"The Effects of the Interactive Metronome® as an Intervention Tool on Decreasing Levels of Aggression and Improving Life Satisfaction with Mild Traumatic Brain Injury and Post-Traumatic Stress Disorder Clients: A Pilot Study of Protocols"

By

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The purpose of this study was to validate the protocols created for the Interactive Metronome[®] (IM[®]) and TRX[®] Suspension Training (TRX[®]) system for use with clients diagnosed with mild Traumatic Brain Injury (mTBI) and Post-Traumatic Stress Disorder (PTSD). Protocols were established matching IM® routines in conjunction with TRX® exercise routines. These were then validated on two healthy male and two healthy female participants. The data collected was collected using the IM® Long Form and Short Form Assessments, the Nine Hole Peg Test, the Canadian Occupational Performance Model and a version of the Overt Aggression Scale. Percentages of change were then compared between instruments and individuals for positive efforts gained, along with additional statistical analyses conducted. Data analysis indicated the use of the IM® in conjunction with the physical challenge of the TRX® provide a positive change maintaining or lowering aggression levels and increasing life satisfaction. The IM® protocols created, paired with the TRX®, were effective instruments used for creating a change in healthy participants. Occupational therapists will be able to benefit from the information collected and use it towards bettering the lives of those with mild TBI and PTSD. Future research with this intervention should anticipate favorable outcomes with mild TBI and PTSD cases.

"The Effects of the Interactive Metronome® as an Intervention Tool on Decreasing Levels of Aggression and Improving Life Satisfaction with Traumatic Brain Injury and Post Traumatic Stress Disorder Clients: A Pilot Study of Protocols"

> A Thesis Presented To The Faculty of the Department of Occupational Therapy East Carolina University

> In Partial Fulfillment of the Requirement for the Degree Master's of Occupational Therapy

> > By Michelle Leigh McBride 2 December 2011

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I. INTRODUCTION AND STATEMENT OF THE PROBLEM

Introduction

Individuals who suffer from a traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD) often experience similar residual symptoms (Miller, 1999). In a study conducted in 1997 by Beckham et al., approximately 75% of male veterans with symptoms of PTSD had engaged in physical aggression over the past year compared to 17% of male veterans who had not been diagnosed with PTSD or a TBI (Beckham, Feldman, Kirby, Hertzberg, & Moore, 1997). Patients and families most often described the neurobehavioral symptoms of TBI to be the most difficult to deal with, along with alienating family members and negatively impacting the social support networks that these individuals diagnosed with TBI may have otherwise had previously (Baguley, Cooper & Felmingham, 2006; Taft, Kaloupek, Schumm, Marshall, Panuzio, King & Keane, 2007). Specifically with aggression, this behavioral symptom often interferes in every aspect of the individual's life, including activities of daily living; thus, limiting the ability to receive the full benefits from additional therapies or achieve recovery in other areas of therapy. Giving attention to the individual's specific needs during the recovery process can lead to greater engagement and motivation on the part of the client, and therefore, improve the satisfaction and intervention outcomes (Phipps & Richardson, 2007).

It is not uncommon to find a strong association between TBI and PTSD, along with other psychological syndromes (Miller, 1999). Traumatic Brain Injuries have been identified, as the signature battlefield injury of the war in Iraq and Afghanistan. Additionally there is a growing number of survivors from TBI who are also suffering from post-traumatic stress disorder. The combination of these two life changing injuries presents a significant challenge that has become a pressing matter. There is little research that addresses the effectiveness of specific early therapy treatment (Giles, 1994).

Statement of the Problem

A variety of evidence through peer-reviewed publications, along with current instructional texts, demonstrate that at this time, there are inadequate interventions for the population of individuals in the military who have sustained a TBI and are also suffering from PTSD (Miller, 1999; Taft et al., 2007). The behavioral issues, such as aggression, associated with these diagnoses often cause additional problems in all areas of therapy treatment and function, thus affecting the individual's broader process of recovery.

Purpose of the Study

The purpose of this study was to validate the protocols created for the Interactive Metronome® (IM®) and TRX Suspension Training® (TRX®) system developed for clients with mild TBI and PTSD. These protocols will be validated by measuring the effectiveness of the IM® and TRX® as a successful intervention in decreasing behavioral aggression levels and providing clients with higher satisfaction in their activities of daily living. The focus of this pilot study was to validate the protocols by using the IM® in conjunction with a physical challenging routine of the TRX® that incorporates rhythmicity of both bilateral upper and lower extremities in an alternating manner, by conducting a completed series of the study designed protocols.

Research Question

The research question relates to determining the effectiveness of the designed protocols on healthy well individuals using the IM® and a physical challenging routine, the TRX®, that incorporates rhythmicity. The specific question that was addressed is: Is the Interactive Metronome® and TRX Suspension Training® protocol series, developed for mild TBI and PTSD symptoms, effective at affecting change in a series of intervention sessions that decrease levels of aggression and improve life satisfaction in normal, healthy young adults?

Assumptions

The results the investigator expected to find include differences in the scores of satisfaction and performance between the pre- and post-tests. The researcher anticipated that this study would produce positive change in well adults, supporting the use of the developed protocols in preparation for further exploration with military members diagnosed with mild TBI and PTSD. These levels were measured through the scores of the Overt Aggression Scale (OAS), the IM® Long and Short Form Assessments, the Nine Hole Peg Test (NHPT) and the Canadian Occupational Performance Model (COPM) interviews. Following the statistical analysis, data was expected to show that with continued use of the IM® equipment and the TRX®, the scores of the IM® Assessments improve over time, denoting an increase in the scores of this assessment tool. As participants continue to use the IM® and the scores were maintained or increased with practice, the expected statistical findings were expected to show the participant's aggression levels lessen when reported on the OAS, as well as the satisfaction rating on the COPM increase significantly, indicating a positive change in satisfaction of daily life. As an additional benefit the participants were expected to improve physically as the TRX® challenges the physical endurance and strength of the body.

Limitations

Limitations of this study include the small pilot population of healthy, well individuals without noted disabilities, so the results cannot be generalized to a larger population. Since the

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pilot study consists of only four healthy, well individuals, the intervention results may not be transferable to the intended population of military personnel diagnosed with mild TBI and PTSD. Another limitation of this study is the additional covariates that could be effecting change on the outcome. These variables could be the additional physical activities the healthy well individuals were doing prior to beginning the study. These limitations are addressed through the design of the study, as all participants will be tested before and after the IM® and TRX® intervention. Given the current lack of specific protocols for the treatment of military personnel who have been diagnosed with mild TBI and PTSD at this time, this study has been developed to address and demonstrate the ability to have successful positive outcomes that influence positives changes for this well population along with others. This design was chosen because it is reflective of typical intervention of which the IM® and TRX® would provide. A noted final limitation is this study did not have a control group.

Ethical Concerns

In the context to which the pilot study participants were recruited, the two male and two female graduate students could have felt coercion from faculty and peers, which in turn, could have made the individuals feel as though they had no choice to participate or not. These issues were addressed by the primary investigator in conjunction with a co-investigator explaining the rights of the participants and giving the individuals a choice in completing the study. The individuals were made aware, through verbal communication and signed consent forms, they always had the opportunity to discontinue their participation at any point during the study.

Significance of the Study

These findings are clinically significant to the field of occupational therapy because they provide support for the treatment protocols created and validation of the effectiveness of the IM® as an intervention. These protocols can be resources for professionals to use to benefit the population they were created for with regards to the treatment of aggression. Providing clients with an opportunity to decrease aggression and increase satisfaction in everyday activities can open new doors for the future of occupational therapy of clients diagnosed with mild TBI and PTSD. Testing the protocols that have been developed will allow for future ease of use for the participants and researchers.

II. REVIEW OF LITERATURE

Introduction

The body of literature presented in this document is a complete and thorough review for the anticipated population the protocols being validated will be directed toward. This will include individuals who suffer from mild traumatic brain injury (TBI) and who have been diagnosed with post-traumatic stress disorder (PTSD). As such, it will encompass the aggression that is often related to mild TBI and PTSD, the occupations and life satisfaction of these individuals, and how occupational therapy can address these diagnoses directly with interventions. These intervention vehicles will be addressed by what is currently available and what exists as opportunities for these individuals, such as the Interactive Metronome® (IM®) and TRX®.

Individuals who have incurred a TBI and PTSD often experience similar residual symptoms. The traumatic injury that the individual experiences to cause the TBI can, and often is, the same experience that leads the individual to be diagnosed with PTSD (Sbordone, 1999; Hoge et al.,2004). Depending on the circumstances in which the TBI occurred, PTSD can either develop from the same incident or be completely unrelated (Ferreir-Auerbach, Erbes, Polusny, Rath & Sponheim, 2010). Patients and families most often describe the consequences of a TBI most difficult to deal with are the neurobehavioral and neuropsychiatric affects (Baguley et al., 2006). The behavioral symptom of aggression often interferes in every area of the person's life, including activities of daily living; thus, limiting the ability to receive the full benefits from other therapies or achieve in other areas of the recovery process. Attention to clients' priorities and needs during the therapy intervention can lead to greater engagement and motivation on the part of the individual; thus, improving satisfaction and intervention outcomes (Phipps & Richardson, 2007).

Traumatic Brain Injury

Traumatic Brain Injury (TBI) is a complex injury with a broad spectrum of symptoms and disabilities (Brain Injury Association, 2006). TBI is caused by an impact to the head from a direct blow or a sudden movement. The effects can be minor to extreme resulting in physical, cognitive, behavioral and/or emotional difficulties. According to the Brain Injury Association (2006), 1.5 million people sustain a TBI annually and 80,000 people experience onset of long term disabilities following a TBI. These injuries most often occur in the general public through transportation accidents, such as car, motorcycle and bicycle accidents with 20% of civilian TBI occurring from violence and 3% occurring from sports related injuries (National Institute of Neurological Disorders and Stroke, 2010). For individuals over seventy-five years of age, falls are the number one cause of TBI (National Institute of Neurological Disorders and Stroke, 2010).

Currently, over 5.3 million Americans are living with a disability as a result of a TBI (Ferguson & Coccaro, 2009). Mild brain injuries are the most prevalent type of TBI and often missed at the time of initial injury. The symptoms of mild TBI vary widely from individual to individual, but common experiences among survivors are short-term memory loss, headaches, difficulty concentrating or paying attention, disorientation, having impaired judgment, depression, irritability and emotional disturbances, agitation or increased anxiety and impulsive behaviors (Wheeler, 2010; Traumatic Brain Injury, n.d.). These symptoms of mild TBI often overlap with the symptoms of PTSD, making it difficult to differentiate the symptoms of the two. People who sustain a mild TBI, can become symptomatic at the time of the incident or for up to weeks following the event. A mild TBI is characterized by loss of consciousness or disorientation for less than 30 minutes and immediate post injury symptoms are referred to as post concussive syndrome (Traumatic Brain Injury, n.d.). Post traumatic amnesia, which is the

length of time from the injury to the moment that the individual regains ongoing memory of daily events, lasts less than an hour to be considered a mild TBI (Tipton-Burton, McLaughlin & Englander, 2006). Although the immediate amnesia and post concussive syndrome last for a short time, mild TBI symptoms often persist and affect the resumption of life roles and activities for individuals (Radomski, Davidson, Voydetich & Erickson, 2009; Traumatic Brain Injury, n.d.).

