane, 2005). According to Crane (2005), quality of life is multidimensional including physical, material, and social well-being domains. Physical well-being is having the capacity for mobility, having access to adequate health care, wellness, and nutritional needs. Material well-being is taking ownership for personal possessions and having employment opportunities.

Social well-being is having an adequate support system and being able to participate in one's environment (Crane, 2005). Quality of life is an important consideration when working with persons with mental retardation because it promotes person specific interventions that will create meaningful outcomes for the individual (Crane, 2005). Quality of life can be evaluated objectively (through day to day factual life circumstances or environmental contexts that make up favorable life conditions) and subjectively (through family and staff or more importantly through the person's own experience and satisfaction level) (Vreeke, Janssen, Resnick, & Stolk, 1997).

There is limited published research about individuals with mental retardation and the effects of anxiety on quality of life (Lunsky & Benson, 2006). One study by Picardi, Rucci, Girolamo, Santone, Borsetti, and Morosini (2006) assessed subjective quality of life, demographics, diagnosis and psychopathological symptoms of 1492 mentally ill patients, including schizophrenia, personality disorders, and mental retardation, at state residential facilities throughout Italy. The WHOQOL-Bref was used to assess quality of life, the Global Assessment of Functioning (GAF) to assess the individual's level of psychological, social, and occupational functioning, and the Physical Health Index (PHI) to asses the physical health status and the level of physical disability of the individual (Picardi et al., 2006). The WHOQOL-Bref is a self report instrument developed by the World Health Organization that explores various dimensions of quality of life. Questions are broken down into 4 domains (physical domain, psychological domain, social relationships, and environment).

> The four domains include the following facets: (1) physical domain: pain and discomfort, energy and fatigue, sleep and rest, mobility, activities of daily living, dependence on drugs and medical aids, and work capacity; (2) psychological domain: positive feelings, thinking, learning, memory and concentration, self-esteem, bodily image and appearance, negative feelings, and religion/spirituality/personal beliefs; (3) social relationships: personal relationships, social support, and sexual activity; (4) environment: physical safety and security, home environment, financial resources, health and social care, opportunities to acquire new information and skills, participation in and opportunities for recreation/leisure, physical environment and transport. (Picardi, et al., 2006, pp. 373)

Domain scores range from 0 to 100, with higher scores indicating better QOL. Although this questionnaire was designed as a self-report instrument, it can be modified based on level of assistance the individual requires (Picardi et al., 2006).

The researchers used multivariate analyses to determine the relationship between select patient characteristics and WHOQOL-Bref scores and found that individuals with mental retardation who have depression or anxiety disorders report significantly lower levels of physical and psychological QOL than individuals without those disorders (Picardi et al., 2006).

According to Bramston & Fogarty (1995) each individual evaluates stressful situations differently based on his or her perception of the experience and ability to cope with the experience. When an individual is unable to effectively cope with a stressful

situation, the situation can be perceived as a threat to her/his well-being (Bramston & Fogarty, 1995). Researchers believe that if stress and anxiety triggers can be identified and decreased, then an individual's quality of life can be improved (Janssen, Schuengel & Stolk, 2005; Picardi et al., 2006).

Because the author found minimal published research on the use of physiological measures on quality of life in individuals with mental retardation, she included research conducted with other populations. These studies provide an understanding of the types of programs that could have the potential to impact the quality of life of persons with mental retardation. Hui et al. (2006) compared two behavioral relaxation programs, progressive relaxation and I, for their effectiveness on positively changing physiological measures related to anxiety and the impact of the interventions on quality of life in persons with cardiac problems. The study took place in the outpatient occupational therapy unit at a hospital in Hong Kong. There were a total of 59 subjects who completed the study who were medically stable, cognitively functional, and had motor impairments that did not impede participation in the relaxation activities. Assessment measures included demographic and clinical data, heart rate and blood pressure, quality of life, anxiety, and general health. Quality of life was measured using the Chinese versions of Short Form 36 (C-SF36) of the quality of life assessment, which measures eight domains of three aspects of health: functional status; well-being; and health transition. The eight domains were: Physical function, Role disruption caused by physical difficulties, Role disruptions caused by emotional difficulties, Social functioning, Mental health, Vitality, Perception of general health (GH), and Body pain. The State-Trait Anxiety Inventory (C-STAI)

measured both state and trait anxiety. The General Health Questionnaire (C-GHQ-12) measured the general psychological status of an individual. Using a Chi-square test, results showed that progressive relaxation significantly decreased systolic and diastolic blood pressure and heart rate, as well as decreased anxiety ratings, and increased the mental health aspect of the quality of life questionnaire. Also, *qigong*, was effective at lowering systolic blood pressure, anxiety ratings and improving scores on seven out of eight domains of the quality of life scale. Researchers concluded that both progressive relaxation and *qigong* exercises improved quality of life in reference to physiological measures of blood pressure and heart rate (Hui et al, 2006). This study supports the use of relaxation techniques to improve quality of life and reducing anxiety.

The first section of this literature review provided support for the use of relaxation in reducing stress and linked stress reduction to quality of life (Campo, Sharpton, Thompson, & Sexton, 1997). If relaxation techniques could be effective in reducing stress and increase quality of life, would care providers of a person with mental retardation teach these techniques?

Evaluating the Value of Interventions using Social Validity

Relaxation techniques may improve the quality of life of persons with mental retardation if they are used with the population. Because persons with mental retardation often interact with care providers, one way to increase the utilization of this type of intervention is to gain acceptance by the care providers. Kurt and Tekin-Iftar (2008) suggest that both the effectiveness of an intervention and its social validity aspects are important when selecting appropriate procedure. Social validity assesses the social

acceptability of an intervention program (Kazdin, 1977) by asking how staff feel a treatment might affect the life of the participant and if they feel the particular area of research is meaningful for the participant (Francisco & Butterfoss, 2007). If a treatment is socially valid and has positive behavioral outcomes, then the treatment is more likely to be adopted and implemented by others (Francisco & Butterfoss, 2007).

Social validity is often assessed by people who would be responsible for implementing the particular intervention with the specific population. A study by Kurt and Tekin-Iftar (2008) compared the effectiveness and efficiency of constant time delay and simultaneous prompting procedures with an embedded instruction format on the acquisition of various leisure skills by pre-school students with autism. Results showed that both treatments were effective at teaching leisure skills to three out of four children in the study. At the end of the study, instructors and professors who taught children with mental retardation at universities in Turkey were provided with a packet of information and asked about the importance of the goals of the study, the acceptability of the interventions used, and the importance of the results of the study. Eleven people participated in the social validation questionnaire and they all reported that the goals of the study were important. Nine of them agreed that teaching leisure skills would contribute to the quality of life and life satisfaction of the children. Ten participants reported they would use embedded techniques in their classrooms and seven participants reported that this technique would be convenient practice to use in an inclusion setting. As stated previously, just because a treatment is effective does not mean it can be realistically applied to practice. Overall, the professors and instructors responded

positively to the social validation questions and felt the research was worthwhile and could be applied to the clinical setting (Kurt & Tekin-Iftar, 2008).

Another study by Green, Reid, Rollyson, and Passante (2005) evaluated an enriched teaching program compared to a baseline program for reducing resistance to teaching and accompanying negative affect among three people with profound multiple disabilities. Results indicated that the enhanced teaching program decreased resistance and unhappiness during teaching sessions for all 3 participants. Following the study, staff familiar with the participants completed a social validity survey concerning the participants' receptiveness to the intervention, enjoyment of the program, ease of administration and preference of the intervention. The majority of staff reported the participants liked and enjoyed the enriched teaching. The ease of administration was reported to be between "neither easier nor harder" than the baseline program and "a whole lot easier." All teachers reported they would rather carry out the new teaching program than the baseline program (Green et al., 2005). Based on the Kurt and Tekin-Iftar (2008) and the Green et al. (2005) studies, the study reported in this thesis assessed social validation by asking staff familiar with the participant about the importance, relevance, and practicality of the study's hypothesis and findings.

Social validity can also be evaluated by the participants themselves. A study comparing the isolated effects of a memory training technique and two types of performance feedback (i.e. digits correct and incorrect per minute) on sixth grade students' mathematical fluency and accuracy used student report to assess social validation (Codding, Eckert, Fanning, Shiyko, & Solomon, 2006). Social validity of the

intervention was assessed by the students using the *Acceptability Assessment-Student Version* (Eckert, 1999). A verbal description of the intervention was provided and then a 4-point rating scale was provided, with a 4 indicating "liked intervention very much". All participants rated each intervention favorably (*M*=3.33) indicating they liked the interventions (Codding et al., 2006). This approach provided insight into how the participants themselves perceived the intervention and which they thought was most effective. For the current study, staff were surveyed because relaxation strategies are not typically self-taught by individuals with mental retardation and therefore would need to be taught by the staff. Therefore the author decided that the social validity that was most useful was that assessed by the staff.

Anxiety Research and Physiological Measures Related to Anxiety

According to the Merck Manual (Beers, Porter, Jones, Kaplan, & Berkwits, 2006), "anxiety is a distressing, unpleasant emotional state of nervousness…often accompanied by physiological changes and behaviors similar to those caused by fear" (p. 1672). Anxiety arouses an individual's sympathetic nervous system and changes physiological measures including increasing muscle tension (Hoehn-Saric & McLeod, 2000), heart rate (pattern of rising and falling beats) and the cycle of inhaling and exhaling (Schwartz & Andrasik, 2003). During high stress situations as well as everyday situations, an individual may feel tense, short of breath, and have increased perspiration (Hoehn-Saric & McLeod, 2000). Moderate levels of anxiety can be good for increasing attention or coping behaviors. When anxiety becomes severe, however, it can be counterproductive and interfere with functioning (Hoehn-Saric & McLeod, 2000).

Heart rate is one of the most commonly used indices of arousal because it is easy to measure. Freeman, Homer, and Reichle (1999) explored the relationship between increased physiological measures and problem behaviors in two individuals with severe mental retardation and multiple problem behaviors. Heart rate was recorded every 15 seconds using a chest belt. The researchers gathered baseline data during which the participants acclimated to the equipment and researchers observed them for problem behaviors. Heart rate was then measured during a fixed period where the participant was video-recorded during a time when problem behaviors were likely to occur, the activities occurring were highly predictable, and the activity required motor movement. For participant number one, a significant increase in heart rate across sessions occurred with an increase of 6 heartbeats per minute. Statistical significance was set at $\alpha=0.001$ or $\alpha=0.05$. Problem behaviors reported were self-biting, aggression, and disruptive behaviors. There was, however, a low likelihood of increased heart rate in the 15 seconds preceding a problem behavior. For participant number one, there was a significant probability of heart rate increase following self-biting and aggressive behaviors, compared to disruptive behaviors. Results also revealed an abnormal cyclical pattern in heart rate for participant number one ranging from an average of 60 beats per minute to 111 beats per minute over a 9-day period. There was also a change in the level of problem behaviors on high versus low average heart rate days. When his heart rate was low, there were higher levels of problem behaviors compared to when his heart rate was high. On low average heart rate days, there was a higher significant probability of heart rate increase for self-biting and disruptive behaviors. During high average heart rate

days, there was a lower probability of heart rate increase for self-biting and disruptive behaviors. For participant number two, there was a significant increase in heart rate of 7 beats per minute across sessions. Results showed an increase in heart rate during and after finger biting and slapping, however analysis showed no increase in heart rate prior to these behaviors as seen with participant number one. For participant number two, although the slapping hitting behavior required a larger amount of physical exertion, there was a low probability of heart rate increase. A significant probability of heart rate increase was found following both finger biting, requiring low physical exertion, and slapping, requiring higher physical exertion (Freeman et al., 1999).

In the Freeman et al. study, heart rate was shown to increase in reaction to periods of high agitation. The study investigators concluded that individuals who consistently react to situations and events with increased physiological arousal may be more anxious (Freeman et al., 1999). The findings of Freeman et al. provide a foundation for the current study's comparison of physiological measures over time as a measure of anxiety.

A study by Hartley and MacLean (2005) assessed stress, coping skills, perception of control, and psychological distress of 88 adults with mild mental retardation. The self-report Lifestress Inventory was used to assess daily events or life situations that people with intellectual disabilities have reported to be stressful. Coping strategies were assessed through the sentence completion stem ''When I have this problem, I...'' Psychological measures included the Birleson Depressive Short Form Self-Rating Scale to evaluate depressive symptoms and the Glasgow Anxiety Scale for People with Intellectual Disabilities to assess self-report measures of anxiety. To assess perception of

control, participants used a 4-point Likert scale to answer the question "Was that situation one that you could control or do something about?'' for every stressful event identified on the Lifestress Inventory. The average number of stressful events experienced was 10.53 out of 30 daily life situations, and the mean rating of stress impact was 2.84 on a 4 point scale. Stressful events reported to occur most frequently were Negative Interpersonal Relations stressors and Coping stressors. The stressful events with the highest mean stress impact values included getting along with supervisor/staff, relationship with family, and choosing what to do with free time. A Pearson product-moment correlation indicated that stress impact was positively correlated with psychological distress. The majority of participants (69.3%) reported using all active, distraction, and avoidant coping strategies to deal with stressful events, and only a small number (4.5%) reported using only one type of coping strategy. Bonferroni-corrected Wilcoxon related-samples comparisons indicated that the use of active coping was greater than the use of avoidant coping ($M = 0.25$, $SD = 0.19$) and distraction coping ($M = 0.18$, $SD = 0.16$). Bonferroni-corrected paired-samples t tests revealed that active coping was significantly higher for General Worry than for Negative Interpersonal Relations stressors and higher for Coping stressors than for Negative Interpersonal Relations. Bonferroni-corrected paired-sample t tests revealed that avoidant coping was significantly higher for Negative Interpersonal Relations than for General Worry stressors and Coping stressors. Perceptions of control were positively related to active coping, and negatively related to avoidant coping. Active coping was related to less psychological distress when the individual perceived a higher control of a situation. The implications of

this study suggest that decreasing stress- inducing situations, increasing accurate perceptions of control, and increasing active coping skills may reduce psychological distress among people with mild mental retardation (Hartley & MacLean, 2005). The current study investigated two types of coping techniques that can be used by a person with mental retardation during stressful situations and the researchers chose the techniques based on their potential for active coping and potential to increase a sense of control in the individual. Specifically, the techniques needed to be simple to learn, accessible and available to the individual, and acceptable to the care providers.

Relaxation Techniques and Anxiety

Research indicates that relaxation techniques that promote a passive and focused state of mind, such as guided imagery, progressive muscle relaxation, deep breathing, diaphragmatic breathing (Smith & Jackson, 2001), paced respiration (Schwartz & Andrasik, 2003), and relaxation training can decrease anxiety in a number of populations. In order to determine which of these techniques might be a reasonable intervention for the population included in this current study, the researcher reviewed the literature on five techniques.