Specifically within the military, TBIs are often caused by physical training, bullets/shrapnel, blasts, motor vehicle accidents and air/water transport (Schneiderman, Braver & Kang, 2008). Based on data of troops returning from Operation Iraqi Freedom, the military TBI prevalence ranges from 13% to 33% (Brain Trauma Foundation, 2011; Hoge et al., 2004). Most civilians with mTBI recover completely within 3-6 months, but some may develop persistent neuropsychiatric symptoms (Carroll et al., 2004). Both Military and civilian mTBI present similarly with common symptoms.

In the Military healthcare system, the diagnosis is begun by the Brief Traumatic Brain Injury Screen that was developed by the Defense and Veterans Brain Injury Center to detect mild TBI (Schwab et al., 2007). Following the screening, traditional medical evaluations such as the Ranchos Los Amigos Scale and Glasgow Coma Scale described later in the texts, are completed for full diagnosis (Traumatic Brain Injury, n.d.). Differentiating a mild TBI from the more severe TBI are the results from the MRI or CAT scan. The results from a mild TBI often appear normal, but the individual has cognitive problems, attention deficits, mood swings and frustration. A more severe TBI can have a Post-Traumatic Amnesia duration of more than four weeks whereas the duration of Post-Traumatic Amnesia of a mTBI is usually 5-30 minutes (Tipton-Burton, McLaughlin & Englander, 2006). This information not only affects the diagnosis, but the treatment intervention, as well, and will be discussed further in the literature.

Post-Traumatic Stress Disorder

Post-traumatic stress disorder is a form of anxiety disorder that develops after an exposure to a traumatic or terrifying event (National Institute of Mental Health, 2010). Some examples of these events include being in a bad car accident, witnessing sexual or violent physical assault, natural disaster, and military combat. These events usually leave the person with a feeling of lack of control that leads to intense emotion and confusion, among many other symptoms (National Institute of Mental Health, 2010). These individuals often experience persistent frightening memories about the event, sleep problems, become easily agitated and startled, and feel detached or numb to certain situations. These noted experiences lead to acts of aggression when an individual is not able to control emotions and impulsivities (National Institute of Mental Health, 2010).

Acute symptoms of PTSD last for one-to-three months and those lasting longer than three months are categorized as chronic. Symptoms developing after six months following the trauma are considered those of delayed-onset PTSD (Sbordone, 1999). The three different categories of PTSD symptoms are re-experiencing, hyper-arousal, and avoidance (National Institute of Mental Health, 2010). While the DSM-IV claims that approximately 50% of PTSD cases resolve within three months, another study found that about 50% of patients with PTSD were still experiencing symptoms more than one year post trauma (Davidson, Hughes, Blazer & George, 1991). The general population that has a lifetime history of PTSD is estimated at 7.8% (Kessler, Sonnega & Bromet, 1995). If PTSD is not treated it will continue to be symptomatic

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and those individuals may need to try different treatments to see what works best with the specific symptoms they are experiencing (National Institute of Mental Health, 2010).

Post-traumatic stress disorder is often seen comorbidly with TBI in military personnel (Cifu, Cohen, Lew, Jaffee & Sigford, 2010). The category of symptoms that overlaps most with those symptoms of a TBI are the hyper-arousal symptoms which are constant and make an individual feel angry. These symptoms are being easily startled, feeling on-edge, or having angry outbursts (National Institute of Mental Health, 2010). Prior studies of non-combat related TBI suggest that approximately one fourth of those injured would develop PTSD, however, recent reports from the Veterans Administration Polytrauma Support Clinic Teams Conference suggests that the rate of PTSD among injured veterans is much higher (Kim et al., 2007). Combat injuries increase the risk of developing PTSD resulting in the prevalence of PTSD among combat veterans to be around 16% assessed one year after returning from Iraq (Hoge et al., 2007; Hoge & Castro, 2006). The conclusion of a study by Bryant (1996) reveals that a conscious recall of the traumatic event is a prerequisite for the development of PTSD symptoms. Following a tour in Iraq, a cross-sectional survey of over 2,500 Army personnel was collected and it was observed that the highest prevalence of PTSD occurred among those soldiers who had a mild TBI and within three months of the mild brain injury patients reported some symptoms of PTSD (Schneiderman, Braver & Kang, 2008; Evans, 1992). Mild TBI's strong association with PTSD may likely be due to life-threatening combat experiences that can result in mild TBI or PTSD, along with these symptoms of PTSD being manifested from the brain injury (Hoge et al., 2008).

Aggression in Traumatic Brain Injury and Post-Traumatic Stress Disorder

Overlapping symptoms cloud the understanding of the relationship between PTSD and post TBI symptoms (Schneiderman, Braver & Kang, 2008). Individuals with brain damage in the

orbital frontal cortex, often exhibit socially disinhibited interaction behaviors (Radomski, 2008). These focal lesions of the brain are usually seen in the anterior lobes and inferior surfaces of the frontal and temporal lobes due to the brain scraping the skull over irregular bony structures (Radomski, 2008). Damage to the orbital frontal cortex impairs one's ability to regulate impulses and social behavior, resulting in attentional impairments (Dyer, Bell, McCann & Rauch, 2006; Radomski, 2008). This disinhibition can lead to offensive and often physical aggressive behavior (Yuen, 1997).

The human brain contains over 100 billion neurons and several times that number of cells, which support those neurons (Brain and Behavior Clinic, 2009). This statistic only begins to cover the complex system that the brain encompasses. The stretching, compression or physical forces on the brain during a TBI have the potential to negatively impact these delicate structures (Brain and Behavior Clinic, 2009). A common type of mild TBI can be explained through the coup-contrecoup occurrence. This injury occurs when the brain bounces back and forth inside the skull. The coup injury happens when the head stops abruptly because of an impact and the brain then collides into the skull. The contrecoup injury occurs secondary, when the brain bounces and impacts the opposite side of the skull (Brain Injury Association, 2011). The damage this causes in the brain usually affects the scope of the individual's entire life, including activities of daily living and overall satisfaction with every aspect of life.

Individuals with PTSD often experience similar emotional and behavioral disturbances following the stress. These behaviors are manifested through extreme irritability, pervasive edginess, impatience, and quick anger over seemingly trivial matters (Miller, 1999). This leads to frustration in the individuals and will sometimes cause them to act out in violent manners and take risks that are threatening to themselves and others. There is strong association of TBI and impulsivity, violence, substance abuse and anti-social behavior which is then exacerbated by the effects of post-injury PTSD (Miller, 1999).

Following the brain injury, psychosocial stressors, such as unemployment, boredom, frustration, depression, and difficulty coping with physical and cognitive decline often play a role in the disinhibition of aggression and other behavioral issues, (Dyer et al., 2006). These behavioral problems are a major source of distress for both those diagnosed with TBI and their relatives (Draper, Ponsford & Schonberger, 2007). Caregivers have reported "brain injuryrelated behavior patterns, such as aggression, are the most difficult aspects to adjust to" (Baguley et al., 2006, pp.46). This area of family cohesiveness is most relevant to occupational therapy treatment because therapists often focus on family education and involvement along with client treatment.

Traumatic Brain Injury and Post-Traumatic Stress Disorder and Daily Occupations

The term occupation and related concepts such as activity, task and work can be interpreted in very broad terms. The specific meaning of an occupation is only fully known and understood by the individual engaging in the occupation and interpreting the context to which it is being carried out (Crepeau, Cohn & Schell, 2009). The occupations performed or experienced in each person's life are motivated by the human nervous system, which has a pervasive need to act (Kielhofner, 2008). In the Model of Human Occupation, there are essentially three interrelated components that make up the human: 1) volition, 2) habituation and 3) performance capacity. Volition is the motivation to engage in occupation. Habituation is the process by which occupation is organized into patterns and routines. Performance capacity is the physical and mental abilities needed to performed skilled occupations. These components each contribute

different, but complimentary, functions to what we do and how we experience our being within various surroundings (Kielhofner, 2008).

Daily occupations are often habitual and generally taken for granted (Crepeau, Cohn & Schell, 2009). Previous life habits and patterns for individuals with a mild TBI and PTSD have been interrupted by the condition. The situation is often made worse for individuals with mild head injuries because, appearing superficially "normal", they are often expected to continue life roles and occupations immediately (Miller, 1999). Since these familiar social, temporal and physical habits have been adjusted, the individual often has to acquire new tendencies for previously familiar ways to become consistent and comfortable again. In the life of these individuals, simple daily occupations can provide some structure, choice and purpose. In a study by Gutman (1999), a few themes that described the inability to meet male role expectations were expressed by males who had been diagnosed with TBI. These specific areas expressed were re-establishing community member roles, developing friendships and dating relationships, and participating in meaningful activities (Gutman, 1999).

Life Satisfaction with Traumatic Brain Injury and Post-Traumatic Stress Disorder

During the process of recovery for a person with a TBI and concurrent PTSD, the physical recovery is often influenced and directly affected by the change in life roles and overall life satisfaction (Haertl et al., 2009; Gutman 1999). Traditionally, occupational therapy has focused on the use of meaningful activity to foster health and well-being of the client, but the profession has since moved away from occupation towards a more component based practice (Haertl et al., 2009). Despite this trend, there is still importance in occupational therapy's values of occupational involvement and meaning in clients' lives (Haertl et al., 2009). Overall life satisfaction and meaning in an individual's life are the components of greatest importance following recovery of any trauma. Giving attention to clients' priorities and desires during the intervention can lead to greater engagement and motivation on the part of the client; therefore, improving satisfaction and intervention outcomes (Phipps & Richardson, 2007). Because life satisfaction is directly related to the roles and activities one participates in throughout life, an occupational therapists role in recovery is important.

The International Classification of Functioning, Disability and Health (World Health Organization, 2001) describes participation in daily activities as an interaction between people's abilities and the contexts in which they live (Stark, Somerville & Morris, 2010). This participation in an activity or occupation can lead to satisfaction for the individual, most likely increasing self-efficacy or satisfaction in the activity; therefore, increasing the sense of purpose within that occupation. Several studies have demonstrated a client-centered goal setting process can result in the increase in both perceived performance efficacy and client satisfaction in the neurological rehabilitation context (Phipps & Richardson, 2007; Stark, Somerville & Morris, 2010). For clients with mTBI and PTSD, qualitative and quantitative findings have indicated that therapy was effective in helping the participants rebuild the roles and activities that enhanced their post-injury role satisfaction (Trombly, Radomski, Trexel, & Burnett-Smith, 2002). Therapy that is goal specific, aimed at achieving independence in activities and participation in roles that are important to the individual allows the client to have more control over their outcome (Trombly et al., 2002). A client direct approach has been shown to provide better outcomes for the individual (Trombly et al., 2002). Individuals who collaborate with the therapist to generate their own goals are more likely to be motivated to take ownership of and increase participation in the formulated goals (Doig et al., 2010).

The client's satisfaction and perceived performance of current life activities and occupations can be measured by the Canadian Occupational Performance Measure (COPM), which is an individualized, client-centered and client-rated, semi-structured interview assessment tool based on the Canadian Occupational Performance Model (Law et al., 1998). The COPM is designed to identify problems in areas of occupational performance across self-care, leisure and productivity (Law et al., 1990). The client categorizes specific tasks in these three areas and then rates them on a scale of importance, between 1 and 10; with 1 being a low score and 10 being the highest. The COPM also facilitates client-centered goal setting and helps evaluate goal attainment, along with the client's perception of performance and satisfaction, also on an importance scale of 1 to 10 (Doig at al., 2010).