Guided imagery is the use of verbal instruction for relaxation and breathing techniques as well as descriptions of pleasing images (León-Pizarro et al., 2007). Because the author found no published research concerning the use of guided imagery with persons with mental retardation, she reviewed studies using guided imagery with other populations. A study about the anxiety of cancer patients by León-Pizarro et al. (2007) evaluated the efficacy of relaxation techniques and guided imagery with 66

patients undergoing cancer treatment during hospitalization. The study group was given a cassette tape to listen to at home and at the hospital with instructions on head to toe relaxation and breathing techniques, as well as descriptions of pleasing images individualized to each person. The researchers found that the relaxation techniques and guided imagery significantly reduced levels of anxiety and depression. This reduction led to enhanced quality of life as evaluated by the two scales of the Cuestionario de Calidad de Vida QL- CA-Afex (CCV). There was a statistically significant decrease in the Body Discomfort Scale for the study group compared to the control group, and a reduction in the Psychosocial Disorder Scale although not statistically significant (León-Pizarro et al., 2007).

Progressive muscle relaxation was originally developed as a way of reducing anxiety by teaching individuals to relax their muscles. This leads to a reduction in muscle tension and then a decrease in measures of physiological arousal associated with muscle tension. This reduction can help decrease anxiety and increase an individual's sense of well-being (Paterson, 1987). Progressive relaxation (PRT) is a relaxation technique that has been studied with persons with mental retardation (Lindsay et al., 1989).

Utilizing muscle tension/release, PRT has been found to indirectly reduce autonomic arousal related to anxiety. PRT consists of tensing certain muscle groups above normal levels, and then releasing that tension. For example, a participant would be instructed to focus his/her attention on his/her dominant hand and forearm, and make a fist while allowing his/her upper arm to remain relaxed (Bernstein & Given, 1984).

Lindsay et al. (1989) compared an abbreviated form of PRT (abbreviated as APR) to a behavioral relaxation technique (BRT) on reducing anxiety defined by the Behavioral Anxiety scale in individual and group settings for persons with moderate to severe mental retardation. They found that the Individual-BRT group was significantly less anxious ($P<.01$) than the Group-APR group, the Individual-APR group, and the control group. The Group-BRT showed significantly less anxiety than the control group, and the Individual-APR group showed less anxiety than the control group. The post-treatment period showed that the Individual-BRT group had significantly less anxiety than the Group-APR group, the Individual-APR group, and the control group. The Group-APR group showed significantly less anxiety than the control group, and the Individual-APR group showed significantly less anxiety than the control group. There were significant decreases between baseline and post-treatment measures for the Individual-APR group and the Group-APR group. Although the BRT was shown to have a greater impact on anxiety, APR was still shown to reduce anxiety levels compared to the control group. It was noted that the complexity of the PRT may have affected the results because participants had to conceptualize internal tension and release behaviors, which may have been difficult for persons with severe learning difficulties (Lindsay et al., 1989).

One study investigated the relaxation effects of progressive muscle relaxation (PMR), yoga, and general breathing exercises (Smith, Goc, & Kinzer, 2001). Researchers used the Smith Intercentering Inventory to measure relaxation states, or R-States, after 70 college students had completed a PMR, yoga, or breathing session. R-States indicated different levels of relaxation the participant experienced throughout

different stages of the session; for example quiet (Mental Quiet), discomfort (Stress), at ease (At Ease/Peace), limp (Physical Relaxation), drowsy (Sleepy), energized (Energized), and rested (Rested). Based on significance level of 0.05, PMR was shown to elicit a feeling of Physical Relaxation, followed by a feeling of being At Ease, and finally feeling Energized. Yoga did not evoke any consistently ordered relaxation experiences. Breathing was found to elicit a feeling of being At Ease/Peace, followed by feeling Rested/Refreshed and Energized. It was concluded that the breathing exercise may rapidly reduce psychological tension and stress.

To and Chan (2000) investigated the effectiveness of progressive muscle relaxation at reducing aggressive behavior in persons with mild to moderate mental retardation. A squeeze toy was used to increase subjects' interest in learning and their understanding of the tension-release cycle. The total frequency of aggressive behaviors was reduced from 136 behaviors pre-training and 116 post-training, which represents a 14.71% decrease. After training, there was a noted decrease in the frequency of 10 behaviors, however an increase in 3 behaviors. With a level of significance level set at .05, there was no significant difference between the pre-assessment and post-assessment scores for all items and the total scores. This lack of significant improvement was attributed to the possibility that there was not a transfer of learning. It was noted that although participants were able to practice muscle relaxation during the testing session with multiple cues from the researcher, they were unable to generalize the technique for use in other life situations.

Calamari, Geist, and Shahbazian (1987) used a treatment package design consisting of progressive muscle relaxation, auditory electromyographic (EMG) biofeedback, modeling, and positive reinforcement to teach a relaxation strategy to 32 high and low functioning persons with developmental disabilities. Physiological measures of electromyographic recordings and peripheral skin temperature were collected as a measure of relaxation. Because self-reported measures of anxiety are difficult to use with those with severe mental retardation, the researchers chose to use the Relaxation Training Rating Scale to measure specific components of the relaxation behaviors being taught to subjects. With significance level set at 0.05, a significant reduction in EMG levels was reported for the relaxation group. No significant effects were found for peripheral skin temperature. For the Relaxation Training Rating Scale difference scores, a significant difference was found between treatment and control groups with treatment group subjects relaxing more than the control group. The combination of techniques proved to be effective for calming individuals both physiologically and behaviorally (Calamari et al., 1987).

While the published literature discusses the use of multiple relaxation techniques with individuals, the author found no studies that included the population of persons with mild mental retardation. Pellino et al. (2005) attempted to reduce pain and anxiety in hip and knee replacement patients by providing a kit of relaxation tools with a radio/cassette tape player with earphones, a tape of soothing relaxing music, an audiotape that guided the patient through progressive muscle relaxation, a “stress ball” (soft squeezable ball), and a brief booklet with information about use of various forms of relaxation. A total of

65 patients were divided into Group 1 who received only pharmaceutical treatment and Group 2 who received pharmaceutical treatment and the relaxation kit. The State-Trait Anxiety Inventory for Adults (STAI) was used to assess state anxiety and trait anxiety preoperatively and only the State Anxiety scale postoperatively. A modified version of the Brief Pain Inventory (BPI) was used with postoperative patients to report pain ratings (now, worst, and least in past 24 hours) on a 0 (no pain) to 10 (worst pain possible) scale. Patients who were provided a kit used more nonpharmacological measures than those who were not provided a kit. In particular, music (n= 14), a relaxation tape (n= 12), a stress ball (n=12), massage (n= 8), and deep breathing (n=17) were used more by the kit group than the control group with a statistical significance of 0.05. There were no significant differences in postoperative pain intensity, control of pain, or anxiety between groups. The group that received the kit used significantly less opioids (M=19.06; SD=12.89) on postoperative day 2 compared to the control group (M=33.67; SD= 29.51). There were significant positive relationships between the intensity of pain and opioid. There were negative correlations between both worst pain and pain now and the ability to control and decrease pain. This means that higher levels of pain were associated with a decreased ability to control and decrease pain. Average postoperative state anxiety was significantly positively correlated with trait anxiety, worst pain and pain now, and opioid intake. This indicates that those with higher pain and opioid intake were more likely to have higher anxiety. Average postoperative anxiety were negatively correlated with the ability to control and decrease pain. This means that those individuals who were able to control and decrease their pain were more likely to have less anxiety (Pellino et al., 2005)

and that both the object manipulation and breathing techniques were useful tools for persons experiencing pain.

Stress balls have been used with persons with mild mental retardation. Waller et al. (2007) proposed the use of a stress ball as an alternative to fingernail biting for a boy with mild intellectual disabilities. Fingernail biting was defined by any time the participant was chewing his fingers in his mouth. The participant was given a stress ball to squeeze to replace fingernail biting. When he was observed with his fingers near his mouth, he was given a coded prompt from the teacher to squeeze the ball. He was also taught that he could squeeze the ball any time he felt nervous or anxious as a replacement for fingernail biting. Researchers recorded a baseline of fingernail biting and flicking, then introduced the stress ball, removed the ball, and introduced the stress ball again. They found that not only did the stress ball reduce the amount of fingernail biting from an average of 11.9 to 2.5 times a day, but when the ball was removed and the child no longer had an outlet for his anxiety, he resorted to verbal aggression and an increasing trend was noted in fingernail biting of 3.2 times a day (Waller et al., 2007). This study supports the use of adaptive strategies to manage anxiety in persons with intellectual disabilities.

The current literature describes three breathing techniques that appear to impact anxiety. They are deep breathing, diaphragmatic breathing, and paced respiration. Deep breathing involves taking a deep breath, holding it for a set count, and then exhaling slowly, whereas paced respiration teaches a patient to maintain slow breathing without holding one's breath (NIH, 1996). Diaphragmatic breathing is taking deep, even and

steady breaths, using the diaphragm, with minimum movement of the chest (Kaushika, Kaushika, Mahajana, & Rajesh, 2005).

Smith & Jackson (2001) compared breathing exercises and relaxation states. Participants were social service employees who performed a set of four breathing exercises. These exercises were stretching and breathing, diaphragmatic breathing, breathing through lips, and deep breathing (slow breathing). After performing an exercise for five minutes, participants were given the Smith Relaxation States Inventory to rate how they felt at that moment. Based on a significance level of 0.05, deep breathing had a statistically significant impact on relaxation states compared to all the other breathing exercises. Because few research studies have been conducted on the effects of breathing exercises on an individual with mental retardation, the current study applied the positive effects of slow breathing found in a different population to an individual with mental retardation.

A study by Biggs et al. (2003) compared breathing and focusing techniques on the ability to reduce anxiety in high and low anxious dental patients. Participants were given written instructions for diaphragmatic breathing and asked to sit in a room by themselves and follow the instructions to control their breathing. Researchers were looking at physiological measures of anxiety; whereby slower and deeper breathing was indicative of reduced anxiety. Based on significance level of 0.05, they found no significant reduction in anxiety for either method. A noted limitation for the diaphragmatic breathing was that no assistive equipment, such as a monitor to visualize breathing or

verbal cues, was used during the treatment and there was a lack of participant practice and mastery of the skill (Biggs et al., 2003).

McCaul et al. (1979) addressed physiological and psychological responses to threat in 105 male college students. Participants were separated into three groups: (a) Paced Respiration group who regulated their breathing at one half the normal rate, (b) Normal Regulation group who regulated their breathing at the normal rate, and (c) Control group who did not regulate their breathing rate while waiting to receive an electrical shock. There was also a subject group who were in a no-threat condition with no use of breathing techniques. Subjects in a no threat condition were not threatened with shocks, did not regulate their breathing, and were not provided with expectations. Based on a significance level of 0.05, electrodermal activity and heart rate measures showed statistically significant higher levels during the threat condition compared to the no-threat condition groups. These results indicate that the threat manipulation was effective in increasing subjects' physiological arousal and reported anxiety. It was found that the slow-breathing condition showed a significant decrease in finger pulse volume and electrodermal activity, and significantly slowed respiration rate compared to the other conditions. The results indicate that the threat manipulation was effective for increasing subjects' physiological arousal and reported anxiety, and the respiration manipulation was effective for decreasing physiological measures (McCaul et al., 1979).

The paced respiration technique is often accompanied by a rhythmic device so the individual can coordinate his/her breathing with the device. Slowing respiration through pacing was found to affect physiological measures by decreasing heart rate and

increasing skin temperature, in effect, lowering anxiety (Schwartz & Andrasik, 2003). In a study by Clark and Hirschman (1990) involving high anxiety alcohol-dependent males, participants were separated into a paced respiration group and an attention control group. Physiological measures were recorded and an anxiety self-rating scale was given at the beginning and end of each of the two sessions. During the first session, the paced respiration group listened to a series of audio-recorded tones for 10-minutes and was asked to inhale and exhale according to the tones. During the second session, they were asked to self-regulate their breathing according to the tones they had heard in the previous session. Self-reported measures of anxiety and skin conductance measures were reduced after the paced respiration procedure. When participants were asked to self-regulate, their measures more closely resembled the control group, indicating a need for external cueing for paced respiration and a longer training period. The researchers suggested that paced respiration should be studied in other populations who exhibit high levels of anxiety.

Justification for Current Study

The literature includes the following relaxation techniques: guided imagery, progressive muscle relaxation, deep breathing, diaphragmatic breathing, paced respiration, and relaxation training. Although guided imagery has been found to reduce anxiety in other populations, the current study's researchers believed that this technique required more abstract ideation than the subject population would be able to adequately perform. Because the research concerning paced respiration and deep breathing involving persons with mental retardation is so limited, the researchers decided to use

paced respiration to simplify the task and avoid asking the participant to “take a deep breath” and “hold the breath”. Because of the difficulty experienced by the participants in the To and Chan study of internalizing components of progressive relaxation, the current study’s researchers felt that a modified version of progressive relaxation should be used. Specifically the researchers chose to implement an object manipulation technique using a squeeze ball utilizing tension and release of hand muscles.

This study’s goal was to implement and improve upon strategies discussed in the current literature concerning anxiety-reducing techniques in persons with mild mental retardation and to further the base of knowledge. Therefore, the chosen interventions were a paced respiration technique and object manipulation technique.

Chapter Three: Methods

In the present study, researchers implemented a paced respiration technique and an object manipulation technique and compared their effects on physiological measures of anxiety for a person with mild mental retardation. The first hypothesis of this single subject design (SSD) was that paced respiration would be more effective than object manipulation at reducing physiological measures of anxiety. The second hypothesis was that staff would respond positively concerning the social validity of this study.

The methods section is organized by design, procedural integrity, researchers, setting and materials for the SSD, subject and consent, instrumentation for SSD, data for SSD, procedures for Nexus 10, paced respiration protocol, object manipulation protocol, social validity study, and data analysis.

Design

The research team consisted of a graduate student in occupational therapy (the author of this thesis), the faculty thesis director, and an occupational therapy staff member at the state residential facility where the participant in this study resides. For part one of the study, the researchers used a single subject alternating treatment design with one male participant. In single subject designs, the participant serves as his own control, so the participant is compared to himself (McReynolds & Kearns, 1983). A single subject design (SSD) was chosen because larger samples are difficult to manage in the natural setting. There is little research on the use of paced respiration specifically for persons with mental retardation. A SSD allowed investigators to focus on one individual, test procedures over repeated sessions and observe responses particular to that individual, which can produce valuable information

for future implementation with larger samples. A benefit of SSD is that the repeated implementation of a treatment enables investigators to control for threats to internal validity (Dattilo, Gast, Loy, & Malley, 2000).