The COPM's use with individuals with TBI and PTSD has been documented and the validity and reliability have been widely established (Carswell et al., 2004; Jenkinson, Ownsworth & Shum, 2007; Phipps & Richardson, 2007). The COPM is a client directed evaluation tool that enables measurement of real-life performance, meaningful, individualized goals that may not be as sensitive to change or even achievable by using only standardized tests (Rigby &Wilson, 2003). The primary purpose for using an outcome measure, such as the COPM, is to document the effect of the interventions; yet using an outcome measure is also believed to affect aspects of client care, like facilitating goal setting and increasing the focus of therapy on the client (Unsworth, 2000).

Both in clients with mild TBI and other populations, the COPM has been found to be sensitive to change and has been shown to increase participation in the goal-formulation process and perceived ability to manage personal and domestic activities of daily living following rehabilitation (Trombly et al., 2002). Change over time in performance and satisfaction with performance on each goal are deemed to be clinically significant when a pre- to post-intervention change of ≥ 2 points occurs (Law et al., 1998).

In a recent study by Doig, Fleming, and Cornwell (2010) fourteen participants with TBI completed a 12-week, outpatient, goal directed occupational therapy program where a total of 53 goals were created. Using the COPM and the Goal Attainment Scaling (Kiresuk & Sherman, 1968), performance and satisfaction ratings were collected before and following the intervention. As described above, the participant categorized specific tasks in the areas of self-care, productivity and leisure, and then rated those tasks on a scale of importance, between 1 and 10. The clients then also rated their self-perception of their performance and satisfaction, also on an importance scale of 1 to 10, 1 being low and 10 being high (Doig et al., 2010). Following the rating, the intervention was completed. The results indicated a strong sensitivity to change was demonstrated by significant improvements for the total performance ratings following the intervention (Doig et al., 2010). As evidence by its previous use with this population, the COPM is a valuable assessment tool for individuals with mild TBI because it captures those aspects of performance that are not quantifiable and may only be known by the participant and significant other. One of the primary reasons to use an outcome measure is to be able to assess the results of intervention and thus, the impact of work with clients (Law et al., 2005).

Impact on Occupational Therapy

Due to the extent of symptoms and disabilities associated with mild TBI and accompanied PTSD, persons with brain injuries often require varying types of assessments, therapy and rehabilitations services. This interdisciplinary team usually includes occupational therapy, physical therapy, speech pathology, and neuropsychology (Cifu et al., 2010). Occupational therapists, along with the rest of the rehabilitation team, are often called on to begin early intervention programs with clients with mild TBI. Rather than focusing solely on diagnosis, occupational therapists plan and provide intervention based on the individual's unique circumstances, goals, and functional performance (Radomski, Davidson, Voydetich & Erickson, 2009). The occupational therapist may evaluate the client engaging in daily activities at home as well as assess the strengths of that individual and predict what areas could be improved. The occupational therapist may attempt to establish and restore the endurance and strength of the client, along with assisting the client in learning compensatory skills and implementing them to overcome cognitive problems such as memory impairments (Wheeler, 2010). However, some clients with mild TBI characteristically demonstrate agitated behavior, which sometimes manifests itself into full blown aggression and violent and impulsive behaviors. These disruptive behaviors can interfere with a client's rehabilitation potential; thus, limiting the ability to perform well in other areas of recovery due to this one symptom, but as individuals with mild TBI understand their symptoms, they are less likely to overreact to them (Sladyk, 1992; Ponsford, 2005).

Currently, there are few definitive research studies demonstrating exactly how common the associated symptom of aggression is prevalent in clients with mTBI and PTSD. This is presumably due to the fact that characteristics of mTBI and PTSD do not always manifest themselves the same way in every client. It could also be due to the fact that the client's lifestyle factors can influence some symptoms. One study examined inpatient behavior in an acute trauma setting with clients with TBI (Brooke, Questad, Patterson & Bashak, 1992). This study looked at 100 individuals and found only 11% of these patients demonstrated agitated behavior during their short inpatient stay. Another study found 30 of the 89 clients (33.7%) exhibited aggressive behavior, up to 6-months post-discharge (Tateno, Jorge, & Robinson, 2003). Both of these studies used the Overt Aggression Scale to measure these behaviors. Conversely, McKinley, Brooks, Bond, Martinage and Marshall (1981) reported up to 70% of patients' with TBI demonstrated increased aggression and irritability post-TBI (Ferguson & Coccaro, 2009; McKinley, Brooks, Bond, Martinage and Marshall, 1981). Relative reports and reports of violent criminal behavior were used to measure these behaviors as well as another study where it was reported that 64% of individuals with mTBI had temper control issues, whereas 20% exhibited increased violent behavior (Brooks et al., 1986). A more recent study, from Baguley, Cooper and Flemingham (2006), "found significant levels of aggression in approximately 25% of TBI survivors, a finding that remained stable for 5 years following discharge," (p. 52). This particular study also found aggression levels seemed to fluctuate across time within individuals, suggesting aggression is more of a transient behavior verses an organic one, in nature (Baguley et al., 2006). The variety of results could be due to the fact each study was conducted in a different setting, inpatient, outpatient and post-discharge, and also various measures were used to calculate aggressive behavior.

Common Treatments in Aggression

When considering interventions for these aggressive behaviors, there is lacking evidence to confirm what evaluation tool or treatment is most effective. There is also little empirical evidence that exists, guiding occupational therapy evaluation and intervention following a mTBI and PTSD (Radomski, Davidson, Voydetich & Erickson, 2009). There are various ways to measure behavior, psychometrically, such as a standardized Overt Aggression Scale, the Agitated Behavior Scale, relative's reports, and reports of violent criminal behavior among others (Baguley et al., 2006; Radomski, 2008). Because of the varying ways to quantify aggression, there are no clear implications on exactly how to treat, or even definitively measure the effectiveness, of treating the aggressive behavior.

Initial examination for clients with TBI, usually completed by a neurologist, assesses the neurological status of the injury through the Glasgow Coma Scale. This scale is a 15-point scale to test motor, eye-opening, and verbal capabilities. Another scale used to assess the level of TBI is the Ranchos Los Amigos Scale, which measures the levels of awareness, cognition, behavior and interaction with the environment. The levels are assessed by a physician throughout the various stages of recovery as the following levels: Level I: No Response, Level II: Generalized Response, Level III: Localized Response, Level IV: Confused-agitated, Level V: Confusedinappropriate, Level VI: Confused-appropriate, Level VII: Automatic-appropriate, Level VIII: Purposeful-appropriate. These ratings are accompanied by a computed tomography to determine the presence of intracranial hematomas (Radomski, 2008). Once the level of TBI is determined, treatment continues based on the results of the Glasgow Coma Scale and the Ranchos Los Amigos Scale. Traditional treatment for mild TBI includes both in- and out-patient rehabilitation. Inpatient rehabilitation is aimed at optimizing motor, visual-perceptual, and cognitive capacities and abilities. This assists in restoring competence in fundamental selfmaintenance tasks; thus, contributing to the patients behavioral and emotional adaptation and family support (Radomski, 2008). The Polytrauma System of Care, a healthcare system within the military designed to balance access with expertise in TBI, also uses a 22-item postconcussive symptom questionnaire called the Neurobehavioral Symptom Inventory, which better directs the plan of care (Cifu et al., 2010).

Traditional behavioral treatment of aggression with TBI can comprise of aggression replacement techniques, which include differential reinforcement, communication skills, and programming of activities (Jacobson, 1997). Cooke and Keltner (2008) summarize since TBI is such an individual experience, there is great variation in therapeutic response to specific means explaining that there are many ways to address the therapeutic process for different individuals. Frontal lobe injuries affect the perception of time due to possible sustained firing or inhibitory reactions between the neurons in this area (Picton et al., 2006). Summarized by James Phifer, PhD, "frontal lobe controls the development as an interface between limbic system urges and the demands of society. Once these acquired controls are lost as a result of injury, they must be rewired in the same manner they were originally wired..." (Wheeler, 2010, p. 11). Ways to acquire these new brain connections are through continuous training and therapy interventions, such as the Interactive Metronome® (Sabado & Fuller, 2008).

If occupational therapists were able to mitigate the aggression and agitation of clients with mTBI and accompanied PTSD, therapy for additional areas of recovery would be easier to administer and overall, result in more success. Clinicians will often attempt to manage negative behaviors by determining what factors are contributing to the agitation through the individuals' various contexts, such as personal, social and physical. Ways to manage the agitation and aggression include normalizing the environment and providing consistency and predictability to counter the client's confusion (Radomski, 2008). McKinley, Brooks, Bond, Martinage and Marshall (1981) reported up to 70% of patients with TBI demonstrated increased aggression and irritability (Ferguson & Coccaro, 2009). They also reported that 75% of those with PTSD had engaged in physical aggression (Beckham et al., 1997). Caregivers have repeatedly reported the behavioral aggression with their family and friends who have suffered from a TBI are the most difficult to deal with, both in public and in the home (Draper, Ponsford & Schonberger, 2007; Baguley et al., 2006). In its relation to implication for treatment and effects on families and

caregivers, these reasons alone are enough to consider aggression and agitated behavior in mTBI with PTSD clients with further research.

Interactive Metronome®

The Interactive Metronome® (IM®) is a computer-based training program shown to improve attention, coordination, and timing for individuals experiencing a wide range of cognitive and physical difficulties (Interactive Metronome, 2004). Attention, coordination and timing difficulties have been linked to behavioral problems, such as aggression and irritability (Shaffer et al., 2001). IM® is used as a tool in various therapy intervention settings for different trouble areas, including the ability to regulate aggression and impulsivity, and has shown significant improvements gained. Emerging clinical experience, together with Shaffer, et al.'s study (2001), suggests that the IM® may have potential usefulness is a wide range of clinical conditions, and may therefore compliment existing interventions currently being used by therapists showing that it could be useful as a possible additional therapy, alongside other interventions (Koomar et al., 2001; Shaffer et al., 2001).

The IM® purports to work by improving timing and rhythmicity related to motor planning and sequencing, which through this has shown to bring about improvements in behaviors and skills that are important for occupational performance in many areas (Koomar et al., 2001). The client participates by listening to rhythmic beats through specific headphones while trying to anticipate the beat and perform various hand and foot exercises for multiple repetitions. The client then hits a hand or foot switch to coincide with the auditory stimuli. Sensors within the hand and foot switch register these movements and the software analyzes them according to their speed and accuracy (Sabado & Fuller, 2008). The difference between the participant's response and the actual beat is measured in milliseconds and presented as a score; a lower score indicates improved timing and accuracy. The IM® provides drill in rhythm and training, which in turn may influence neural pathways (Sabado & Fuller, 2008). The brain is able to learn through repetition and by the participants maintaining the given beat, the brain is trained to plan, sequence and process information more effectively (Shaffer et al., 2001; Interactive Metronome, 2004).

The IM® is considered in terms a dynamic system theory, which is the same idea that occupational performance is a product of the individual human system, as well as the tasks presented and the environment that the human occupies (Kielhofner & Forsyth, 1997; Phipps & Roberts, 2006). Koomer et al., (2001) describes that with each action or behavior that occurs, the human system or the environment experiences a change, requiring the human system to reorganize so that it can accommodate those experiences. Many occupational therapists frame their practice after the theories of Kielhofner, noting any change in the system between the client factors, the contexts, and the occupations will have an effect on all of the subsystems (Phipps & Roberts, 2006). A similar experience is taking place with the IM® acting as the catalyst of change to the human system, allowing for reorganization in the brain to take place by the influence of timing in the neural pathways. With the IM ® working through timing and sequencing of motions, the idea is proposed that this treatment could have an affect on the plasticity of the brain. This neuroplasticity implies that the brain is capable of long-term changes in function or neural regions in response to physiological stimuli (Gynther, Calford & Sah, 1998).