The current study used an alternating treatment design (ATD). Alternating treatment designs compare two or more treatments to one another, with random alternations of treatment administration. The sessions were counterbalanced by randomly alternating treatments across sessions (Barlow & Hayes, 1979). In order to see significant differences, treatments were alternated over several occasions over time. A predetermined order for treatment sessions was computer generated by randomizing sessions with each treatment conducted an equal number of times. The treatment order can be found in Table 1.

Table 1: Schedule for Treatments by Session

Session #	Treatment
1	Baseline
2	Baseline
3	Baseline
4	Baseline
5	Training
6	Paced respiration
7	Object manipulation
8	Object manipulation
9	Object manipulation
10	Object manipulation
11	Paced respiration
12	Paced respiration
13	Paced respiration
14	Paced respiration
15	Paced respiration
16	Object manipulation
17	Object manipulation
18	Object manipulation
19	Paced respiration

The treatments in the present study were expected to produce immediate results (e.g. within minutes), which is a characteristic of alternating treatments designs. An example of a measure that may show immediate changes is blood pressure. Another characteristic of alternating treatments design is that the results or effects of the treatments are transient in nature, and do not last an extended amount of time.

Baseline data was collected for a few days prior to treatment, followed by several sessions of treatments allowing for changes in performance to become clear (Kazdin, 1980). A minimum of 5 sessions of each treatment was needed (Logan, Hickman, & Harris, 2008), and each treatment needed to be administered an equal number of times (Dattilo et al., 2000). For the current study, researchers administered 7 sessions of each treatment for a total of 14 treatment sessions. After the treatment phase, a best treatment phase occurred, which served as a test for multiple treatment inference. Multiple treatment interference is a combination of both treatments together having a confounding effect on the dependent variable, rather than a single treatment having an effect (Petterson & Loy, 2008). One treatment was chosen for implementation during the best-treatment phase based on analysis of the trend, level, and variability in the data. If the best treatment phase produced similar results to those in the treatment phase, then the researchers could be confident that there was no interaction between the treatments (Dattilo et al., 2000). Optimally, the best treatment data points should lie between the highest and lowest data points from the treatment phase, indicating little to no multiple treatment interference (Petterson & Loy, 2008). Data were collected 5-6 days a week depending on the availability of the researcher and the participant.

After each phase was completed, the next phase began the next session day. Sessions began between 10:58 and 11:27 AM each day for consistency.

Treatments were randomized across days, with one treatment administered a day. Although many studies using ATD administer all treatments within one day, there is precedence for administering one treatment each day. For example, Ahearn, Kerwin, Eicher, Shantz, and Swearingin, (1996) alternated treatments for food refusal. Children with developmental delays who had a history of food refusal were presented with either non-removal of a spoon or physical guidance depending on the feeding session each day. Researchers found that both treatments increased spoon acceptance, although one no more than the other (Ahearn et al., 1996).

Procedural Integrity

Procedural integrity data was collected during at least 33% of sessions for each treatment. The specific sessions were randomly selected and the researcher who is a staff member at the facility evaluated the experimenter's performance using the procedural reliability checklist. He was chosen because an outside observer would increase the participant's arousal level, thereby impacting the research. Procedural integrity was monitored for: a) correct setup of materials, b) correct attachment of physiological equipment, c) correct presentation of materials, d) correct delivery of experimental instructions, and e) accurate recording of time (Eckert, Ardoin, Daisey, & Scarola, 2000). Refer to Appendix A for procedural checklist.

Researchers

All sessions and the social validity study were conducted by a second year graduate student in the Department of Occupational Therapy at East Carolina University. A staff occupational therapy researcher was present at all sessions. He has been working at the state facility for 16 years and has experience working with persons with mental retardation. The graduate student had 2 years of developmental therapy experience with persons with autism and mental retardation. Both the staff occupational therapy researcher and the occupational therapy student were trained in the use of the equipment and in delivering the instructions for each treatment.

Setting and Materials for the SSD

The SSD study took place in the bedroom of the participant. The bedroom was chosen because it had the greatest amount of environmental control, compared to other areas of the house. The blinds in the bedroom were closed to limit distractions from the external environment. The participant sat in a chair with a pillow in his lap upon which to rest his hands, with the chair facing away from the bedroom door. A CD player was placed on the participant's bed, which was used for administering treatment directions to the participant. Previously recorded instructions were projected into the room. During the object manipulation intervention, the researcher kept the stress ball in her possession, out of sight of the participant until it was needed.

Subject and Consent

The participant for this study was a person with mild mental retardation living at a state-operated residential facility for adults with mental retardation. Inclusion criteria were:

1) a client living at the Center, 2) who had a diagnosis of mild mental retardation, 3) was independent in carrying out personal activities of daily living (PADLs), 4) was verbally expressive (so he/she was able to elect not to participate), 5) had documented signs of anxiety throughout his day, 6) was able to tolerate sensors placed on hands, feet, head, and around the waist, and 7) was able to learn new concepts. The staff occupational therapy researcher obtained written consent from the guardian of the participant in the study. The contents of the consent document were initially presented to the guardian by phone and questions from the guardian were answered. Then a copy was mailed to the guardian to be reviewed and signed. When the guardian returned the signed consent form, a copy of the signed consent form was sent to the guardian and the original kept by the investigators. The participant gave verbal assent to participate in the study. The consent form can be found in Appendix B. A monetary incentive of $0.50 was offered to the participant after completion of each session; however after the study began, he requested a $1 bill at every other session and his request was honored. The payment schedule can be found in Appendix C.

Instrumentation for SSD

Physiological responses were measured by a small portable unit called the Nexus-10. Wires with small sensors on their ends were plugged into the unit. The sensors were attached to the participant's body at the fingers, the upper forehead, and a band around the waist. A mildly adhesive medical tape was used to secure the sensors when necessary. The unit utilized Bluetooth wireless technology that sent the data to a nearby computer where it was stored so it could be reviewed and analyzed further (Mind Media B.V., 2006). The researchers could review the data during the session in graphic form and mark start and stop

times for each part of the session, and the occurrence of specific behaviors, interruptions, or other desired information as the data was collected. The Nexus-10 has "8 independent 24-bit AD converters…[supplying] higher bandwidth, more dynamic range (200,000 microvolts) and better resolution. The Nexus-10 was designed with a 1 KHz digital input channel that clinicians can use to indicate digitally when an event has occurred" (Stens Corporation, 2006, More Precision, ¶ 3). As the responses were collected they were transferred wirelessly to a laptop computer. An image of the Nexus-10 unit is available in Appendix D.

Data for SSD

The physiological data collected were electro dermal activity (EDA), electromyography (EMG), skin temperature, respiratory rate (RR), and heart rate (HR). EDA is a measure of skin resistance or conductance that changes in relation to psychological events. When sweat glands are activated, they form a low resistance electrical pathway, which increases skin conductance. In other words, as the number of sweat glands activated increases, the level of skin conductance increases. So, higher levels of skin conductance indicate higher anxiety and lower levels of skin conductance indicate lower levels of anxiety. EDA was measured using two silver/silver chloride sensors electrodes attached to two fingers via Velcro loops with wires leading to the Nexus-10. The EDA sensors were 1 cm in diameter. EMG measures an electrical aspect of muscle contraction through surface sensors that contact the skin above the muscle. EMG sampling rate was 32 samples per second and the raw signal was passed through a 100-200 Hz band pass filter. This particular filter is commonly used to eliminate ECG artifacts (Cram & Kasman, 1998). The

silver/silver chloride sensors used for monitoring EMG activity were 3.2 cm x 2.2 cm. Information was transmitted to the Nexus 10 by cables connecting the EDA and EMG sensors to the Nexus. The surface electrodes were small metallic discs with wires that attached to the Nexus10. The metallic discs snapped onto adhesive pads that attached to the participant's forehead (Schwartz & Andrasik, 2003).

Skin temperature measured sympathetic arousal. When the sympathetic system is aroused, peripheral vasoconstriction occurs, reducing blood volume and cooling the skin (especially in the fingers and toes). So a lower skin temperature indicates higher anxiety and higher skin temperature indicates lower anxiety. Skin temperature was measured using a small electrical probe (thermistor) that was attached to the fingertip using one layer of paper tape with a cable that was connected to the Nexus-10. Respiratory rate measured how many breaths occurred in a minute. Respiration was measured using an elastic band that fit around the participant's waist, with a wire that attached to the Nexus-10. Heart rate was measured using a blood volume pulse sensor that attached to a finger via a finger clip. The BVP "monitors the relative blood flow in the hands (fingers) with near infrared light. This method is also known as photoplethysmography" (Stens Corporation, 2009, ¶ 1). As with the other sensors, information was transmitted through a cable connection between the sensor and the Nexus and then wirelessly to the computer.

Procedures for SSD

Approval for all procedures was obtained from the University and Medical Center Institutional Review Board (UMCIRB) at East Carolina University and the Center's Research Review Committee. UMCIRB approval form can be found in Appendix E. The staff occupational therapy researcher obtained written consent from the participant's legal guardian for participation in this study. The student and staff occupational therapy researchers visited with the participant prior to beginning baseline phase to introduce the occupational therapy student and the study.

A series of 4 baseline sessions were conducted (Nourbakhsh & Ottenbacher, 1994). The participant was connected to the sensors for the Nexus-10, then given 5 minutes to acclimate to the equipment, and then data was collected for 10 more minutes. Every attempt was made to keep the bedroom environment as typical as possible including noise level and movement in the room, with the bedroom door shut. The participant was positioned upright in a backed chair facing away from the door at the foot of his bed. The occupational therapy student researcher was positioned in front of the participant to the left of the bed and the occupational therapy researcher was positioned behind the participant to the right of the bed.

After the 4 baseline sessions were completed, the participant began technique training during the next scheduled session. First, the participant was introduced to the object manipulation technique, which consisted of pre-recorded verbal directions to squeeze a ball according to the protocol described later. Then the participant was taught the paced respiration technique, consisting of pre-recorded verbal directions to control breathing according to the protocol described later. Initially, when the participant could perform each

technique 3 times consecutively with minimal prompting, training would end. During the actual training session however, the participant was able to follow the pre-recorded cues with little to no verbal cues from the researchers, completed each technique one time, then declined the option to practice more times. This session was completed in the participant's bedroom with the door shut. No physiological measures were collected in an attempt to not initially overwhelm the participant. The purpose of this session was to introduce the techniques, not collect data. The participant was already exposed to the Nexus-10 during the baseline phase.

The training for both treatments was conducted on the same day. After the training session, the treatment phase began with only 1 treatment administered each session. Each treatment session began with the sensors being attached, then a 5-minute period of acclimation in which the researcher asked the participant to sit quietly. This acclimation period allowed the participant to adjust to the equipment attached. Stabilization was not necessary during this acclimation period; it was simply a rest period for the participant (Clark & Hirschman, 1990; McCaul et al., 1979). Next, the participant listened to the technique directions and then engaged in the technique for approximately 2 minutes. After completion of the treatment, measures continued to be collected for 10 minutes (Poppen, 1988). This 10-minute period was referred to as the post-treatment period. Based on a study by Poppen (1988), researchers believed that 10 minutes was an adequate amount of time for change in measures to occur. Sessions were based on the randomized schedule previously mentioned. Treatments were administered for a total of 14 sessions, which included 7 sessions for each treatment (Dattilo et al., 2000). After the treatment phase,

researchers compared trend, variability, and levels in the data to determine the most effective treatment, however neither treatment was found to be more effective than the other. Therefore since one treatment had to be chosen, the object manipulation treatment was implemented during the best treatment phase for 5 additional sessions (Logan et al., 2008). Efforts were made to standardize each session to minimize random error.

The physiological data was recorded in 1 second intervals over time and was expected to have variations because of the length of time. Although respiration, EDA, skin temperature and EMG were recorded and the data stored, heart rate was selected as the primary measure to determine treatment effects. Researchers chose heart rate because it is a reliable measure of physiological anxiety (Croft, Gonsalvez, Gander, Lechem, & Barr, 2004; Mezzacappa et al., 1997). Electro dermal activity is often used as an indicator for anxiety (Croft et al., 2004), however because the participant presented with minimal variability in his electro dermal levels during study sessions, researchers concluded that this would not be an effective measure. EMG recordings varied due to movement of the subject. An image of recording data can be found in Appendix F.

Procedures for Nexus-10

After the participant was seated, the researcher cleaned the participant's forehead with an alcohol wipe. Then the respiration band, EDA, HR, skin temperature, and EMG sensors were connected in that order (see checklist in Appendix G for specific locations). Due to the inexperience of the occupational therapy student with research and the Nexus-10, the staff occupational therapist was present at all sessions to ensure the safety of both the researcher and the participant.

Paced Respiration Protocol

Training. The paced respiration technique consisted of pre-recorded instructions played from a CD player and verbal cues for clarification from the researcher (Clark & Hirschman, 1990). When the CD player was started, the researcher asked the participant if he could hear the instructions and the volume was set to the necessary level. The CD had pre-recorded verbal cues of "breathe in" and "breathe out" that changed approximately every 4 seconds, resulting in a paced rate of approximately 7 breaths per minute (McCaul et al., 1979). Approximations were given because researchers did not want to interrupt the participant in mid-cycle. A person blinded to the research study recorded the instructions for the techniques on the CD. According to Sterling, Gottheil, Weinsterin, and Serota (1998) and Zlotnick, Elkin, and Shea (1998), gender matching was not necessary for the voice recording. Although the person who recorded instructions was a male, his selection was based on convenience and his background in voice recording, not on gender matching. The paced respiration instructions lasted 2 minutes (Joseph et. al., 2005; McCaul et al., 1979).

Training consisted of the participant listening to the CD recording without the use of headphones with demonstration from the occupational therapy student as needed while the staff occupational therapist observed. The researcher breathed with the participant during the training phase to serve as a reference. If the participant did not understand what was asked of him, the researcher provided extra explanation and time for practicing. The

participant was asked to place his feet on the floor while sitting in the chair. The purpose of the training session was for the participant to be introduced to the paced respiration using prompts when needed for explanation, not to be able to do the task independently.

Data collection. The researcher brought the participant into his bedroom and he sat in a chair facing away from the door to the bedroom. The researcher told the participant he would be listening to a CD that asked him to breathe in and out. The researcher asked if the participant was ready to start, then pressed play and the participant listened to the CD recording in its entirety. When the audio recording ended, the researcher asked the participant to sit quietly while data continued to be collected.