Previous research on the IM® has proven to be successful in many areas previously mentioned. Bartscherer and Dole (2005) conducted a study to improve timing and coordination in a young male with a diagnosis of ADHD. The seven week training program was preceded and followed with a pre- and post- test of the Bruininks Oseretsky, (Bruininks- Oseretsky, 1978). The study was validated through marked changes in scores on both timing accuracy and several motor subtests. Along with this, the participant's parents reported positive changes in behavior through a verbal interview (Bartscherer & Dole, 2005). Additional research shows the affects of the IM® on an adolescent female with a language-learning disorder. During 15 treatment sessions including the IM® spread evenly over a month, the participant suspended all other language services. The results showed the use of the IM® training with the rhythm and timing had positive effects on language skills through the participant's significant improvements on standard scores of two language tests, the Oral and Written Language Skills (OWLS) and the Expressive One Word Pictionary Vocabulary Test (EOWPVT) (Sabado & Fuller, 2008). The IM® shows promise as an intervention tool in these areas by strengthening the 'neuronetworks' to allow faster and more accurate transmission of information between areas of concern, such as aggression and irritability seen in individuals with TBI and PTSD.

TRX® Suspension Training System

The TRX® Suspension Training System is a full bodyweight exercise system that was created by the U.S. Navy SEALS and developed by Fitness Anywhere®. It is a portable suspension trainer, weighing only two pounds, that allows the user to safely perform hundreds of exercises that build power, strength, flexibility, balance, mobility and prevent injuries. The TRX® is a dynamic, versatile, compact training tool that allows for proprioceptive core stabilization enhancement during rehabilitation exercises for a multitude of conditions (Perkash, 2011). Because this tool is so new, to the knowledge of the investigators, it has not been combined with the IM® or published in any peer-reviewed journal.

Rhythmicity

Rhythmicity is defined most basically as "the state of having a rhythm or the ability to beat," (Merriam-Webster Online Dictionary, 2011). When combined with technology, rhythms can have a therapeutic effect on different systems of the body. Rhythm interventions that involve computerized technology can provide external stimuli through auditory, physical and visual stimulation. In the case of the IM®, the auditory component is the sound of a bell to a rhythmic beat and the physical component requires the individual to hit a trigger switch by executing a movement pattern with their upper or lower extremities to match the beat. The visual component involves either observing one's body movements while executing the movements or the visual biofeedback system that can be provided for the individual if deemed necessary. Studies of sensory integration have shown that auditory stimuli were found to be dominant over visual (Aschersleben & Bertleson, 2003).

Through this type of intervention, studies have been validated as effective through the neural changes measured by a functional Magnetic Resonance Imaging (MRI) following engagement in rhythmic training with auditory cues, (Luft et. al, 2004). Three parts of the brain are bilaterally activated during IM® tasks: 1) the cingulated gyrus, 2) the basil ganglia and 3)the medial brainstem. The cingulated gyrus and the medial brainstem coordinate sensory input with emotions and regulates aggressive behavior (Matthews, Fisher & Denton, 2010). The basil ganglia is a group of nuclei that are directly associated a variety of functions such as cognitive, emotional and routine behaviors. These three parts provide input and output connections to the frontal lobes where cognitive and motor processing occurs and synaptic modulation can be augmented through specific auditory-motor sequencing tasks, such as those provided through the IM® (Alpiner, 2004).

Summary

The literature review provided has been focused on the population and instruments that will be used in research and as part of the expected Operation Re-Entry. The population that was used in this study meet and exceed the standards of a healthy well individual who are reflective of those who enter the military and then later sustain injuries as part of the war effort. A literature review on well healthy individuals, while reflective of this pilot, does not prepare one for the expectations of where outcomes will be applied and therefore not pursued as part of this thesis submission.

Specific factors that contribute to post-injury aggression are unclear (Draper et al., 2007). While uncovering the considering factors that contribute to aggression may be a complex and daunting task, attempting success in various intervention treatments could provide professionals with additional knowledge on how to address the aggressive behavior and enhance progress during therapy. Using coping mechanisms to address many of the symptoms and problems associated with mTBI and PTSD may be an inevitable need for these sufferers, but if intervention methods, such as the IM® along with the TRX®, are able to compliment other therapies, professionals could provide better rehabilitation results. Families, friends, and caregivers of those individuals with mTBI and PTSD agree that intervention that decreases behavioral issues could lead to further treatment success in other areas of concern (Baguley et al., 2006). If these behavioral problems could be addressed, there could be better outcomes in all areas that are of concern for those individuals diagnosed with mTBI and PTSD. Not exploring the effectiveness of these tools, after reviewing previous success in similar areas, would be doing a disservice to those with mTBI and PTSD. Therefore, the specific purpose of this study is to validate the protocols created in order to directly address the treatment outcomes for clients with

mTBI and PTSD by testing the IM® with the TRX® as an effective tool in decreasing behavioral aggression levels and improving life satisfaction.

III. METHODOLOGY

Introduction

A quasi-experimental, pre- and post- test research design was conducted to examine the effectiveness of the Interactive Metronome® (IM®) and TRX® as an intervention tool with pilot participants. This pilot study was conducted with the protocols developed for individuals diagnosed with mild TBI and PTSD with the anticipated results of decreasing behavioral aggression levels and increasing mood affect in the satisfaction of life. These protocols can be found in Appendix C and Appendix D. The design was a pre- and post- test design, where all four pilot participants were assessed with evaluation tools before the intervention and following the intervention. This type of design allowed for most significant results and also helped control the question of other variables, being other treatments or physical activity regimens the participants were receiving. These additional variables could affect the results of the scores on the pre- and post- tests. While this type of design may produce additional confounding variables, by definition, quasi-experimental allows for the individuals in the study to continue the additional therapies that they were receiving. The goal of the study was not to delineate between the best treatment, but rather to confirm the IM® and TRX® protocols developed as an effective method of influencing behavior in mild TBI and PTSD, through this pilot study of four well individuals. The independent variable, which influences the outcome, is the IM® and TRX®. The dependent variables are the results of the scores that come from the assessments, being the Overt Aggression Scale (OAS), Nine Hole Peg Test (NHPT), Canadian Occupational Performance Measure (COPM) and the statistical scores from the IM® Short Form and the IM® Long Form Assessments.

Population

The population for this study included two healthy, well male and two healthy, well female graduate students who could potentially enter the military service as a career option. The subjects were between twenty-one and twenty-four years of age. The population criteria for this pilot study was reflective of the military population in general, in that entry into the military typically is what the protocols have originally been developed for. The type of non-probability sampling used was convenience and purposive. Participants were recruited from the Occupational Therapy program at East Carolina University based on their willingness to participate and availability of time. Two males and two females were recruited by the principal investigator, along with the help of the secondary investigator. Inclusion criteria for the participants include good health status, ability to sustain the specified level of physical activity, and ability to be available at least nine hours a week for four consecutive weeks to complete research protocols. Participants were excluded from the study if they were considered anything other than in good health status, were unable to sustain the specified level of physical activity, or could not reserve the time required to complete protocols.

This pilot study was developed to provide data on the protocols before administering the intervention to the Marines on Active Duty from Camp Lejeune in Cherry Point, North Carolina. However, for the specific purpose of this study, the four well participants were recruited to trial run the protocols created, in order to substantiate the protocol's effectiveness.

Apparatus

The IM® software was installed on provided laboratory laptops. The program's multiple settings were adjusted and prepared to meet the individual treatment needs of each participant and the designed protocols. The IM® incorporates a computerized metronome with guide sounds

via the computer program and technical equipment, consisting of headphones, a hand switch and a foot switch, which are part of the IM® system and standard of care. The client hits a hand or foot switch to coincide with a rhythmic beat that comes through the headphones. Sensors within the hand and foot switch register these hits and the software analyzes them according to their speed and accuracy (Sabado & Fuller, 2008). The difference between the participant's response to anticipating the beat and the actual beat is measured in milliseconds and presented as a score; a lower score indicates improved timing and accuracy. A centered hit is referred to as Super Right On or SRO, which equates to the user as timing their hit with the anticipated sound within a 15 millisecond on either side of the zero point.

TRX® Suspension Training system was incorporated into the protocols of this study. TRX® stands for "total body resistance exercise" and is a portable, light-weight, and versatile piece of exercise equipment that can be used at home, in the gym, or outside by attaching to a variety of surfaces (Fitness Anywhere®, 2011). The TRX® allows the user to perform hundreds of functional exercises that build strength, flexibility, core stability and endurance. This exercise equipment complements the IM® movements during the treatment protocols. The TRX® was selected to balance the IM® because of the similar physical, rhythmic movements that the TRX® provides. Additionally, this was selected over other exercise routines that also provide rhythmic movements and patterns as it allows for movement in all planes of action. The motions of the IM® encourage this movement as well. Refer to Appendix E for a list of the complimenting movements in both the IM® and the TRX®. Adding a physical exercise component to the IM® intervention provides the Military clients, for which the protocols were created, a sense of continued challenge. The IM® consists of repetitive rhythmic motions, while the TRX® allows for some physical activity and adds a physical demand on the neurological system of the individual in addition to the IM® routine. In theory, this challenge will add to the level of motivation and raise the level of expected change as viewed by the participants. This is important as the expectation of the participants prior to the injury was of very high physical challenge. This level of physical stamina also matches that of the population for this study, as all four individuals seek physical challenge and fitness as a part of everyday life.

Protocols

The protocols were developed prior to beginning this study, by a graduate student with the assistance another investigator and the primary advisor. The protocols consist of a combination of seven IM® exercises and seven TRX® exercises per session. Each of the IM® and TRX® exercises last 3-6 minutes, resulting in a total time of between 25-30 minute sessions per participant. The protocols also include a TRX® warm-up and cool-down stretch and an IM® Short Form Assessment for each session. Please refer to Appendix C for a listing of the specific protocols. Please refer to Appendix D and Appendix C for specific on these protocols created. The intent was to start with IM® standard routines and create a TRX® routine that physically challenged the participant in similar physical movements. For example: The IM® has a routine that involves both hands that are moved in a clapping motion, where the person brings the hands forward and claps in the midpoint of the body. The TRX® corresponding exercise would be: Exercise 1: Chest Press toward Midline (Straps are Length Long); (30 Seconds on, 30 Seconds rest for 4 minutes) where the participant would face away from the TRX®, perform exercise with feet beyond shoulder-width. Lower the chest in push-up motion and return to start position.