Object Manipulation Protocol

Training. The object manipulation technique consisted of the participant manipulating a squeeze ball, requiring the participant to contract/relax his upper extremity muscles (Chapman et al, 2006). The squeeze ball was intended to relieve stress through a steady squeezing and releasing of a ball (Chow, 2001). Progressive relaxation also utilizes tension and relaxation of muscles, however throughout the body, not just the hands. For purposes of this study, researchers used the design described by the National Health Committee (1998) for progressive relaxation of squeeze for 7 seconds and release for 10. Using pre-recorded verbal cues of "squeeze, squeeze, squeeze, open" on a CD recording, the participant slowly squeezed the ball for 7 seconds then slowly released for 10 seconds and then repeat this process for a approximately 2 minutes. The same person blinded to the research study that recorded the instructions for the paced respiration technique, recorded the instructions for the object manipulation technique on a CD recording. The participant

squeezed the ball approximately 4 times a minute. Approximations were given because researchers did not want to interrupt the participant in mid-cycle. A time of 2 minutes was given for consistency with the paced respiration technique.

Training consisted of the participant listening to the CD recording without the use of headphones with demonstration from the occupational therapy student researcher. The participant was asked to place his feet on the floor while sitting in the chair. The participant was given a choice of 2 different squeeze balls and selected a gel-filled textured ball, pictured in Figure E. The purpose of the training session was for the participant to perform the object manipulation technique using prompts when needed for explanation, not to be able to do the task independently.

Data collection. The researcher brought the participant into his bedroom and he sat in a chair facing away from the door to the bedroom. The researcher told the participant he would be listening to a CD recording that would ask him to squeeze a ball. The researcher revealed the squeeze ball and demonstrated how to hold the ball. The researcher offered the squeeze ball to the participant and asked him to position his hand with palm facing up. After asking if the participant was ready, the researcher pressed play and the participant listened to the CD recording in its entirety. After the CD ended, the researcher asked the participant to sit quietly.

Social Validity Study

Eight staff members at the state residential facility completed a survey about the social validity of the use of the relaxation techniques for persons with mild mental retardation. The inclusion criteria were: 1) staff who have worked at the Center for over 1

year, and 2) interact with the research participant on a weekly basis. Exclusion criteria were third shift developmental technicians who interacted with the research participant because they were present primarily when he is sleeping. Staff questioned included professional staff (e.g. teacher, psychologist, nurse) and direct care staff (e.g. Developmental Technicians).

At the end of the SSD study, a questionnaire that included a cover letter with a brief summary of the purpose, methods and findings of the study and a series of questions about the usefulness of this research (Francisco & Butterfoss, 2007) was presented to the staff. The staff occupational therapy researcher distributed envelopes with copies of the questionnaire and a researcher addressed stamped envelope so staff could return their responses. Staff meeting the inclusion criteria voluntarily completed the questionnaire and returned it using the addressed stamped envelope.

Responses for questions used a 5-point Likert scale response format ranging from 1 (strongly disagree) to 5 (strongly agree). The questions were: 1) Teaching relaxation techniques to reduce anxiety in persons with mild mental retardation is a concern of staff and caregivers**,** 2) I feel that relaxation techniques can be used to reduce anxiety in persons with mental retardation, 3) I would implement a relaxation technique with my residents if I had research to support its effectiveness, 4) Teaching a relaxation technique to reduce anxiety could contribute to the quality of life for a person with mild mental retardation. The results for each question were summarized and reported using descriptive statistics (Kurt & Tekin-Iftar, 2008).

Data Analysis

The Nexus-10 recorded the physiological data of heart rate, respiration rate, EDA, EMG, and skin temperature and stored it into a computer file. During each treatment session, the Nexus-10 recorded physiological data from the onset of the acclimation period to the end of the 10 minute post-treatment period. These data were recorded every second with a sample rate per second of 2048 SPS (samples per second) for EMG, 32 SPS for EDA, 32 SPS for temperature, 128 SPS for BVP (blood volume pulse), and 32 SPS for respiration. This data was imported into Microsoft Excel for statistical analysis and the creation of line graphs (Dattilo et al., 2000).

Visual analysis. Visual analysis and graphic representation have commonly been used as method of evaluating data in single subject designs (Kazdin, 1984; Ottenbacher, 1986). Data were evaluated by examining changes in level, changes in trend and changes in variability within each session as well as across sessions (Dattilo et al., 2000). A change in level refers to the amount of change of the mean values from one phase to another (i.e. from the acclimation period to the post-treatment period). Variability is a measure of the degree of fluctuation or spread of the data points in a phase. Standard deviation is commonly used as a measure of variability. Trend refers to the direction pattern of a series of data. The steepness of this trend is referred to as the slope of the trend line (Ottenbacher, 1986). Each session was analyzed individually and HR data were plotted on a graph for each session using a simple line graph (Barlow & Hayes, 1979). After the data were plotted, the data points were connected to form a data path. For each graph, the abscissa scale, or *x*-axis, represented the session number. The ordinate scale, or *y*-axis, represented the physiological

measure being plotted on the graph. A trend line was created using Excel for the acclimation, treatment, and post-treatment periods. In addition to each session being analyzed individually, each treatment was analyzed as a whole. The 2-minute treatment period during each session was analyzed to determine whether there was difference in physiological measures while the participant was performing the treatment. The 10-minute post-treatment period was analyzed to determine whether the treatment effects were maintained after the treatment was ended.

The researchers examined changes in levels during the 2-minute treatment period by taking a 5-second interval mean at the beginning and 5-second interval mean at the end of the treatment period and subtracting them. These level changes were then graphed. A drop in heart rate indicated a positive change and a therapeutic treatment. An increase in heart rate indicated a negative change and a non-therapeutic treatment. For each session, fifteen 1-second recordings were averaged during the 2-minute treatment and an average of those averages was calculated. The standard deviation was then calculated for these eight 15-second averages. The 2-minute averages were graphed for the object manipulation and paced respiration techniques. A trend line was added to the graphs to determine direction of the data. It should be noted that the object manipulation protocol ran 13 seconds longer than the paced respiration. The researchers looked at the number of breaths during the treatment period and reported on the variances.

There were many ways to look at whether the treatment effects were maintained. For each session, sixty 1-second recordings were averaged during the 10-minute post-treatment period and an average of those averages was calculated for the 10-minute post-

treatment. The standard deviation was then calculated for these ten 60-second averages. For each session, thirty 1-second recordings were averaged during the 5 minute acclimation period and an average was calculated for the whole 5 minutes. The standard deviation was then calculated for these ten 30-second averages. The researchers looked at the change from the average of the acclimation period to the average of the post-treatment period.

Statistical analysis. In addition to visual inspection, the data across phases were analyzed and compared through descriptive statistics. To determine statistical significance, a t-test, together with a confidence interval, was performed to compare treatment effects of HR averages for each treatment. The data used to calculate the t-test was the differences found between the acclimation period and post-treatment period for each treatment. Due to the small sample size, the t-test cannot be generalized to all persons with mental retardation.

Chapter Four: Results

Techniques

The current study compared the effects of a paced respiration technique and an object manipulation technique on physiological measures of anxiety for a person with mild mental retardation. The first hypothesis was that paced respiration would be more effective than object manipulation at reducing physiological measures of anxiety.

The participant was a male with mild mental retardation in his early thirties with a psychiatric disorder of intermittent explosive disorder/impulsive control disorder. According to his psychologist, he had anxiety-related behavior problems. He was prescribed Haldol, Seroquel, and Tegretol by his physician for behavior problems.

Table 2 displays the summary of HR levels, variability, and linear least squares trend analysis for the acclimation, treatment, and post-treatment periods by session. The level is represented by the average HR, variability by the standard deviation (SD), and trend by the slope either decreasing (-) or increasing. The acclimation period showed a decreasing trend in HR for 37% of the sessions. There was a decreasing trend during the actual treatment for 43% of object manipulation sessions, 28.5% of paced respiration sessions, and 60% of object manipulation best treatment sessions. There was a decreasing trend during the post-treatment period for 57% of the object manipulation sessions, 100% of the paced respiration sessions, and 60% of the best treatment sessions. As seen in Table 3, respiration rate fluctuated between 13.5 and 16 each session, except for the paced respiration session, which had a respiration rate of 7 during the treatment

period. Figure 1 provides a sample image of this data graphically by displaying 30-second intervals of HR for the first object manipulation session.

Table 4 displays descriptive statistics for the average HR during the 5 minute acclimation period minus the average HR during the 10-minute post-treatment period as well as treatment changes within the session for HR and temperature. The means, SD, and slope of the trend lines are provided in this table. Both the paced respiration and object manipulation techniques were shown to slightly lower HR. The mean decrease in HR from the 5-minute acclimation period to the 10-minute post-treatment period was 4.06 (SD 1.36) beats per minute (bpm) for the object manipulation and 2.67 (SD 2) bpm for the paced respiration. The object manipulation best treatment sessions were also shown to be effective in lowering HR by3.29 (SD 1.08) bpm. A change was also shown during the treatments themselves, with a difference between the first 5 seconds and last 5 seconds for paced respiration of 5.47 (SD 5.26) bpm, 1.04 (SD 2.19) bpm for the object manipulation, and 3.28 (SD 5.49) bpm for the best treatment. There was no significant change in temperature throughout. EMG data could not reliably be reported due to interference in the data during participant movements. There was less than a .05 range in EDA levels in each session.

As seen in Figure 2, the object manipulation technique produced a higher difference between the HR averages of the 5-minute acclimation period and the HR average of the 10-minute post-treatment period and revealed an increase trend. Sixty percent of the object manipulation best treatment sessions were between the highest and lowest data points from the object manipulation treatment phase, indicating moderate

multiple treatment inference. As seen in Figure 3, there was a slightly higher difference in HR during the paced respiration treatment period, though not statistically significant. Eighty percent of the object manipulation best treatment sessions were between the highest and lowest data points from the object manipulation treatment phase, indicating minimal multiple treatment interference. Figure 4 represents the mean HR during the treatment administration for each session indicating a range in HR from 79.49 to 96.84 bpm. As seen in the box plot in Figure 5, although both treatments reduced HR, the object manipulation technique was shown to reduce HR slightly more than the paced respiration when comparing the 5-minute acclimation period to the average HR during the 10-minute post-treatment period. Figures 6 shows that the acclimation periods for both treatments produced similar results (PR mean=89.37, OM mean=89.42), while Figure 7 shows that the object manipulation technique had a slightly lower heart rate average during the post period (PR mean=86.99, OM mean =85.36).

A Welch two-sample t-test was conducted to determine whether there was a significant difference between the HR of the two treatment techniques. With α set at 0.05, the two-sample t test was not significantly different between treatments, $t(11.6) = 1.44$, $p = 0.18$, with a confidence interval of (-0.72, 3.50). One-sample t tests were also conducted for the paced respiration technique, object manipulation technique, and the object manipulation best-treatment. There was a significant difference between the acclimation period and post period for paced respiration, $t=3.26$, $p=0.02$, with confidence interval (0.54, 4.22), object manipulation, $t=7.87$, $p=0.0002$, with confidence interval of

(2.80, 5.32), and object manipulation best-treatment t=6.81, p=0.002 with confidence interval of (1.95, 4.63).

Observations

The temperature in the room ranged from 71 to 81° F. For 79% of all sessions, the participant had his head down. Based on observation, the researchers noted a noise level higher than normal conversation level in the environment outside the bedroom for 68% of the sessions. For 38% of the sessions, the participant fell asleep. Procedural reliability was collected during 3 sessions during each treatment with the following results: 99.5% accuracy for paced respiration, 98.5% accuracy for object manipulation, 100% accuracy for best treatment, and 99.32% accuracy for over all sessions.

Social Validity

The second hypothesis was that staff would view the use of relaxation techniques in a positive manner. The respondents in the social validation reported positive opinions regarding the importance of the aims of this research. The return rate for the survey was 87.5 % (7 of 8 participants). Six participants reported they strongly agreed and one agreed that teaching relaxation techniques is a concern of staff and caregivers. All seven participants reported they strongly agreed that relaxation techniques could be used to reduce anxiety in persons with mental retardation. Six participants strongly agreed and one agreed that they would implement a relaxation technique if research supported its effectiveness. Regarding impact on quality of life, six participants strongly agreed and one agreed that teaching a relaxation technique to reduce anxiety could improve quality of life for a person with mild mental retardation.

Figure 1. Object manipulation session 1 graphic dislay

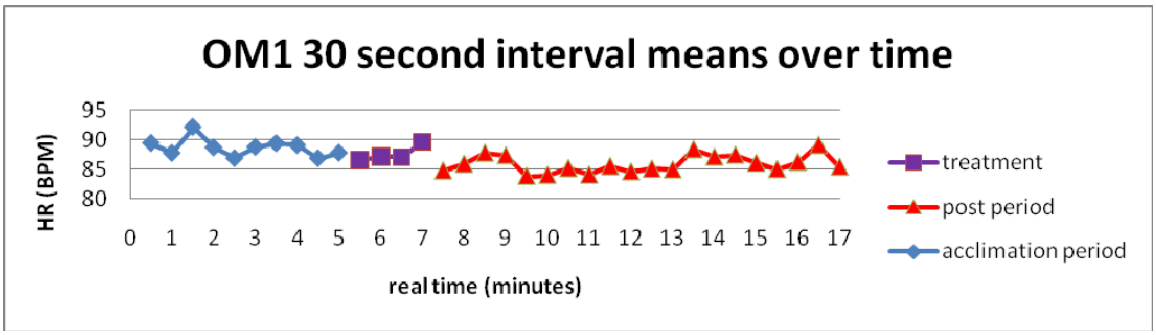
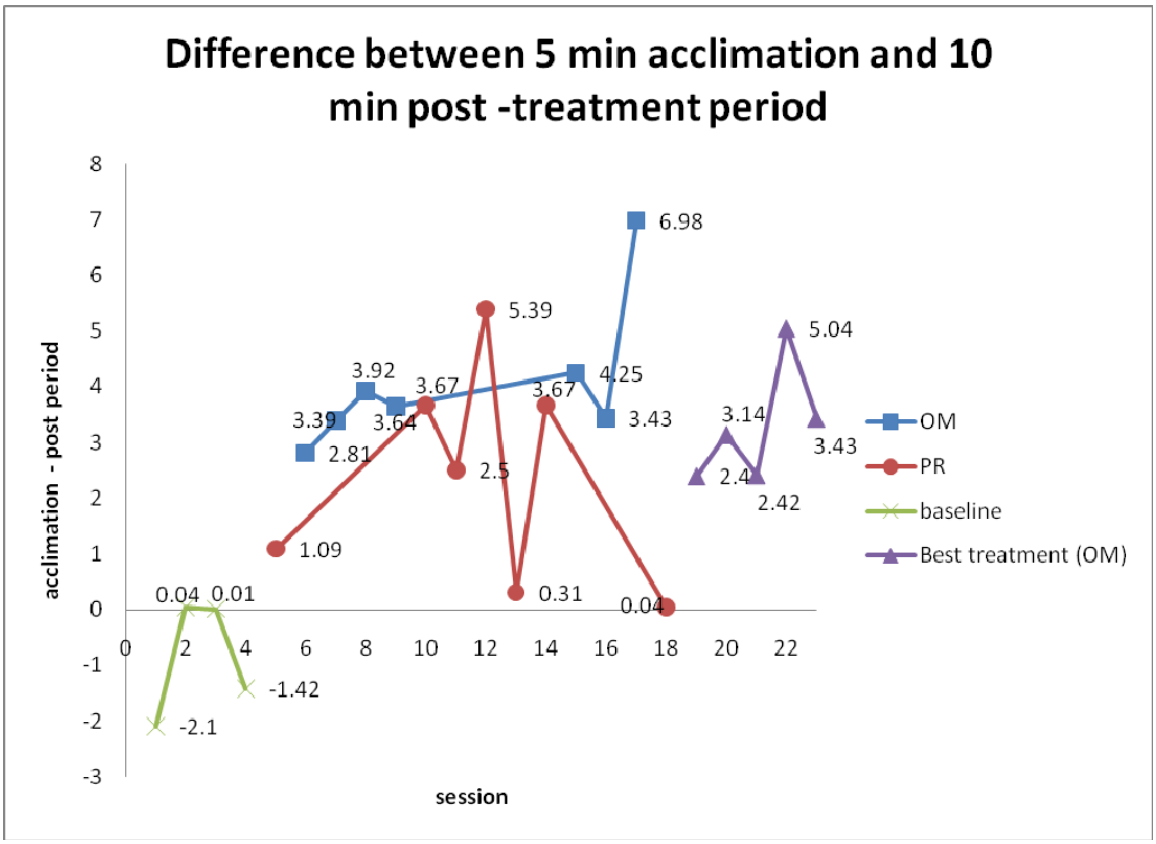


Figure 2. Difference in HR between 5-minute acclimation and 10-minute post-treatment period



Note: OM= object manipulation; PR=paced respiration

Figure 3. Changes in HR during treatments from first 5 seconds to last 5 seconds.

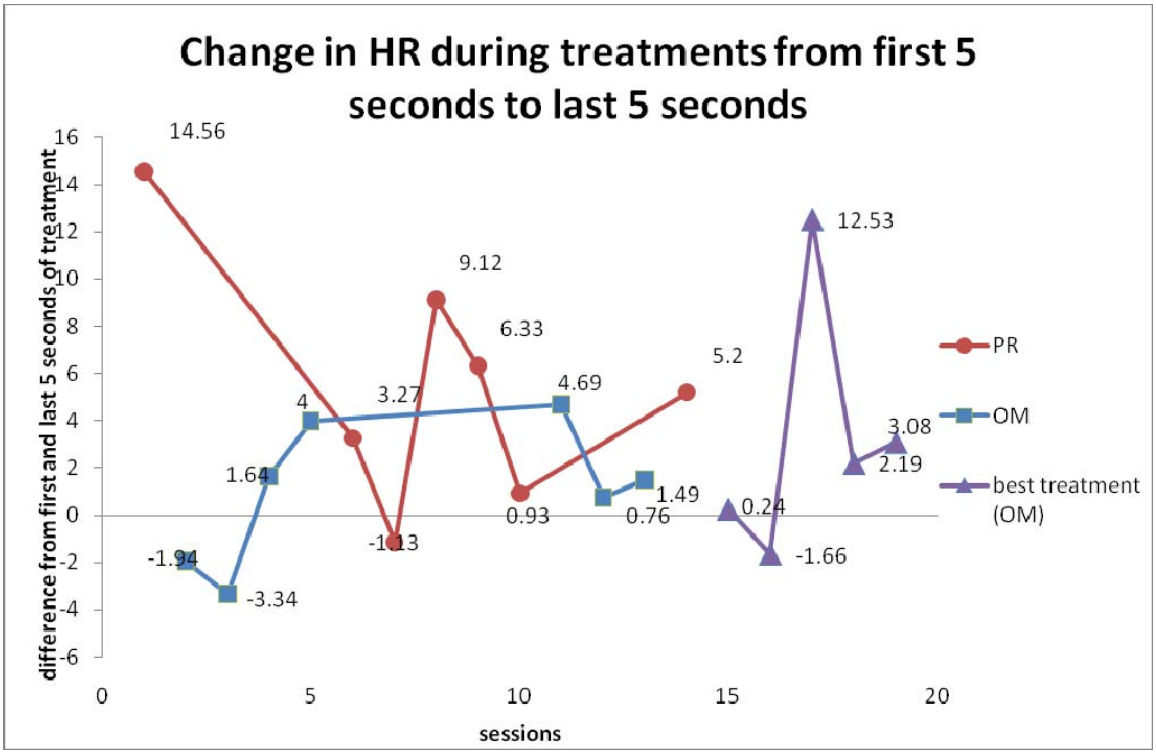


Figure 4. Mean HR during treatments

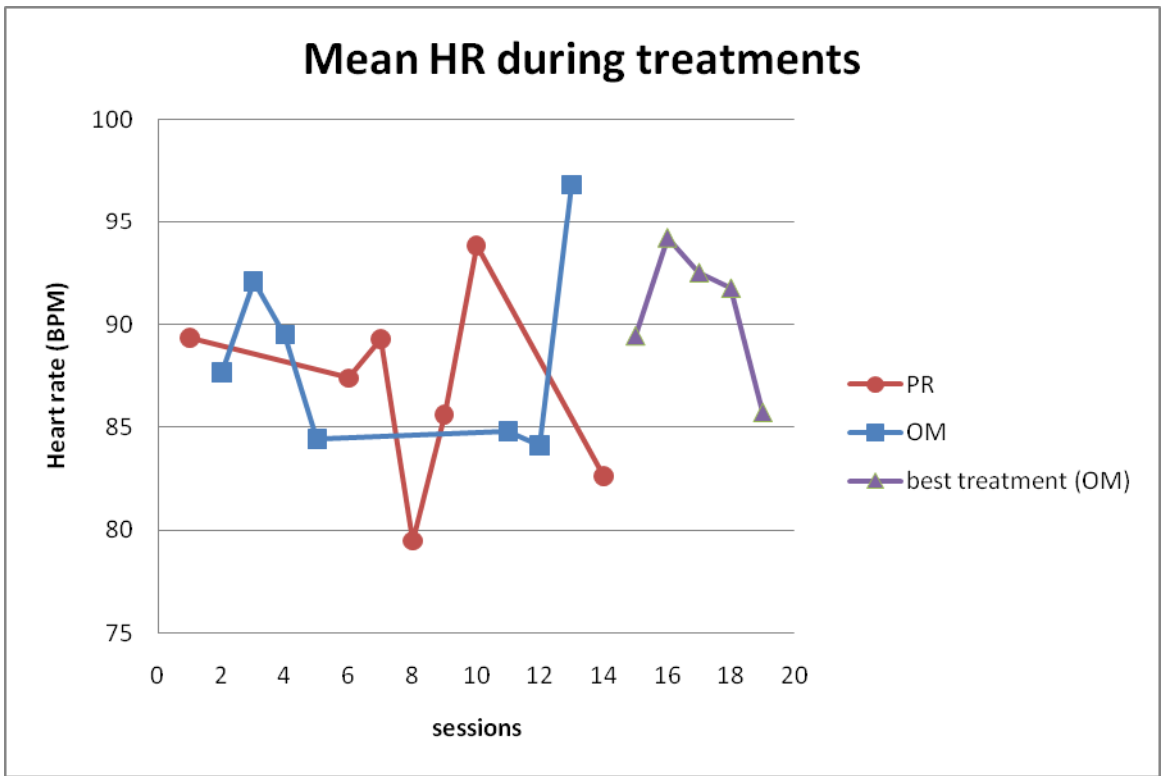
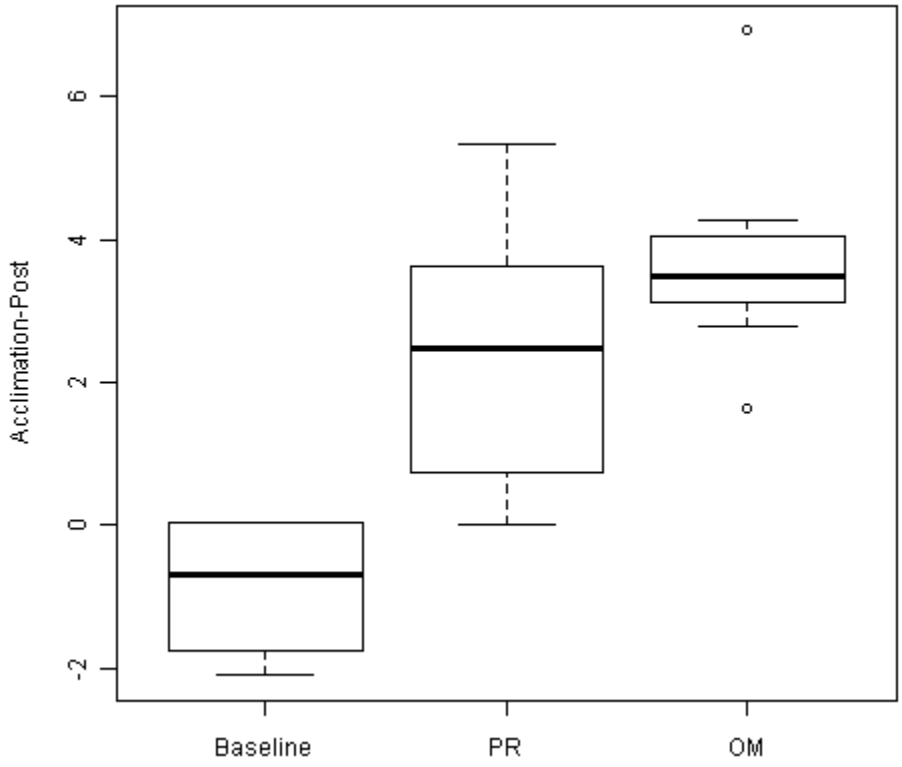
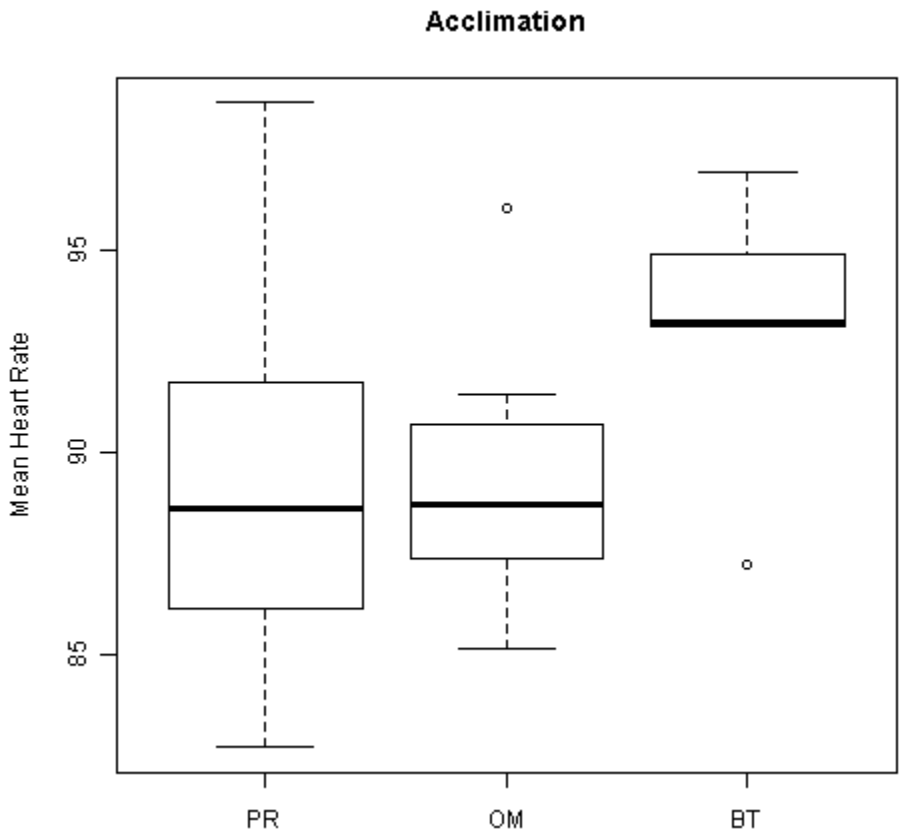


Figure 5. Box plot of acclimation period HR minus post-treatment period HR



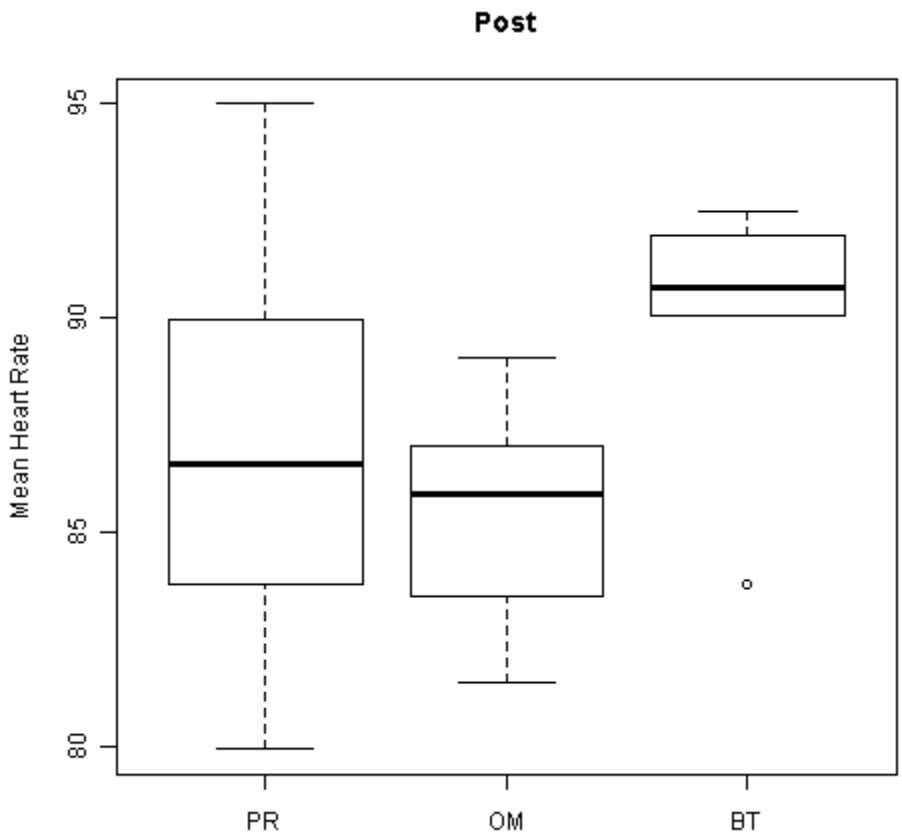
Summary of Figure 5			
	Mean	Median	SD
PR	2.38	2.50	1.99
OM	4.06	3.64	1.36
BT	3.29	3.14	1.08