Instrumentation

The assessments used were the Canadian Occupational Performance Measure (COPM) (Law et al., 1998), the Nine Hole Peg Test (NHPT) (Mathiowetz, Weber, Kashman & Volland, 1985), the IM[®] Short Form and IM[®] Long Form (Interactive Metronome, 2004) and the Overt Aggression Scale (OAS) (Silver & Yudofsky, 1991). The COPM is an interview measure that evaluates the most important areas of performance depending on a series of areas, such as self-care, productivity and leisure. This interview was conducted to obtain important information involving a change in the client's self-perception of occupational performance over time. This assessment was chosen because it provides a quick, yet thorough, evaluation of an individual's performance in daily activities. When considering the COPM, the test-retest reliability was found to be in the acceptable range for both the Performance and Satisfaction scores and additional research conducted has found even more encouraging reliability values of .80 for Performance and .89 for Satisfaction scores (Law et al., 1998). The three types of validity evaluated for the COPM were content, criterion and construct validity. The content validity was strong, based on the expression of the characteristics that it expresses through how it defines occupational performance. The criterion validity was proven strong through recent studies saying that the COPM was more successful in identifying problems of individual occupational performance where-as open ended questions raised broader issues. The construct validity was supported through research that considered the correlations between the COPM scores and performance components (Law et al., 1998). This evaluation allowed for the researchers to consistently measure the client's affect and what specific everyday tasks that the individual was finding frustrating or difficult. The COPM was chosen to be used with the mTBI and PTSD diagnosed population because previous investigations into the clinical use of the COPM have found it to be sensitive to change in brain injury rehabilitation, neurological rehabilitation and brain-injury specific group rehabilitations programs (Doig, Fleming, Kuipers, Cornwell, 2010). Due to the healthy well nature of this study's participants chosen for the pilot study, the COPM

interview was modified slightly and conducted by the investigator who administered it in a way to allow participants to identify mild deficits in their everyday life skills they wish to improve. Some examples include increasing study attention time, decreasing stress during deadlines, improving organization and time management skills, or improve sense of coordination. Investigators expect participants to show trends of improvement on COPM scores, but not reaching the level of statistical significance due to the well baseline of the pilot population. Refer to Appendix B for a copy of the COPM.

The Nine-Hole Peg Test (NHPT) is an instrument commonly used by occupational therapists to quickly and accurately assess finger dexterity (Grice et al., 2003; Mathiowetz et al.,1985). The NHPT measures the time it takes for the client to place individual pegs in nine holes arranged in 15 millimeter intervals in three rows. After successful placement of all pegs, the client removes them individually. This instrument was chosen for the study because it is easy to administer and gives a quick assessment of a person's finger dexterity and allows for a measurement and percentage of change to be calculated. In addition, while not of focal point of change, it allows the measurement of change of the physical skill that is not directly practiced or trained by either intervention, yet can be measured as a system change. The NHPT was used as a pre- and post-test evaluation tool during this study. In 1985, a research study examined the reliability of the NHPT in 26 healthy young female adults (Mathiowetz et al., 1985). To examine intra-rater reliability, participants were re-assessed with a one week interval by the same rater. Results showed excellent agreement for the right hand and adequate agreement for the left with Pearson correlations (r = 0.69; r = 0.43). In regards to interrater reliability, the Pearson correlation coefficients showed excellent agreement for both the right and left hand (r = 0.97; r =0.99), respectively (Mathiowetz et. al, 1985). In 2003, another study was conducted to examine

the reliability of the NHPT after the design was slightly modified. The interrater and test-retest reliability of the commercially available Smith & Nephew Rehabilitation version of the NHPT was established by evaluating 25 occupational therapy student volunteers (Grice et al., 2003). Seven hundred and three subjects, ranging from 21 to 71+ years, were tested to establish norms, using the standard protocol (Grice et al., 2003). These norms showed high interrater reliability and only moderate test-retest reliability, which support original norms previously published in the 1985 study (Grice et al., 2003; Mathiowetz et al., 1985).

The Overt Aggression Scale (OAS) was designed to assess observable aggression or violent behavior rather than tendencies. It consists of four separate categories: 1) Verbal Aggression, 2) Physical Aggression, 3) Physical Aggression Against Self and 4) Physical Aggression Against Others (Silver & Yudofsky, 1991). Within each category, aggression is rated according to its severity. The second part of the scale takes into account the rate of staff or family member intervening in an observed aggressive behavior. The information obtained consists of the number and severity of aggressive incidents that have occurred in the past week. Scores can range from 0.0 to 16.9 on the OAS. The highest level of aggression, 16.9 is severe aggression that involves hurting self or others, lighting objects on fire and causing extreme harm to something. Endorsement of any of items one or more times in the past week was an indicator or aggressive behaviors. There are not norms established for this scale. This scale was chosen, as it is one of the most common and reliable scales used to evaluate the severity and levels of aggression in adults (Alderman, Knight & Morgan, 1997). Studies evaluating the reliability of the OAS used methods consistent with common clinical practice and consistently found the reliability to be excellent (Alderman, Knight & Morgan, 1997). There was less reliability upon ratings of incidents where multiple interventions were used as compared to incidents when a

single intervention was used. The criterion validity data of the OAS has not been presented or published in a study (Giles & Mohr, 2007). Due to the well baseline nature of the pilot study participants, investigators were not expecting strong measures of aggression through this assessment. Please refer to Appendix A for the OAS.

Procedure

International Review Board approval was obtained through East Carolina University. Once passed, participants met with the two graduate investigators to conduct intake protocols. One of these graduate students was the primary investigator and the other was a secondary investigator. The four participants included in the study were two healthy females and two healthy males. All participants were students who had right hand dominance and full range of motion to conduct all physical activities required. Intake protocols were established through consent forms, a series of interviews and assessments that were completed individually between one of two graduate investigators and one participant at a time. These interviews included the assessments of the COPM, OAS, NHPT and the IM® Short Form and IM® Long Form. The initial interview and intake protocol meeting did not last more than one hour. First, the IM® Short Form was conducted to get an initial score. The IM® Short-Form Assessment was a 2minute evaluation tool that assessed the participant's motor, attention and processing skills by using both hands to clap on the beat of the metronome and also clapping both hands with a reference tone added. The COPM was conducted to gain the self-perception scores of performance and satisfaction of occupations in the participant's life. The OAS was then conducted to measure their levels of aggression as well as any intervention provided during episodes of aggression. Next, the NHPT was conducted and hand dominance noted. Finally, the IM® Long Form Assessment was conducted on the IM® device. The Long-Form Assessment is a 20 minute evaluation that provides baseline data that encompasses both upper and lower extremities both bilaterally and in isolation (Interactive Metronome, 2009).

For the convenience of the participants, the IM® intervention treatments were conducted in multiple settings. Two of the participants always completed the full IM® and TRX® intervention protocols in the apartment lab located at the East Carolina University Health Sciences Building. The other two participants consistently completed the intervention treatment in one of their apartment settings. An investigator was present at all sessions and made sure the environment was free of distraction to allow all the participants a consistent environment. Both the IM® and TRX® are mobile units that were created for use in varied locations. All procedures conducted by the investigators were overseen by the advising research faculty member of the Occupational Therapy Department of East Carolina University.

Within the next week of this initial meeting, the primary investigator familiarized the participants with the IM® and the TRX®. This interaction was informal and allowed the participants to ask questions, learn from one another's questions and familiarize themselves with the intervention program. Basic protocols were previously established by a separate research review, using the IM® and the TRX® in complimenting ways. These specific protocols can be reviewed in Appendix C. The participants were provided with additional training manuals that could be used if further questions arose. These training manuals included descriptions of the protocols established with the IM® and the TRX®. Following this session, the participants met again with at least one investigator to review and clarify any uncertainties of the participant. Participants met with investigators throughout the next four weeks to execute the designed protocols. These ten sessions lasted around 60 minutes and overall included about 30 minutes of the TRX® and about 30 minutes of the IM®. Specifically, each session included six-seven

intermittent, around 4 minute sessions with the IM[®] and the TRX[®], with the two participants alternating between the two devices. The number of IM[®] repetitions in the protocols was created in concordance with the amount of repetitions of which the IM[®] purports to affect change. Specific example sessions can be seen in Appendix D. This session includes the IM[®] and the TRX[®], as did the nine sessions between the pre-test and the post-test.

Following the nine intervention sessions, the same pre-test assessments were completed post-test by the same investigator that administered the pre- test assessment. These post-test assessments were conducted by the investigators in the same manner as the pre- test assessments were. The assessment tools were used to collect data on the areas of aggression, behavior and satisfaction in daily activities that the IM® purports to effect change. The value of measuring these changes allowed for the determination of a variety of factors that may affect perceptions of self and ability in mTBI and PTSD clients.

IV. Analysis of Data

Introduction

The purpose of this study was to validate the protocols created for the Interactive Metronome® (IM®) and the TRX Suspension Training system (TRX®) for use with clients diagnosed with mild Traumatic Brain Injury (mTBI) and Post-Traumatic Stress Disorder (PTSD). The specific research question addressed if the IM® and TRX® protocol series, developed for mild TBI and PTSD symptoms, affected change in decreasing levels of aggression and improving life satisfaction in normal, healthy, young adults through a series of intervention sessions. In keeping with the methodology, the results of the data gathering were analyzed using the statistical process most appropriate for each instrument.

Data Analysis & Results

Data analysis began by organizing and categorizing the data by participant and instruments. The Statistical Package for the Social Sciences (SPSS), version 10.0, was used for data analysis along with Microsoft Excel. The significance level was set as $\alpha = .05$ for all analyses, reflecting conventional statistical procedures. It should be noted that due to small population size, validity of statistical measures is less than optimal, but helps establish expectations for futures studies and outcomes review. Parametric *t*-tests were conducted to assess change of functional measures between the two time points, the pre-test evaluation and the posttest evaluation. Percentages of change were observed in the NHPT and the IM® Short and Long Forms.

Overt Aggression Scale Results.

When considering all participants data from the Overt Aggression Scale (OAS), although the overall level of aggression did decrease, the results did not conclude to be significant from pre-test to post-test. For the four pilot study participants, an independent-sample *t*-test was conducted on the data to compare the pre-test aggression scores and the post-test aggression scores. The *t*-test produced an overall p-value result of 0.39 which is not significant. The lowest score that can be reported on the OAS is 0.0 and the highest score, reporting extreme aggression is 16.9. The sum of pre-test level for all participants combined was 4.0, with a mean of 1.0 and a standard deviation of 1.41. The post-test results showed a total level of aggression at only 2.0, (mean = 0.5, SD = 0.58). Table 1: *Overt Aggression Scale Scores for all Participants* shows their individual scores for pre- and post- test aggression levels.

Table 1

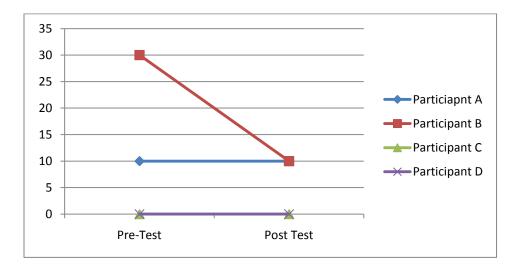
| | Pre-Test Scores | Post-Test Scores |
|---------------|-----------------|------------------|
| Participant A | 1 | 1 |
| Participant B | 3 | 1 |
| Participant C | 0 | 0 |
| Participant D | 0 | 0 |

Overt Aggression Scale Scores for all Participants

There was not a considerable difference in scores for the participants, considering the highest amount of aggressive acts was 3.0 and the lowest number of aggressive acts was 0.0. Participant A had both pre-test and post-test score of 1.0, which shows no change occurred

during the intervention for this participant regarding aggression levels. Participant B had a pretest score of 3.0 and a post-test score of 1.0 which demonstrates a change in the level of aggression during the intervention provided. Both Participant C and Participant D did not show aggression prior to the intervention or following the intervention during post-testing. The OAS, as mentioned above, is designed to assess observable aggression or violent behavior rather than tendencies. Within each category, aggression is rated according to its severity. The severity of the aggression shown by these participants was very low. Figure 1, *Pre-Test and Post-Test Overt Aggression Scale scores by participant,* depicts the graphic representation of the participants score on the OAS.

Figure 1



Pre-Test and Post-Test Overt Aggression Scale scores by participant

*For purposes of graphing, OAS scores were multiplied by 10 to provide a more visually relevant and understandable graph

Canadian Occupational Performance Measure Results.