Figure 6. Box plot of acclimation period mean HRs by treatment



Summary of Figure 6			
	Mean	Median	SD
PR	89.37	88.59	5.24
OM	89.42	88.70	3.56
BT	93.06	93.19	3.62

Figure 7. Box plot of post-treatment period mean HRs by treatment



Summary of Figure 7			
	Mean	Median	SD
PR	86.99	86.59	5.11
OM	85.36	85.89	2.74
BT	89.77	90.70	3.48

Table 2 Summary to level, variability, and trend analysis for Acclimation, Treatment, and Post-treatment Periods by Session

		Acclimation Period			Treatment Period			Post Period		
Session	Treatment	HR avg	HR SD	HR trend	HR avg	HR SD	HR trend	HR avg	HR SD	HR trend
1	PR 1	92.34	1.90	-0.29	89.36	2.36	-0.54	91.25	2.66	-0.51
2	OM1	88.70	1.55	-0.20	87.66	1.46	0.42	85.89	1.39	0.16
3	OM2	91.41	1.15	-0.31	92.08	1.23	-0.09	88.02	1.27	-0.27
4	OM3	89.94	1.74	0.33	89.49	0.64	0.02	86.02	2.74	0.06
5	OM4	85.16	1.42	0.09	84.42	1.92	-0.56	81.52	1.54	-0.34
6	PR2	88.59	1.01	-0.08	87.39	0.94	-0.10	84.92	1.29	-0.23
7	PR3	91.11	0.82	-0.11	89.28	0.82	0.18	88.61	2.05	-0.55
8	PR4	85.34	1.85	-0.21	79.49	1.76	0.25	79.95	2.03	-0.36
9	PR5	86.90	0.88	0.11	85.62	1.51	-0.13	86.59	1.37	-0.40
10	PR6	98.63	2.46	-0.48	93.83	1.84	0.55	94.96	2.75	-0.67
11	OM5	86.74	1.35	-0.19	84.82	0.96	-0.14	82.49	1.43	-0.41
12	OM6	87.98	1.16	0.08	84.13	1.11	-0.15	84.55	1.43	0.11
13	OM7	96.04	1.85	0.10	96.84	1.99	0.16	89.06	2.66	-0.79
14	PR7	82.71	1.56	0.01	82.63	2.05	0.46	82.67	1.94	-0.39
15	OM1 BT	99.1	1.56	-0.27	89.44	1.81	-0.04	90.7	1.95	0.39
16	OM2 BT	93.19	2.18	0.39	94.22	3.03	-0.20	90.05	2.26	-0.62
17	OM3 BT	94.87	2.17	0.14	92.52	2.15	-0.39	92.45	2.25	0.14
18	OM4 BT	96.92	1.22	-0.02	91.76	4.5	-0.39	91.88	1.84	-0.52
19	OM5 BT	87.2	2.57	-0.72	85.71	3.64	-0.06	83.77	1.61	0.32

Note:

Acclimation period

- HR avg is the average generated by the biotrace system over the 5 minutes of the acclimation period during each session
- HR SD is determined by generating 30-second interval averages over the 5 minutes and then determining the standard deviation of these numbers using excel. There were a total of ten 30-second intervals.
- HR trend is determined by graphing the 30-second interval averages from the 5 minute acclimation period and generating a trend line using excel

Treatment period

- HR avg is the average generated by the biotrace system over approximately 2-minutes during the treatment period of each session.
- HR SD is determined by taking 15-second interval averages over the 2-minutes and then determining the standard deviation of these numbers using excel. There were a total of eight 15-second intervals for paced respiration (PR) and nine 30-second intervals for the object manipulation (OM)
- HR trend is determined by graphing the 15-second interval averages from the 2-minute treatment period and generating a trend line using excel

Post Period

- HR avg is the average generated by the biotrace system over the 10minutes of post- treatment during each session
- HR SD is determined by taking 60-second interval averages over the 10minutes and then determining the standard deviation of these numbers using excel. There were a total of ten 60-second intervals.
- HR trend is determined by graphing the 60-second interval averages from the 10-minute post-treatment period and generating a trend line using excel

Table 3. Respiration Rate for Sessions by Period

Session	Treatment	Acclimation Period RR	Treatment Period RR	Post Period RR
1	PR 1	15	7	15
2	OM1	15	15	14.5
3	OM2	15	15	14
4	OM3	14	15	14
5	OM4	14	15	14
6	PR2	14.5	7	14.5
7	PR3	15.5	7	14.5
8	PR4	13.5	7	13
9	PR5	14	7	14
10	PR6	16	7	15
11	OM5	14.5	14.5	14
12	OM6	15	15	14
13	OM7	16	16	14.5
14	PR7	14	7	14
15	OM1 BT	14	16	15.5
16	OM2 BT	15.5	16	14.5
17	OM3 BT	15	15.5	15
18	OM4 BT	15.5	15	14.5
19	OM5 BT	14	14	14

Note:

Acclimation period

- RR is the number of breaths per minute (respiration rate) the participant took during the 5 minute acclimation period

Treatment period

- RR is the number of breaths per minute (respiration rate) the participant took during the 2 minute treatment period

Post Period

- RR is the number of breaths per minute (respiration rate) the participant took during the 10-minute post-treatment period

Table 4. Descriptive statistics for Acclimation-Post period and treatment changes for HR and temperature

		Paced Respiration	Object manipulation	OM best treatment
Temp during treatment	mean	94.41	94.69	93.98
	min	92.03	93.39	92.20
	max	96.03	96.16	94.8
Temp change	min	-0.19	-0.10	-0.87
	max	0.98	0.59	0.12
Accl-Post Temp	mean	-0.66	-0.32	-0.33
	min	-2.08	-0.97	-0.55
	max	0.06	0.23	0.15
Accl-Post HR	mean	2.67	4.06	3.29
	SD	2.00	1.36	1.08
	slope of trend line	-0.08	0.19	0.40
Change in HR during treatment	mean	5.47	1.04	3.28
	SD	5.26	2.91	5.49
	slope of trend line	-0.66	0.31	0.95

Note:
- Acclimation-post HR: The average HRs for the acclimation period minus the average HRs for the post-treatment period was used. The mean and standard deviation of these differences are reported. The slope of the trend line was generated from the "Difference between 5-min acclimation and 10-min post-treatment period" graph using Excel.
- Change in HR during treatment is the change in HR from first 5 seconds to last 5 seconds during the treatment period. The mean and standard deviation of these changes is reported. The slope of the trend line was generated from the “Change in HR during treatments from first 5 seconds to last 5 seconds” graph using excel.
- Temperature during treatment: The average temperatures generated by the biotrace system during the 2-minute treatment period were used. The mean, minimum, and maximum of these averages are reported.
- Temperature changes: The change in temperatures from the first 5 seconds of the treatment period to the last 5 seconds of the treatment period. These minimum and maximum of these averages were reported.
- Acclimation-Post Temp: The average temperatures for the acclimation period minus the average temperatures for the post-treatment period were used. The mean, minimum, and maximum of these differences were reported.

Chapter Five: Discussion

The purpose of this study was to compare the efficacy of a paced respiration technique versus an object manipulation technique on physiological measures related to anxiety of a person with mild mental retardation. Both techniques demonstrated a trend toward anxiety reduction. Staff members at the residential facility where the individual resides agreed teaching relaxation techniques to residents has value and that if such techniques reduced anxiety, then quality of life could be improved.

Physiological Data

Both the paced respiration and object manipulation treatments showed a significant decrease in heart rate after the participant engaged in the treatment technique, indicating a decrease in anxiety. There was, however, no substantial difference between treatment effects. The participant stated that he preferred using the squeeze ball.

In a single subject design study, Waller et al. (2007) also found that object manipulation was effective at reducing anxiety in an individual with mental retardation. While SSD studies must be interpreted with caution, there is some modest support for the use of a object manipulation to reduce anxiety in this population.

According to the physiological data, the participant was able to slow his breathing rate to 7 breaths a minute while listening to the paced respiration technique, although these effects were not carried over into the post-treatment period. The participant was also able to pace his HR with his breathing while performing the paced respiration technique. A study by Sakakibara and Hayand (1996) supports use of a slow respiration technique to therapeutically lower heart rate responses in patients with anxiety. There

were no reportable changes in EMG, skin temperature, or EDA levels. Other researchers found mixed results with relaxation techniques reducing physiological measures of anxiety. Calamari et al. (1987) found that a relaxation treatment package significantly decreased EMG levels; however had no significant effect on skin temperature. McCaul et al. (1979) found that slow breathing significantly reduced electrodermal activity, respiration rate, and finger pulse volume, however not heart rate.

The participant was able to understand and follow directions throughout the study. He learned the routine of each session, knew the order the electrodes were placed, and knew he was to sit still and quietly. He performed the treatment techniques the first time he practiced them and followed the verbal directions each session. The participant remembered the payment schedule and reminded the researchers. Payment for sessions enticed the participant to continue the study and he was vested enough in the incentive to suggest a modification to the payment schedule.

Quality of the Study

The reliability of this study was strengthened by several elements. The sessions were conducted multiple days a week using consistent times, location, and set up. Pre-recorded directions allowed each protocol to be consistently administered. Although a baseline phase was not necessary for an alternating treatment design, researchers chose to implement a baseline period to determine whether just sitting for a long period reduced physiological levels. As seen in Figure 1, baseline changes from the acclimation period to the post-treatment period resulted in little to no effect on HR. This means that just sitting quietly with the equipment on did not reduce heart rate. Therefore, the changes in

heart rate were due to the treatments and not an effect over time. There was a noted increase in skin temperature from the baseline acclimation to the post-treatment period for 3 out of 4 baseline sessions, indicating a decrease in arousal. This change in temperature was not observed during the treatment phase as shown in Table 4.

There were several limitations to this study. The participant's HR was variable each day, which could have affected the change in HR. External events prior to arriving to the sessions may have affected variability in HR each day. If the participant's HR started high, there was a greater chance of change compared to starting with a lower HR. There was little to no EDA response for the participant throughout sessions, although other reported research found significant changes in EDA. The actual treatment length of 2 minutes may have been too short to see significant effects. Because little research has been done with this population, it was difficult to determine an adequate length of time that would make a difference.

Another limitation was the length of quiet time before and after the treatment period. During these times the participant sat with head down and fell asleep several times. While the researchers chose 10 minutes because they wanted a sufficient time to show effects, 10 minutes may have been too long for this participant.

The seating arrangement for the participant could have presented a limitation. The participant sat in a hard backed chair with no arm rests or head support. As noted in the results, the participant was observed tilting his head down to his chest during several sessions as well as falling asleep in this position. The sudden movement when the participant awoke caused spikes in the data. When these movements caused a spike in the

data, the spikes were marked as artifacts and discarded. Also, physiological data when a person is sleeping may not accurately represent when the person is awake and at rest. A possible solution could be to position the client in a slightly reclined position to provide more neck stability so the neck does not drop down. Also, treatment effects overlapped, making it difficult to determine a true best treatment. Due to time constraints, two best treatment phases were not feasible. Because there was only 1 participant in this study, it is difficult to generalize results beyond the participant himself.

Social Validity

The findings regarding the social validity of this study showed that staff responded positively. A survey of staff opinion for social validity is supported by previous research (Green et al., 2005). Previous research also supports surveying individuals who would be responsible for implementing a technique to the target population (Kurt & Tekin-Iftar, 2008). The practical application of these findings suggests that staff members may be agreeable to being trained on teaching relaxation techniques to people with mental retardation. It should be noted that staff were provided with a summary of the aims and results of the current study which may have biased staff opinions.

Suggestions for Future Research

Based upon the finding of this study, future research could focus in four areas. First, because this participant learned the techniques without difficulty, the next step could integrate the relaxation technique into his/her day. Second, it would be useful to see the individual would learn integrate the technique without incentives. Third, since a

treatment length of 2 minutes may not be an adequate amount of time to see a significant change in physiological data, future research compare the effectiveness of the two techniques using an increase in intervention time and/or shorter post-treatment time periods. Finally, a change to an ABAC design might eliminate multiple treatment interference as well as allow for comparison between and within multiple participants.

Implications for Occupational Therapy Practice

Because anxiety is a common concern for persons with mental retardation, it is important to investigate effective coping techniques. The results of this study suggest that it is possible for a person with mental retardation to follow a relaxation training protocol and reduce some physiological indices of anxiety. The positive results of this study also suggest that it may be possible for a person with mental retardation to learn to use a relaxation technique in daily life to reduce anxiety and subsequently enhance his/her quality of life. Occupational therapists working with this population can implement these techniques with their clients to increase their occupational performance in everyday activities by reducing those cognitive issues that negatively impact performance. When a client engages in "quiet and effortless actions that interrupt physical and mental activity (such as relaxation techniques)," a relaxed state can occur (American Occupational Therapy Association, 2008, p. 632).

Conclusion

Based on the literature review and the results of the social validation portion of this study, there is a need for anxiety research and coping/relaxation techniques for persons with mental retardation in order to increase quality of life for these individuals.

The current study revealed that both the paced respiration and object manipulation techniques showed a decrease in heart rate and this could be linked to reduced anxiety.

References

Ahearn, W. H., Kerwin, M. L., Eicher, P. S., Shantz, J., & Swearingin, W. (1996). An alternating treatments comparison of two intensive interventions for food refusal. *Journal of Applied Behavior Analysis, 29*(3), 321-332.

American Association on Mental Retardation. (2002). *Mental retardation: Definition, classification, and systems of supports*. Washington DC: American Association on Intellectual & Developmental Disability.

American Occupational Therapy Association. (1999). Management of occupational therapy services for persons with cognitive impairments (statement). *The American Journal of Occupational Therapy, 53*(6), 601-607.

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

Barlow, D. H., & Hayes, S. C. (1979). Alternating treatments design: One strategy for comparing the effects of two treatments in a single subject. *Journal of Applied Behavior Analysis, 12*, 199-210.

Beers, M. H., Porter, R. S., Jones, T. V., Kaplan, J. L., & Berkwits, M. (2006). *The Merck manual of diagnosis and therapy*. Whitehouse Station, NJ: Merck Research Laboratories.

Bernstein, D. A., & Given, B. A. (1984). Progressive relaxation: Abbreviated methods. In R. L. Woolfolk & P. M. Lehrer (Eds.), *Principles and practice of stress management* (pp. 43-69). New York: The Guilford Press.