The Canadian Occupational Performance Measure (COPM) categorizes three general areas of occupation: self-care, productivity, and leisure (Law et al., 2005). The focus of the

COPM is toward problem areas as perceived by the client and becomes very client based. It was anticipated that with this population the problems identified would not be categorically intrusive on their lives and often times situational or considered normal daily responses to demands on typical student lives. An increase in score is desirable, showing better performance and satisfaction of that performance in the participant's areas of concern. Participant A showed an increase of 0.75 (from 5.75 pre-test to 6.50 post-test) on Performance and 0.75 (4.25 pre- test to 5.0 post-test) on their Satisfaction of their abilities in their areas of concern. Participant B showed a larger increase in scores, of 1.0 on Performance (from pre-test of 3.75 to 4.75) and 2.0 on Satisfaction of areas of concern (from 2.75 during pre- test to 4.75 during post- test). This shows significant change for this participant. Participant C did not show notable change between pre- and post- testing, resulting in a 0.0 for change on the Performance score and 0.2 on their Satisfaction score. Participant D demonstrated a change of 1.0 (from 6.25 pre-test to 7.25) for their Performance of their areas of concern and a 0.5 score of change for Satisfaction (from 7.5 pre-test to 8.0 post-test). Table 2: Pre-test and Post-test COPM Raw Scores of all Participants below shows this data as well as specific areas of concern.

For the four participants in this pilot study, the mean number of occupational performance goals identified using the COPM was 4.25, with a range between 4.0 and 5.0. Overall, there was a mean change in performance from pre- to post- test of 0.69 points (SD= 0.47) and a mean change in satisfaction from pre- to post- test of 0.86 points (SD= 0.79). Previous studies show that a change of 2 or more points on the COPM usually represents at least 0.75 of a standard deviation, which is considered moderate to large change and a clinically important difference (Law et al., 1994). As the mean result for both Performance and Satisfaction were below 2 points, there was not clinically significant data for this population.

Table 2

| | Participant A | | Participant B | | Participant C | | Participant D | |
|--|--|--------------|---|--------------|---|--------------|--|--------------|
| | Performance | Satisfaction | Performance | Satisfaction | Performance | Satisfaction | Performance | Satisfaction |
| Pre-Test | 5.75 | 4.25 | 3.75 | 2.75 | 6.0 | 5.4 | 6.25 | 7.5 |
| Post- Test | 6.5 | 5 | 4.75 | 4.75 | 6.0 | 5.6 | 7.25 | 8.0 |
| Change (Pre- Test to Post- Test) | 0.75 | 0.75 | 1.0 | 2.0 | 0.0 | 0.2 | 1.0 | 0.5 |
| Areas of Concern | Time management skills, notebook organization between classes, time for the gym, time for friends and movies | | Time for healthy cooking, following agenda book, leisure time for self, socializing with friends | | Time management skills, managing stress levels, budgeting finances, cooking, Participating in leisure/social activities | | Balance and coordination, organize finances, become more organized with work, have more motivation and endurance during exercise | |

Pre-test and Post-test COPM Raw Scores of all Participants

The Nine Hole Peg Test Results.

The Nine Hole Peg Test (NHPT) results came from an independent samples *t*-test conducted to compare the overall time it took the participants to complete the NHPT on the right and left hand for the pre- and post-test evaluations. As previously stated, all of the participants hand a right-hand dominance. The results of the four participants scores combined consisted of the right hand p-values of 0.33 and the left hand p-values of 0.13. These combined results are not significant at the 0.05 level.

The right and left hand percentage of change for each participant are shown in Table 3: *Percentage of Change for Nine Hole Peg Test* below. A positive rate of change is preferable due to the nature of the NHPT assessment. The number of seconds' decreases as the participant's coordination and speed improve. As seen below, the rate of change for Participant A was significant on the left hand, but not on the right. The opposite is true with both Participant B and Participant C, as their right hand improvements were far higher than the left hand improvements. Participant D had the least varying results between hands, as the right hand percentage of change was 1.70% and their left hand percentage of change was -5.70%.

Table 3

| Participant | Hand Dominance | Right Hand % of change | Left Hand % of change | | |
|-------------|----------------|------------------------|-----------------------|--|--|
| Α | Right | 3.00% | -18.00% | | |
| В | Right | -11.00% | 1.80% | | |
| С | Right | -25.00% | -1.30% | | |
| D | Right | 1.70% | -5.70% | | |

Percentage of Change for Nine Hole Peg Test

The IM® Short Form Results.

All sessions began and concluded with the IM® Short Form Assessment which includes two exercises, Task One and Task Two. Task One consists both hands, clapping together and Task Two consists of the same exercise with added guide sounds to provide auditory cueing, alerting participants of the timing of their performance. The scores of all participants Task One and Task Two are described below. For all participants, a paired, independent *t*-test was run to compare each session to the previous session and also the very last session to the very first session for both Task One and Task Two. Refer to appendix D for a detailed explanation of each session.

Participant A

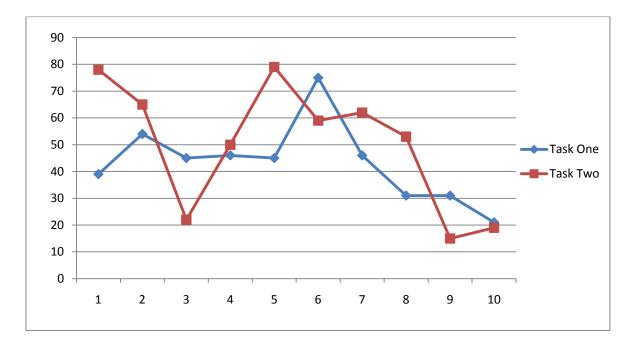
Task One: Both Hands

In session one, the task average was 39ms as compared to 54 ms in session two. There was then a decrease in task average time down to 45 ms in session three, for which Participant A was consistent on through session seven, with the exception of an unexpected 75 ms for session six. Following session six, there is a steady decline from 46 ms in session seven to 31 ms for both session eight and session nine. Participant A decreased his task average to 21 ms in their last session. The *t*-tests conducted did not provide evidence for significant figures from session to session or from the last session compared to the very first. Again, due to small population size, validity of statistical measures is less than optimal.

Task Two: Both Hands with Guide Sounds

In session one, the task average was 78 ms as compared to 65 ms in session two. There was then a large decrease in task average time down to 22 ms in session three, for which Participant A was not consistent with, as their score increased to 50 ms in session four. Once again, this participant's task average increased in session five with 79 ms and stayed in the higher range through session eight with 59 ms in session six, 62 ms in session seven and 53 ms in session eight. Participant A then decreased their task average to 15 ms in session nine and 19ms in their last session. The *t*-tests conducted did not provide evidence for significant results from session-to-session or from the last session compared to the very first. The following Figure 2: *Task Average of IM*® *Short Form (in milliseconds) for each Session- Participant A*, shows the trends in a chart form. The parametric *t*-test conducted produced a p-value of 0.31, which although not clinically significant, is a notable change for the overall change over the sessions.

Figure 2



Task Average of IM® Short Form (in milliseconds) for each Session- Participant A

Table 4: *Participant A Results from IM*® *Short Form*, depicts the specific numeral results of Participant A by each session, the scores for Task One and Task Two, along with the comparison to previous sessions. The averages are shown in milliseconds.

Table 4

| Participant A | Results | from | IM® | Short | Form |
|---------------|---------|------|-----|-------|------|
| | | | | | |

| Session | Task 1: MS Average | Task 2: MS Average | P-value compared to previous session | P-value compared to first day |
|---------|-----------------------|-----------------------|--|----------------------------------|
| 1 | 39 | 78 | | |
| 2 | 54 | 65 | 0.95 | 0.95 |
| 3 | 45 | 22 | 0.37 | 0.57 |
| 4 | 46 | 50 | 0.48 | 0.66 |
| 5 | 45 | 79 | 0.52 | 0.39 |
| 6 | 75 | 59 | 0.87 | 0.81 |
| 7 | 46 | 62 | 0.57 | 0.76 |
| 8 | 31 | 53 | 0.16 | 0.30 |
| 9 | 31 | 15 | 0.49 | 0.42 |
| 10 | 21 | 19 | 0.74 | 0.31 |

MS= milliseconds

Participant B

Task One: Both Hands

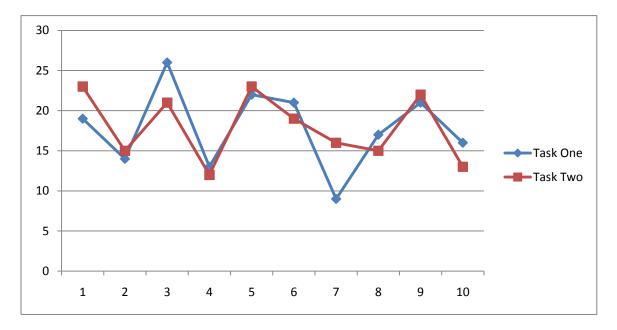
In session one, the task average was 19 ms as compared to 14 ms in session two. There was then a slight increase in task average time up to 26 ms in session three. From session three to session four Participant B decreased their task average to 13 ms. There was then a slight increase to 22 ms in session five, where they stayed consistent in session six with 21 ms. In session seven, there was a great decrease in task average score with 9ms off of the beat. Session eight increases slightly to 17 ms and again to 21 ms in session nine. The final session shows a decrease of 5 ms, taking session ten to 16 ms. The *t*-tests conducted for this IM® Short Form assessment did not provide evidence for significant figures from session-to-session or from the last session

compared to the very first. No significance was anticipated given the inability to do comparative means with the low numbers in the population used in this study.

Task Two: Both Hands with Guide Sounds

In session one, the task average was 23 ms as compared to only 15 ms in session two. There was then an increase in task average time to 21 ms in session three, for which Participant B was not consistent with, as the score decreased to 12 ms in session four. Once again, the task average increased in session five with 23 ms and then was decreased again in session six with 19 ms, even more in session seven with 16 ms and all the way down to 15 ms in session eight. Participant B then very slightly increased the task average to 22 ms in session nine and back down to 13 ms in the last session. The *t*-test conducted produced a p-value of 0.31 from the last session compared to the very first , which is the most notable of all participants, but still not clinically significant. No significance was anticipated given the inability to do comparative means with the low numbers in the population used in this study. The following Figure 3: *Task Average of IM Short Form (in milliseconds) for each Session- Participant B*, provides this information and trends in a chart form.

Figure 3



Task Average of IM® Short Form (in milliseconds) for each Session- Participant B

Below, Table 5: *Participant B Results from IM*® *Short Form*, depicts the specific numeral results of Participant B by each session, the scores for Task One and Task Two, along with the comparison to previous sessions. The averages are shown in milliseconds.

Table 5

| Session | Task 1: MS Average | Task 2: MS Average | P-value compared to previous session | P-value compared to first day |
|---------|-----------------------|-----------------------|--|-------------------------------------|
| 1 | 19 | 23 | | |
| 2 | 14 | 15 | 0.14 | 0.14 |
| 3 | 26 | 21 | 0.20 | 0.68 |
| 4 | 13 | 12 | 0.11 | 0.18 |
| 5 | 22 | 23 | 0.06 | 0.49 |
| 6 | 21 | 19 | 0.34 | 0.80 |
| 7 | 9 | 16 | 0.34 | 0.11 |
| 8 | 17 | 15 | 0.58 | 0.34 |
| 9 | 21 | 22 | 0.17 | 0.80 |
| 10 | 16 | 13 | 0.18 | 0.31 |

Participant B Results from IM® Short Form

Participant C

Task One: Both Hands

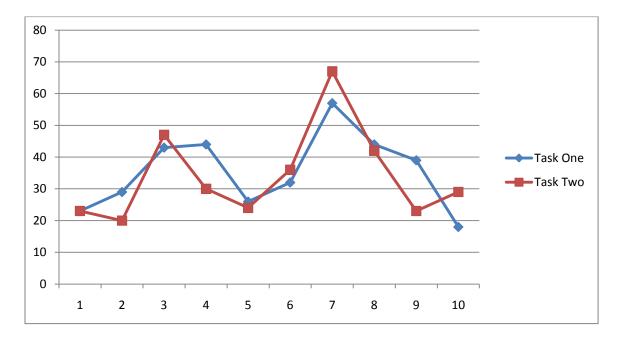
Just as with the past two participants, a t-test was again run to compare each session to the previous session and also the very last session to the very first. In session one, the task average was 23 ms as compared to 29 ms in session two. There was then an increase in task average time up to 43 ms in session three. From session three to session four Participant C stayed consistent with the task average of 44 ms. There was then a slight decrease to 26 ms in session five, where the score stayed pretty consistent in session six with 32 ms. In session seven, there was an increase in task average score with 57 ms off of the beat. Session eight decreases slightly to 44 ms and again to 39 ms in session nine. Session ten then decreased to 18 ms. The *t*-tests

conducted did not provide evidence for significant figures from session to session or from the last session compared to the very first.

Task Two: Both Hands with Guide Sounds

In Session one, the task average was 23 ms as compared to only 20 ms in session two. There was then an increase in task average time to 47 ms in session three, for which Participant C was not consistent with, as the score decreased to 30 ms in session four. Once again, the task average decreased in session five with 24 ms and then was increased again in session six with 36 ms, even more in session seven with 67 ms and then down to 42 ms in session eight. Participant C then decreased their task average to 23 ms in session nine and then slightly up again to 29 ms off of the beat in their last session. An overall p-value of 0.94 was the result of a *t*-test conducted with the figures from session to session and from the last session compared to the very first. No significance was anticipated given the inability to do comparative means with the low numbers in the population used in this study. The following Figure 4: *Task Average of IM Short Form* (*in milliseconds*) for each Session- Participant C, provides this information in a chart form.

Figure 4



Task Average of IM® Short Form (in milliseconds) for each Session- Participant C

Table 6: *Participant C Results from IM*® *Short Form,* depicts the specific numeral results of Participant C by each session, the scores for Task One and Task Two, along with the comparison to previous sessions. The averages are shown in milliseconds.

Table 6

| Session | Task 1: MS Average | Task 2: MS Average | P-value compared to previous session | P-value compared to first day |
|---------|-----------------------|-----------------------|--|-------------------------------------|
| 1 | 23 | 23 | | |
| 2 | 29 | 20 | 0.80 | 0.80 |
| 3 | 43 | 47 | 0.20 | 0.06 |
| 4 | 44 | 30 | 0.54 | 0.30 |
| 5 | 26 | 24 | 0.30 | 0.30 |
| 6 | 32 | 36 | 0.20 | 0.11 |
| 7 | 57 | 67 | 0.07 | 0.08 |
| 8 | 44 | 42 | 0.20 | 0.03 |
| 9 | 39 | 23 | 0.34 | 0.50 |
| 10 | 18 | 29 | 0.27 | 0.94 |

Participant C Results from IM® Short Form

MS= milliseconds

Participant D

Task One: Both Hands

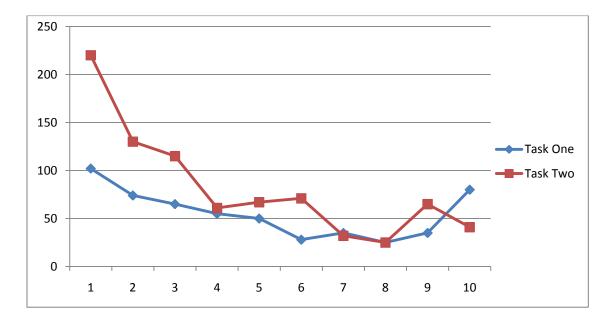
In session one, the task average was 102 ms off of the beat as compared to only 74 ms off of the beat in session two. There was then a decrease in task average time down to 65 ms in session three. From session three to session four Participant D stayed pretty consistent with the task average, with a slight decrease to 55 ms. There was then another slight decrease to 50 ms in session five. Session six created a larger decrease, down to 28 ms off of the beat. In session seven, there was an increase in task average score to 35 ms off of the beat. Session eight decreases slightly to 25 ms and again goes back up to 35 ms in session nine. The final session shows an uncharacteristically large increase to 80 ms. The *t*-tests conducted did not provide

evidence for significant figures from session to session or from the last session compared to the very first. No significance was anticipated given the inability to do comparative means with the low numbers in the population used in this study.

Task Two: Both Hands with Guide Sounds

In session one, the task average was high, at 220 ms as compared to 130 ms in session two. There was then a decrease in task average time to 115 ms in session three, for which Participant D was not consistent with, as their score decreased to 61 ms in session four. Session five provided a slight increase to 67 ms, and then increased again in session six with 71 ms. In session seven, there was a 50% decrease to 32 ms off of the beat, and even more in session eight with only 25 ms. Participant D then increased their task average to 65 ms in session nine and then back down to 41 ms in session ten. The overall decrease from the first session as compared to the last session provided a *t*-test p-value of 0.42, which although not clinically significant, is a more notable change than Participant C. Significance was not anticipated given the inability to do comparative means with the low numbers in the population used in this study. The following Figure 5: *Task Average for IM*® *Short Form (in milliseconds) for each Session- Participant D*, provides this information in a chart form.

Figure 5



Task Average for IM® Short Form (in milliseconds) for each Session- Participant D

Below, Table 7: *Participant D Results from IM*® *Short Form*, depicts the specific numeral results of Participant C by each session, the scores for Task One and Task Two, along with the comparison to previous sessions. The averages are shown in milliseconds.

Table 7

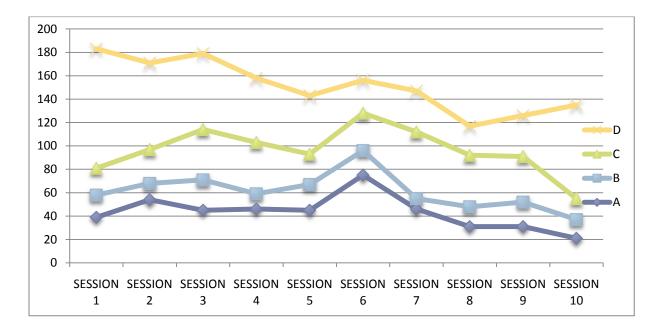
| Session | Task 1: MS Average | Task 2: MS Average | P-value compared to previous session | P-value compared to first day |
|---------|-----------------------|-----------------------|--|-------------------------------------|
| 1 | 102 | 220 | | |
| 2 | 74 | 130 | 0.31 | 0.31 |
| 3 | 65 | 115 | 0.16 | 0.28 |
| 4 | 55 | 61 | 0.38 | 0.32 |
| 5 | 50 | 67 | 0.94 | 0.29 |
| 6 | 28 | 71 | 0.61 | 0.21 |
| 7 | 35 | 32 | 0.61 | 0.28 |
| 8 | 25 | 25 | 0.11 | 0.26 |
| 9 | 35 | 65 | 0.34 | 0.24 |
| 10 | 80 | 41 | 0.81 | 0.42 |

Participant D Results from IM® Short Form

Clinical Trends of IM® Short Form Data

The Figure 6 below shows the overall Short Form scores for all participants over the 10 sessions. The participants had similar trends in their data when observed in this raw data seen below in Figure 6: *Clinical Trends of IM*® *Short Form of all Participants*. Although the participants all had varying scores, the trends of each participant's scores on the IM® Short Form seem to be very similar, as evidence by the steady decline in scores over the ten sessions and the slight peak in session six.

Figure 6



Clinical Trends of IM® Short Form of all Participants

The IM® Long Form Results

The IM® Long Form results can be seen in Table 8: *IM*® *Long Form Results for all Participants*. Overall, three out of the four participants made large gains in their timing accuracy over the course of the sessions. A *t*-test was conducted to compare the task average (in milliseconds) of the IM® Long Form pre-test evaluation to the IM® Long Form post-test evaluation. The results from the four participants were compared in a paired, two tailed *t*-test that provided a p-value of 0.28. This shows that the data is not clinically significant at the 0.05 level.

Table 8

| | Adjusted Pre- MS | Pre- SRO | Adjusted Post- MS | Post- SRO | % of Change |
|---------------|---------------------|----------|----------------------|-----------|-------------|
| Participant A | 58.6 | 12.90% | 40.6 | 27.10% | 30.80% |
| Participant B | 24.4 | 45.50% | 17.2 | 56.60% | 29.70% |
| Participant C | 36.8 | 28.80% | 46.5 | 20.10% | -26.20% |
| Participant D | 158.9 | 3.20% | 108.3 | 11.10% | 31.90% |

IM® Long Form Results for all Participants

MS= milliseconds SRO= Super Right On percentage

Participant A began the IM® pre-test with an overall timing accuracy of 58.6 ms off of the beat. By the end of the ten sessions, during the post-testing, Participant A had decreased this to 40.6 ms. This was an overall improvement of 30.8% from pre- to post- test. The areas of this participant's largest improvement included the first and last exercise in which bilateral hand tasks were used together, one without guide sounds and one with guide sounds, making gains of 50% and 74% increase, respectively.

Participant B began the IM[®] pre-test with an overall timing accuracy of 24.4 ms off of the beat. By the end of the ten sessions, during the post-testing, Participant B had decreased this to 17.2 ms. This was an overall improvement of 29.7% for this participant. For this participant, there was a very steady and consistent percentage of change of the task average for the majority of exercises from the first session to the last session. Large gains were made in the exercises using the right hand only, using both heels and balancing with either foot and tapping the other to the beat.

Participant C began the IM® pre-test with an overall timing accuracy of 36.8 ms off of the beat. By the end of the ten sessions, during the post-testing, Participant C had increased to

46.5 ms. This was an overall decrease in score by 26.2%. The areas of this participants largest improvements included tasks using bilateral hand tasks along with the provided guide sounds, as the percentage of change for the task average for this exercise was 40%. Participant C struggled in the exercises using both heels and using the right heel, as there was a task average decrease of -157% and -175%, respectively.

Participant D began the IM® pre-test with an overall timing accuracy of 158.9 ms off of the beat. By the end of the ten sessions, during the post-testing, Participant D had decreased this to 108.3 ms. This is an overall improvement of 31.9% for this individual. The areas of this participant's largest improvements included tasks with using bilateral hand tasks without guide sounds, with an 80% of change and also using the right hand only, with a percentage of change of 66%. The exercises that were most difficult for this participant were using the right toe and using the left toe, as they had decreases in percentage of performance change from pre- to post-task average scores of -97% and -54%, respectively.

All *t*-tests conducted gave notable, if not clinically significant, data for these previous evaluations. Multiple statistical analyses were completed to maximize opportunities for significant results. Since the TRX® suspension system did not have measurable way to assess change, this apparatus was not used in order to collect data, but rather balance the rhythmic movements of the IM® and provide additional proprioceptive input to the muscles and joints.