Biggs, Q. M., Kelly, K. S., & Toney, J. D. (2003). The effects of deep diaphragmatic breathing and focused attention on dental anxiety in a private practice setting. *Journal of Dental Hygiene: JDH / American Dental Hygienists' Association, 77*(2), 105-113.

Bramston, P., & Fogarty, G. J. (1995). Measuring stress in the mildly intellectually handicapped: The factorial structure of the Subjective Stress Scale. *Research in Developmental Disabilities. 16*(2), 117-31.

Brewster, J., & Montgomery, A. (2005). Stop winding me up. *Learning Disability Practice, 8*(4), 16-20.

Calamari, J. E., Geist, G. O., & Shahbazian, M. J. (1987). Evaluation of multiple component relaxation training with developmentally disabled persons. *Research in Developmental Disabilities, 8*(1), 55-70.

Campo, S. F., Sharpton, W. R., Thompson, B., & Sexton, D. (1997). Correlates of the quality of life of adults with severe or profound mental retardation. *Mental Retardation, 35*(5), 329-337.

Chapman, R. A.,, Shedlack, K. J., & France, J. (2006). Stop-think-relax: An adapted self-control training strategy for individuals with mental retardation and coexisting psychiatric illness. *Cognitive and Behavioral Practice*, 13, 205–214.

Chow, A. E. (2001). In Lee Communications I. (Ed.), *Therapeutic squeeze ball* (482/49 ed.). Champlin, MN: A63B 23/16.

Clark, D. M., & Hirschman, K. (1990). Effects of paced respiration on anxiety reduction in a clinical population. *Biofeedback and Self-Regulation*, 15(3), 273-284.

Codding, R. S., Eckert, T. L., Fanning, E., Shiyko, M., & Solomon E. (2007). Comparing mathematics interventions: The effects of cover-copy-compare alone and combined with performance feedback on digits correct and incorrect. *Journal of Behavioral Education*, *16*(2), 125-141.

Crane, L. (2005). Quality-of-life assessment for persons with mental retardation. *Assessment for Effective Intervention, 30*(4), 41-49.

Croft, R. J., Gonsalvez, C. J., Gander, J., Lechem, L., & Barr, R. J. (2004). Differential relations between heat rate and skin conductance, and public speaking anxiety. *Journal of Behavior Therapy and Experimental Psychiatry, 35,* 259-271.

Dattilo, J., Gast, D. L., Loy, D. P., & Malley, S. (2000). Use of single-subject research designs in therapeutic recreation. *Therapeutic Recreation Journal, 34*(3), 253-270.

Davis, E., Atezaz Saeed, S., & Antonacci, D. J. (2008). Anxiety disorders in persons with developmental disabilities: Empirically informed diagnosis and treatment reviews literature on anxiety disorders in DD population with practical take-home messages for the clinician. *Psychiatr Q*, *79*, 249–263.

Eckert, T. L. (1999). Acceptability Assessment-Student Version. Unpublished manuscript, Syracuse University.

Eckert, T. L., Ardoin, S. P., Daisey, D. M., & Scarola, M. D. (2000). Empirically evaluating the effectiveness of reading interventions: The use of brief experimental analysis and single case design. *Psychology in the Schools, 37*(5), 463-473.

Esbensen, A. J., Rojahn, J., Aman, M. G., & Ruedrich, S. (2003). Reliability and validity of an assessment instrument for anxiety, depression, and mood among individuals with mental retardation. *Journal of Autism and Developmental Disorders, 33(6), 617-629.*

Francisco, V. T., & Butterfoss, F. D. (2007). Social validation of goals, procedures, and effects in public health. *Health Promotion Practice, 8*(2), 128-133.

Freeman, R. L., Horner, R. H., & Reichle, J. 1999. Relationship between heart rate and problem behaviors. *American Journal on Mental Retardation*, *104*(4), 330-345.

Glenn, E., Bihm, E. M., & Lammers, W. J. (2003). Depression, anxiety, and relevant cognitions in persons with mental retardation. *Journal of Autism and Developmental Disorders, 33(1), 69-76.*

Green, C. W., Reid, D. H., Rollyson, J. H., & Passante, S. C. (2005). An enriched teaching program for reducing resistance and indices of unhappiness among individuals with profound multiple disabilities. *Journal of Applied Behavior Analysis, 38*(2), 221–233.

Hartley, S. L., & MacLean, W. E. (2005). Perceptions of stress and coping strategies among adults with mild mental retardation: Insight into psychological distress. *American Journal of Mental Retardation*, *110*(4), 285-297.

Hoehn-Saric, R., & McLeod, D. R. (2000). Anxiety and arousal: Physiological changes and their perception. *Journal of Affective Disorders, 61*(3), 217-224.

Hui, P. N., Wan, M., Chan, W. K., & Yung, P. M. (2006). An evaluation of two behavioral rehabilitation programs, qigong versus progressive relaxation, in

improving the quality of life in cardiac patients. *Journal of Alternative and Complementary Medicine, 12*(4), 373-378.

Incentive. (n.d.). *Dictionary.com Unabridged (v 1.1)*. Retrieved December 19, 2008, from Dictionary.com website: http://dictionary.reference.com/browse/incentive.

Janssen, C. G. C., Schuengel, C., & Stolk, J. (2005). Perspectives on quality of life of people with intellectual disabilities: The interpretation of discrepancies between clients and caregivers. *Qual Life Res*, *14*, 57–69.

Joseph, C. N., Porta, C., Casucci, G., Casiraghi, N., Maffeis, M., Rossi, M., & Bernardi, L. (2005 Oct). Slow breathing improves arterial baroreflex sensitivity and decreases blood pressure in essential hypertension. *Hypertension, 46*(4), 714-718.

Kaushika, R., Kaushika, R. M., Mahajana, S. K., & Rajeshb, V. (2005). Biofeedback assisted diaphragmatic breathing and systematic relaxation versus propranolol in long term prophylaxis of migraine. *Complementary Therapies in Medicine*,*13*, 165-174.

Kazdin, A. E. (1977). Assessing the clinical or applied importance of behavioral change through social validation. *Behavioral Modification*, *1*, 427-452.

Kazdin, A. E. (1982). *Single case research designs: Methods for clinical and applied settings*. New York: Oxford University Press.

Kazdin, A. E. (1984). Statistical analyses for single-case *experimental* designs. In D. H. Barlow & M. Hersen (Eds.), *Single case experimental designs: Strategies for studying behavior change* (2nd ed.) (pp.285-324). New York: Pergamon Press.

Kurt, O., & Tekin-Iftar, E. (2008 May). A comparison of constant time delay and simultaneous prompting with embedded instruction on teaching leisure skills to children with autism. *Topics in Early Childhood Special Education, 28*(8), 53-64.

Lane, K. L., Kalberg, J. R., & Menzies, H. M. (2009). Developing school wide programs to prevent and manage problem behaviors: A step-by-step approach. New York: The Guilford Press.

León-Pizarro, C., Gich, I., Barthe, E., Rovirosa, A., Farrús, B., Casas, F., et al. (2007). A randomized trial of the effect of training in relaxation and guided imagery techniques in improving psychological and quality-of-life indices for gynecologic and breast brachytherapy patients. *Psycho-Oncology, 16*(11), 971-979.

Lindsay, W. R., Baty, F. J., Michie, A. M., & Richardson, I. (1989). A comparison of anxiety treatments with adults who have moderate and severe mental retardation. *Research in Developmental Disabilities, 10*(2), 129-140.

Logan, L. R., Hickman, R. R., Harris, S. R., & Heriza, C. B. (2008). Single-subject research design: Recommendations for levels of evidence and quality rating. *Developmental Medicine & Child Neurology, 50*, 99-103.

Lunsky, Y., & Benson, B. A. (2001). Association between perceived social support and strain, and positive and negative outcome for adults with mild intellectual disability. *Journal of Intellectual Disability Research*, *45*(2), 106-114.

McCaul, K. D., Solomon, S., & Holmes, D. S. (1979). Effects of paced respiration and expectations on physiological and psychological responses to threat. *Journal of Personality and Social Psychology, 37*(4), 564-571.

McReynolds, L. V., & Kearns. K. P. (1983). *Single-subject experimental designs in communicative disorders.* Baltimore: University Park Press.

Mind Media B.V. (2006). *Wireless Monitoring and Biofeedback*. Retrieved December 20, 2008, http://www.mindmedia.nl/english/nexus10.php.

National Health Committee. (1998). Guidelines for assessing and treating anxiety disorders. Wellington: NHC.

NIH Technology Assessment Panel on Integration of Behavioral and Relaxation Approaches into the Treatment of Chronic Pain and Insomnia (1996 July 24/31). Integration of behavioral and relaxation approaches into the treatment of hronic pain and insomnia. *JAMA. 276(4),* 313-318.

Nourbakhsh, M. R. & Ottenbacher, K. J. (1994). The statistical analysis of single-subject data: A comparative examination. *Physical Therapy, 74*(8), 768-776.

Ottenbacher, K. J. (1986). Evaluating clinical change: Strategies for occupational and physical therapists. Baltimore: Williams & Wilkins.

Paterson, C. E. (1987). *Progressive relaxation: A meta-analysis.* MI: Bell & Howell.

Pellino, T. A., Gordon , D. B., Engelke, Z. K., Busse, K. L., Collins, M. A., Silver, C. E., & Norcross, N. J. (2005 May/June). Use of nonpharmacologic interventions for pain and anxiety after total hip and total knee arthroplasty. *Orthopedic Nursing. 24*(3), 182-90.

Picardi, A., Rucci, P., Girolamo, G., Santone, G., Borsetti, G., & Morosini, P. (2006). The quality of life of the mentally ill living in residential facilities Findings from a national survey in Italy. *Eur Arch Psychiatry Clin Neurosci*, *256*, 372–381.

Poppen, R. (1988). Behavioral relaxation training and assessment. New York: Pergamon Press.

Romanczyk, R.G., & Gillis, J. (2006). Autism and the physiology of stress and anxiety. In M. G. Baron, *Stress and coping in Autism* (pp. 183204). New York, NY, US, Oxford University Press.

Roth, W. T. (2005). Physiological markers for anxiety: Panic disorder and phobias. *International Journal of Psychophysiology: Official Journal of the International Organization of Psychophysiology,* 58(2-3), 190-198.

Schwartz, M. S. & Andrasik, F. (2003). *Biofeedback: A practitioner's guide* (3rd ed.). New York: The Guilford Press.

Singh, N. N., Sood, A., Sonenklar, N., & Ellis, C. R. (1991). Assessment and diagnosis of mental illness in persons with mental retardation: Methods and measures. *Behavior Modification, 15,* 419–443.

Smith, C. J., & Jackson, L. (2001). Breathing exercises and relaxation states. In J. C. Smith (Ed.). Advances in ABC relaxation: Applications and inventories. New York: Springer Publishing Company.

Smith, J. C., Goc, S. N., & Kinzer, D. J. (2001). Initial trial of the Smith Intercentering Inventory: Progressive muscle relaxation versus yoga stretching versus breathing relaxation. In J. C. Smith (Ed.). Advances in ABC relaxation: Applications and inventories. New York: Springer Publishing Company.

Stens Corporation. (2006). *Nexus 10*. Retrieved September 22, 2008, from http://www.stens-biofeedback.com/products/nexus10.htm.

Stens Corporation. (2009). *Sensors*. Retrieved October 14, 2009 from https://bear.he.net/~stens/epistore/?category=Sensors.

Sterling, R. C., Gottheil, E., Weinstein, S. P., & Serota, R. (1998). Therapist/patient race and sex matching: treatment retention and 9-month follow-up outcome. *Addiction, 93*(7), 1043-1050.

Suzuki, S., Kumano, H., & Sakano, Y. (2003). Effects of effort and distress coping processes on psycho-physiological and psychological stress responses. *International Journal of Psychophysiology, 47*(2), 117-128.

Technique. (n.d.). *Dictionary.com Unabridged (v 1.1)*. Retrieved December 19, 2008, from Dictionary.com website: http://dictionary.reference.com/browse/technique.

To, M. Y. & Chan, S. (2000). Evaluating the effectiveness of progressive muscle relaxation in reducing the aggressive behaviors of mentally handicapped patients. *Archives of Psychiatric Nursing, 14*(1), 39-46.

Vreeke, G. J., Janssen, C. G. C., Resnkick, S., & Stolk, J. (1997). The quality of life of people with mental retardation: In search of an adequate approach. *International Journal of Rehabilitation Research, 20*, 289-301.

Waller, R. J., Kent, S., & Johnson, M. (2007 July). Using teaching prompts and habit reversal to reduce fingernail biting in a student with attention deficit hyperactivity disorder and a mild intellectual disability. *Teaching Exceptional Children Plus, 3*(6).

Zlotnick, C, Elkin, I, & Shea, M. T. (1998). Does the gender of a patient or the gender of a therapist affect the treatment of patients with Major Depression? *Journal of Consulting and Clinical Psychology, 66(*4), 655-659.

Appendix A

Procedure Checklist

Check list for procedure. This will evaluate the reliability of the treatment implementation. Someone will observe the participant in both conditions 33% of the time and use the checklist to identify if the procedure is being followed. Reliability will be reported as a percent.

General procedure:

- ☐ Blinds in bedroom closed.
- ☐ Computer is placed on bed side facing away from the door.
- ☐ CD player is on participant's bed facing the participant.
- ☐ CD is set to correct protocol.
- ☐ Alcohol wipes present.
- ☐ Chair present for participant to sit in
- ☐ Chair present for researcher to sit in.
- ☐ Participant's chair is facing away from door.
- ☐ During the object manipulation sessions, squeeze ball is in researcher's possession.
- ☐ Have equipment laid out on bed.

- ☐ Open Nexus program.
- ☐ On a separate comment sheet, make a record of the protocol performed.
- ☐ Ask the participant, "_____, do you want to do the activity today?" If yes, the investigator will proceed with the session.
- ☐ If he/she does not respond to the question, the researcher will explain that he/she can refuse to participate or stop participation at any time during a session.
- ☐ Following this explanation, the investigator will again ask the question. If the participant says no or does not respond, the session will be ended.
- ☐ For respiration, wrap respiration belt around the participant's waist in line with the navel.
- ☐ Have participant sit in the chair facing away from the door.
- ☐ Put a pillow in the participant's lap.
- ☐ Use an alcohol wipe to clean the participant's forehead and C7 land mark on the back of the neck where the sensors will be attached.
- ☐ For electro-dermal activity (EDA), attach two sensors to the palm side of fingertips on middle and ring finger of the right hand.
- ☐ For heart rate, attach PPG sensor to index finger of right hand.
- ☐ Place a piece of tape on the back of the participant's hand to hold down the PPG sensor.

- ☐ For temperature, attach temp probe to ulnar side of thumb approximately 1 inch from the tip of the right thumb with two pieces of tape.
- ☐ For EMG, using the number 1 leads place two sensors to the forehead approximately one quarter inch (6.35 mm) above each eyebrow directly in line with each pupil in order to measure contractions of the frontalis muscle. Do this by asking the participant to look straight at me and then follow the line of the eyebrow.
- ☐ Place the ground wire on the C7 land mark on the back of the neck.
- ☐ Plug EMG lead into Nexus-10 (C&D).
- ☐ Plug EDA lead into Nexus-10 (E).
- ☐ Plug temperature lead into Nexus-10 (F).
- ☐ Plug heart rate lead into Nexus-10 (G).
- ☐ Plug respiration lead into the Nexus-10 (H).
- ☐ Make sure the participant's feet are on the floor.
- ☐ Tell the participant "I want you to sit quietly and sit as still as you can".
- ☐ Start recording on the computer to begin the 5 minute acclimation period.
- ☐ After 5 minutes, make a mark on the computer to note end of the acclimation period (5 min). (To make a mark press enter and write in note). Program will continue to record throughout session.

(Circle either paced respiration or object manipulation)

_____

During Paced Respiration

☐ Tell the participant "You are going to listen to a tape that will ask you to slowly breathe in and out."

☐ Say "I want to you sit comfortably, ok?"

☐ Say "I am going to start the tape, are you ready?"

During Object Manipulation

☐ Tell the participant "You are going to listen to a tape that will ask you to squeeze a ball.

☐ Open your hand without wires with your palm facing up like mine (demonstrate).

☐ Researcher will show squeeze ball to participant.

☐ Researcher will demonstrate how to hold the ball palm up.

☐ Say "I want you to hold the ball like this."

☐ Give the ball to the participant.

☐ Ensure that the participant is holding the ball palm up.

☐ Tell the participant "I want you to sit comfortably, ok?"

☐ "I am going to start the tape, are you ready?"

_____

- ☐ Begin appropriate technique on the audio recording device.
- ☐ After the introductory instructions are done, stop the audio recording device.
- ☐ Ask the participant if they understand the instructions.
- ☐ Start the audio recording device after the participant indicates understanding
- ☐ Make a mark on the computer when the actual technique begins (begin technique).
- ☐ When tape ends, make a mark on the computer and note the ending of the technique (end technique).
- ☐ Stop the audio recording device.

- ☐ During post-treatment, tell the participant "Now I want you to sit quietly again and sit as still as you can."
- ☐ Continue recording for 10 minutes.
- ☐ At 10 minutes, make a mark (10 min).
- ☐ After 10 minutes, stop recording.
- ☐ Name the file with a short session description, such as BL1 for baseline session 1.
- ☐ Remove the EMG wires.
- ☐ Remove heart rate sensor.

- ☐ Remove the EDA sensor.
- ☐ Remove temperature sensor.
- ☐ Remove the waist band.
- ☐ Thank the participant.
- ☐ Ask the participant how he prefers to be paid for the session.
- ☐ Tell the participant s/he can leave.
- ☐ Record room temperature.

Ball squeezing procedure tape:

Now, we are going to squeeze a small ball. You will squeeze the ball with your hand palm up, like me. When I say squeeze, squeeze, squeeze, I want you to slowly squeeze the ball. When I say open, I want you to slowly open your hand but still hold the ball. We will practice; I will do it with you. Ready? Squeeze, squeeze, squeeze, open, squeeze, squeeze, squeeze, open. Do you understand? (stop the tape). (If understand restart tape) Now we are going to start. Ready? Squeeze, squeeze, squeeze, open… (The actual squeezing will last approximately 2 minutes.)

Paced respiration procedure tape:

Now, we are going to practice slow breathing. When I say breathe in, I want you to slowly breathe in through your nose. When I say breath out, I want you to slowly breathe out through your mouth. I will say breath in, then count to 3, then say breath out and count to 3. We will practice. I will do it with you. Ready? Breathe in, 1, 2, 3, breathe

out, 1, 2, 3. Remember to breathe in through your nose and breathe out through your mouth. Do you understand? (stop the tape) (if understand restart tape) We are going to start… Ready… ok breathe in 1, 2, 3, breathe out 1, 2, 3.... (The actual breathing will last approximately 2 minutes.)

INFORMED CONSENT FORM

Title of research study: Comparison of two relaxation techniques to reduce physiological indices of anxiety in a person with mild mental retardation (MR)

Principle Investigator: Beth Velde, PhD, OTR/L; Sub investigators: Skip O'Neal, MS, OTR/L, Courtney Kenner OTS

Institution: East Carolina University and Center

Address: Department of Occupational Therapy, 3305 Health Sciences Building, East Carolina University Greenville, NC 27858

Telephone #: Beth Velde- (252) 744-6196

Skip O'Neal- (252) 208-4056

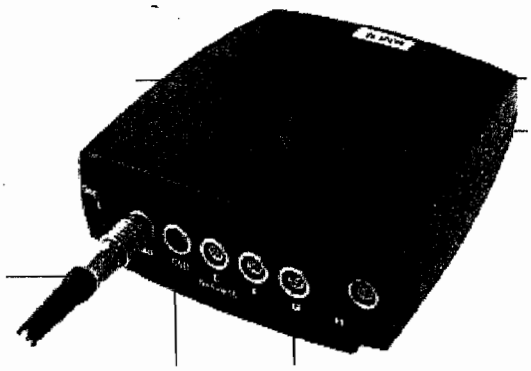
This consent document may contain words that you do not understand. You should ask the person reviewing this form with you to explain any words or information in this consent form that you do not understand.

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, and Courtney Kenner, OTS. Dr. Velde is a professor at the East Carolina University (ECU) Department of Occupational Therapy, Skip O'Neal is a staff occupational therapist at Center, and Courtney Kenner is working on her master's degree in the ECU Occupational Therapy program. The purpose of this single participant research study is compare two different relaxation exercises--a breathing exercise and squeezing a stress ball. We want to see if anxiety can be reduced by either of these exercises. Anxiety can increase heart rate, sweating, muscle tension, skin temperature or breathing rate so we will be recording these during each session throughout the study. The study will occur over approximately 10 weeks and include recording information in the home environment for 8 days, then 19 days of using relaxation techniques.

PLAN AND PROCEDURES

During the ball squeezing exercise, _____ will squeeze a stress ball while listening to verbal directions recorded on an audio-playback device. During the breathing exercise, _____ will breathe in and out at a set rate while listening to directions from an audio-playback device. Throughout the study, _____'s physiological responses (sweat levels, heart rate, muscle tension, skin temperature, and rate of breathing) will be recorded using a small, portable unit called the Nexus-10 (pictured below) and information will be sent to a laptop computer. Sweat levels will be measured using two small, mildly sticky sensors attached to the palm or fingertips. Heart rate will be measured by a sensor that slides onto a finger. Muscle tension will be measured by two small, mildly sticky sensors that attach to the forehead muscles. Skin temperature will be measured by a small sensor attached to a finger. Rate of breathing will be measured by an elastic belt placed around _____ 's waist. The Nexus-10 unit is pictured below.



This unit is small, about 8 inches in width, and battery operated. Wires with small sensors on their ends are plugged into the unit.

During the first 8 sessions, the sensors will be attached and _____ will sit quietly for 5 minutes to get used to the sensors, then sit quietly for another 10 minutes. During the sessions using relaxation exercises, the sensors will be attached and _____ will sit quietly for 5 minutes to get used to the sensors, then listen to and perform the relaxation exercise, then sit quietly for 10 minutes. Each session is estimated to last 20 to 30 minutes. All sessions will be conducted in _____'s bedroom at Center.
A staff member at Center will be present at all sessions. After all sessions have been completed, the investigators will analyze the data from all sessions to determine which exercise was most effective.

POTENTIAL RISKS AND DISCOMFORTS

Before each session, the investigator will ask "_____, do you want to do the activity today?" If _____ says yes, the investigator will proceed with the session. If _____does not respond to the question, the researcher will explain _____can refuse to participate or stop participation at any time during a session. Following this explanation, the investigator will again ask the question. If _____says no or does not respond, the session will be ended.

The exercises could cause mild anxiety. If _____shows the signs or behaviors of anxiety that are identified in the individualized behavior program written by a licensed psychologist employed at Center, the current research session will be stopped and the response plan outlined in the behavior program will be implemented. Skip O'Neal and the familiar staff(s) in the home will be trained on the program.

POTENTIAL RELATED RISKS TO SUBJECT
There is no known related risk to the research participant.

POTENTIAL BENEFITS
If either of the two exercises in this study is effective at reducing the physiological measures indicative of anxiety, the relaxation exercise may be used on a daily basis. _____will receive a small monetary compensation of $0.50 after each session.

ALTENTATIVE COURSE OF TREATMENT
The alternative treatment is the current behavior plan on file for _____.

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 with a fictional 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 participant.

TERMINATION OF PARTICIPATION
Participation is voluntary and the participant or guardian may withdraw consent at any point in the study.

COSTS OF PARTICIPATION
There is no cost to participate.

COMPENSATION AND TREATMENT FOR INJURY
The policy of East Carolina University and/or Pitt County Memorial Hospital does not provide for payment or medical care for research participants because of physical or other injury that results from this research study. Every effort will be made to make the facilities of the School of Medicine and Pitt County Memorial Hospital available for care in the event of injury.

VOLUNTARY PARTICIPATION
Participation in this study is voluntary. If you decide that _____ should not be in this study after it has already started, participation may be stopped at any time without losing any benefits normally received.

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 at (252)-744-6196 (days)
  (252)-975-6857 (nights and weekends)
- Skip O'Neal at (252)-208-4056 (day)
  (252)-527-3211 (nights and weekends)

If you have questions about _____'s rights as a research participant, you may call the

- Chair of the University and Medical Center Institutional Review Board at phone number (252)-744-2914 (days)
- BSOM Risk Management, (252) 744-1857

CONSENT TO PARTICIPATE

Title of research: Comparison of two relaxation techniques to reduce physiological indices of anxiety in a person with mild mental retardation (MR)

Please check the box below indicating the parent/guardian's opinion that the participant is not able to give written consent/assent.

I have read all of the above information, asked questions and have received satisfactory answers in areas I did not understand.
My signature indicates my agreement for _____ to participate in this study.

_____

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

WITNESS: I confirm that the contents of this consent document were orally presented; the participant or guardian indicates all questions have been answered to his or her satisfaction, and the guardian has signed the document.

_____

Witness's Name **(Print)** **Signature** **Date**

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

_____

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

_____

Principle Investigator's **(Print)** **Signature** **Date**

UMCIRB APPROVED FROM 12.3.08 TO 12.2.09

Appendix C

Payment Schedule

Baseline Session 1:	
Baseline Session 2:	$1.00
Baseline Session 3:	
Baseline Session 4:	$1.00
Training Session	
Treatment Session 1:	$1.00
Treatment Session 2:	
Treatment Session 3:	$1.00
Treatment Session 4:	
Treatment Session 5:	$1.00
Treatment Session 6:	
Treatment Session 7:	$1.00
Treatment Session 8:	
Treatment Session 9:	$1.00
Treatment Session 10:	
Treatment Session 11:	$1.00
Treatment Session 12:	
Treatment Session 13:	$1.00
Treatment Session 14:	
Best treatment Session 1:	$1.00
Best treatment Session 2:	
Best treatment Session 3:	$1.00
Best treatment Session 4:	
Best treatment Session 5:	$1.00
Total	$13.00

Appendix D

***Stens Corporation* Nexus-10**

* Retrieved from http://www.stens-biofeedback.com/products/nexus10.htm

Appendix E IRB approval

FILE COPY

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

MAILED 12·30·08

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

FROM: UMCIRB

DATE: December 30, 2008

FAXED 12·30·08

RE: Full Committee Approval of a Study

TITLE: "Comparison of Two Relaxation Techniques to Reduce Physiological Indices of Anxiety in a Person with Mild Mental Retardation (MR)"

UMCIRB #08-0716

The above referenced research study was initially reviewed by the convened University and Medical Center Institutional Review Board (UMCIRB) on **12.3.08.** The research study underwent a review and approval of requested modifications on 12.22.08 by the Chairperson. The UMCIRB deemed this **unfunded** study **no 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 **12.3.08** to **12.2.09**. The approval includes the following items:

- Internal Processing Form (dated 12.16.08)
- Informed Consent (dated 11.24.08) (revised version received on 12.22..08)
- Payment Schedule (dated 11.24.08)
- Social Validity Questionnaire (dated 11.24.08) (revised version received on 12.22..08)

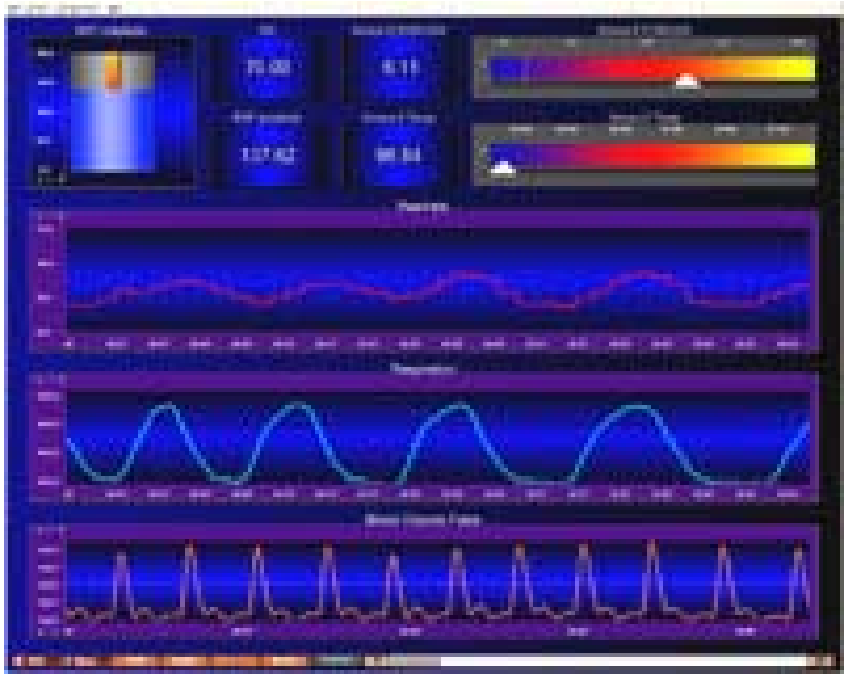
The following UMCIRB members were recused for reasons of potential for Conflict of Interest on this research study: None

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 F

Example of data recoded from Nexus 10.



* Retrieved from http://www.stens-biofeedback.com/products/nexus10.htm

Appendix G

Image of squeeze ball used during the research.