Summary

One of the challenges faced by studies where there is a small population is the ability to reach clinically significant change. Even if significance were to be noted, the population is so small that it is only attributable to those who participated in the study. In many instances this pilot is also reflective of the trends and changes that are seen in the clinical setting where a low number of clients are available to track changes. In many respects, this raw data shows the trends and changes as much as one would expect in a clinical analysis/clinical trend. The ability to see and note change is the function and design of statistical data. The charting provided in this chapter and study was reflective of that plotting and demonstrative review of change in a small populations. In short, often it is trends that lead us to further investigation. The data collected and presented in this section is reflective of these trends.

V. Summary of Findings

Discussion

This pilot study was conducted in order to validate the protocols created for the Interactive Metronome® (IM®) developed for Wounded Warriors diagnosed with mild Traumatic Brain Injury (mTBI) and Post-Traumatic Stress Disorder (PTSD). An overview of these specific protocols can be found in Appendix C and a detailed explanation can be found in Appendix D. This was tested by measuring the effectiveness of the IM®, along with the TRX®, as a successful tool in decreasing behavioral aggression levels and providing clients with higher satisfaction in their activities of daily living. The focus of this pilot study was on the protocols and using the IM® in conjunction with the TRX®, a physical challenging routine that incorporates rhythmicity of both bilateral upper and lower extremities in an alternating manner.

Several notable changes in levels of aggression and life satisfaction occurred that might be attributable to the IM® and TRX® intervention, including the changes observed on the Overt Aggression Scale (OAS), the Canadian Occupational Performance Measure (COPM), Nine Hole Peg Test (NHPT), the IM® Long Form and the IM® Short Form.

Overt Aggression Scale

The changes that occurred with the OAS, although not significant, were still notable due to the nature of the well population the pilot study covered. These pilot study participants were not known to have any behavioral issues or aggressive tendencies prior to participating in the study. The results were not expected to be significant because of the low level of aggression noted during the pre-test for all four participants. The pre-test level for all participants was a sum 4, which is a low level of aggression considering it is an average of 1 aggressive incident per participant in a week. Zero aggressive incidents is the lowest score and 16.0 is the highest score

possible. These scores demonstrate there was not much room for improvement within this scale. Participant A had both pre- test and post-test score of 1, which shows no change occurred during the intervention for this participant regarding aggression levels. Participant B had a pre-test score of 3 and a post-test score of 1 which demonstrates a decrease in the level of aggression during the intervention provided, which was the goal of the intervention. Both Participant C and Participant D did not show aggression prior to the intervention or following the intervention during post-testing. This was likely due to the initial able-bodied nature of the participants. The OAS, as mentioned above, is designed to assess observable aggression or violent behavior rather than tendencies. The severity of the aggression shown by these participants was very low, with examples such as yelling verbal insults that occurred during sports games. It should be noted that while these participants were viewed as "normal and well young adults" the stressors experienced during examinations time, high demand in course work and student abilities were part of the standard challenges they faced. Through those high-stress life events, the OAS indicated that the participants had not increased the levels of aggression. Possibly leading to conclude that the protocol series, while adding an additional demand on the participants student time also produced a positive outlet for aggression, as minimal or no change was noted.

Canadian Occupational Performance Measure

The Canadian Occupational Performance Measure (COPM) categorizes three general areas of occupation: self-care, productivity, and leisure (Law et al., 2005). As mentioned previously, a change of 2 or more points on the COPM represents clinically important difference (Law et al., 1994). As the mean result for both performance and satisfaction were below 2 points, there was not clinically significant data for this population. Once again, due to the well nature of the four pilot study participants, the number of occupational performance issues and goals were

very low because of the high functioning ability that these pilot participants reported during the pre-testing and again during post-testing. They showed an increase of 0.75 points on both Performance and Satisfaction of abilities in the various areas of concern. This is an expected change of a well individual attempting to work on areas of slight concern. Participant B showed a larger increase in scores, of 1.0 on Performance and 2.0 on Satisfaction of areas of concern. This shows significant change for this participant because of the 2.0 score for Satisfaction.

Participant C did not show much of a change between pre-testing and post-testing, resulting in a 0.0 for change on their Performance score and 0.2 on their Satisfaction score. This could be due to the high levels of Performance and Satisfaction ratings that Participant C reported during pre-testing, leaving little room for improvement. Participant D demonstrated a change of 1.0 for their Performance of their areas of concern and a 0.5 score of change for Satisfaction. This participant's score could also be due to the initial high scores for both Performance and Satisfaction.

For the four participants in this study, the mean number of occupational performance goals identified using the COPM was 4.25, with a range between 4.0 and 5.0. Overall, there was a mean change in performance from pre- to post- test of 0.69 points and a mean change in satisfaction from pre- to post- test of 0.86 points. These lower scores were to be expected because the participants were not beginning the study with obvious deficits in overall life performance and satisfaction, like would be expected from the population for which the protocols were created.

Nine Hole Peg Test

The Nine Hole Peg Test (NHPT) results for the four pilot participants consisted of a sum of the right hand p-values 0.33 and the left hand p-values at 0.13. Although neither of these was

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significant, according to the Standard Norms of the NHPT, all participants obtained scores during the pre-test for the age category that were very near or within the normal range, (Age 21-25, the Norms: Right = 16.4,SD= 1.65, Left= 17.53, SD = 1.73). The scores of the NHPT are presented in Table 9: *Nine Hole Peg Test times (in seconds) for Pre-Test and Post-Test & Norms*, to provide clear indications of findings.

Table 9

| Participant | Pre-Test | | Post-Test | | Percentage of Change | |
|-------------|----------|------|-----------|---------|----------------------|--------|
| | Right | Left | Right | Left | Right | Left |
| Α | 16.5 | 21.6 | 17 | 17.7 | 3% | -18% |
| (Norms) | | | (16.41) | (17.53) | | |
| В | 16.7 | 16.3 | 14.9 | 16.6 | -11.00% | 1.80% |
| (Norms) | | | (16.41) | (17.53) | | |
| С | 20.8 | 23.2 | 15.6 | 20.2 | 25.00% | -13% |
| (Norms) | | | (16.04) | (17.21) | | |
| D | 18 | 21 | 18.3 | 19.8 | 1.70% | -5.70% |
| (Norms) | | | (16.04) | (17.21) | | |

Nine Hole Peg Test times (in seconds) for Pre-Test and Post-Test & Norms

*Norms are bold and italicized below post-test score for appropriate age and sex of each participant

On the right hand, Participant C scored slightly higher than the norm and Participant A, C, and D scored extremely close, but slightly higher than the NHPT norms for their age category. As seen in Table 9, the rate of change for Participant A was considerable on the left hand, but not on the right. This could be due to the fact that Participant A was right handed, and therefore, did not have far to improve on the right hand, but did have gains to make on the left hand, as observed. The opposite is true with both Participant B and Participant C, as their right hand improvements were far higher than the left hand improvements. Possible explanations for this include the tasks that included right hand exercises were easier and more enjoyable while in the IM® and therefore gave more attention to these. Participant D had the least varying results between hands, as her right hand percentage of change was 1.70% and their left hand percentage of change was -5.70%. This was similar to the expected results, as investigators did not anticipate large changes in these pilot participants.

IM® Short Form Assessment

All protocol sessions began and concluded with The IM® Short Form evaluation which gave data information on Task One, which involves both hands clapping without guide sounds and Task Two, which include guide sounds (a tone to tell participants whether they are hitting before or after the beat) with both hands clapping. Both Task One and Task Two comprise of 54 repetitions each. For some participants the guide sounds are helpful and for other participants the guide sounds are distracting, preventing them from achieving their best score. Overall, the IM® Short Form results showed a general decrease in average of milliseconds off the beat for the four participants. A low task average in milliseconds off of the beat is favorable for all participants; the lower the task average, the closer the participant is to getting right on the metronome beat.

For Participant A, there was a definite overall decrease from session one to their last session. For Task One, their first average was 39 ms and the final session average was 19 ms and for Task Two, the first average was 78 ms and the final session average was 21 ms. For Task One, there was a large increase between session five and session six, which could be due to an "off" day altogether for this participant. However, from session six to the final session there was a steady decrease in task average scores, which was to be expected. Regarding Task Two, there was an uncharacteristic decrease in millisecond average for session three, which cannot be explained. Following the great score in session three, Participant A's task average increased again to 79 ms and then began a steady decrease overall through the last session, however there were slight increases throughout the sessions, such as between session six and session seven and between session nine and session ten.

While two participants had drastic decreases in their numbers, Participant B had a steady decrease over the course of all sessions. This participant's range of numbers was much smaller, showing his consistency over the course of the sessions. Because this participant began with such low task average score, there was not much room for improvement. As explained in the results, in session seven, there was a large decrease in scores, from which the participant then increased his time in the eighth and ninth session, and then decreased again in the final session. These variable scores could be attributed to the time of year that this participant concluded this research, as it was the week of final exams which cause additional stress on the participant, thus hindering their ability to perform their best.

Participant C did not show an overall improvement on the scores for the IM® Short Form. Towards the middle point of the intervention, such as session five through session seven, there seemed to be a large increase in their scores. The scores then begin to decrease from session seven through the last session, with the exception of Task Two which slightly increases during session ten. The changes in results were not significant for this participant. The reason could be the time of year that the participant was completing the research, such as final exams occurring during this time and excess stress being placed on the participant. Another potential explanation could include a possible change the motivation; if she lacked motivation for completing the task to the best of their ability the possible apathetic nature could cause skewed data.

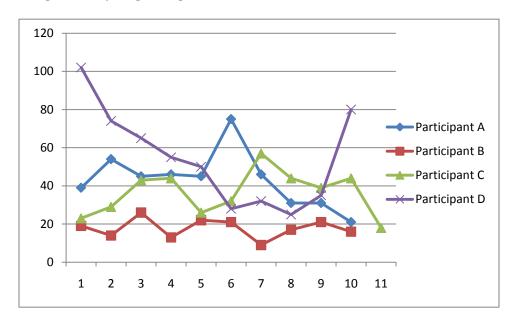
64

Participant D had a notable decrease in task average scores over the course of the sessions. Since the participant began with such high task average scores in the first few sessions, there was area for decline in the scores during the sessions. Although all of the data produces similar trends in all the participants, seen throughout the charts, the specific task averages in milliseconds are drastically different for each participant. This demonstrates the wide range of skill applied and achieved by each individual throughout these sessions.

Comparison of all participants: Task One and Task Two

For purposes of discussion, Figure 6: *Comparison of all participants: Task One* and Figure 7: *Comparison of all participants: Task Two* are presented. As seen below in Figure 6, the trends are similar, with all participants decreasing over time. Seen in session 6 and session 10 are outliers that are unexplained, however had the number of participants been higher, these would have most likely been accounted for.

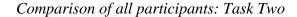
Figure 7

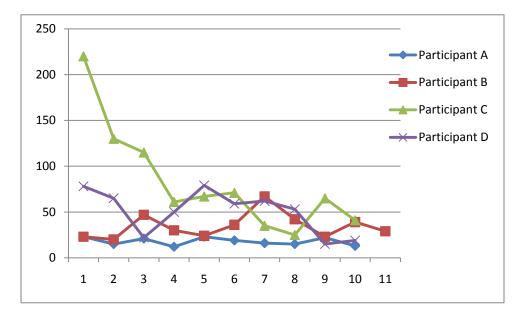


Comparison of all participants: Task One

Just as is seen in Figure 6, Figure 7: *Comparison of all participants: Task Two*, there is an overall decreasing trend in participants. Although there was improvement over time with all participants, had there been a larger number of participants (n), these trends would have been more obvious with the separation of the tasks.

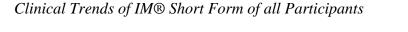
Figure 8

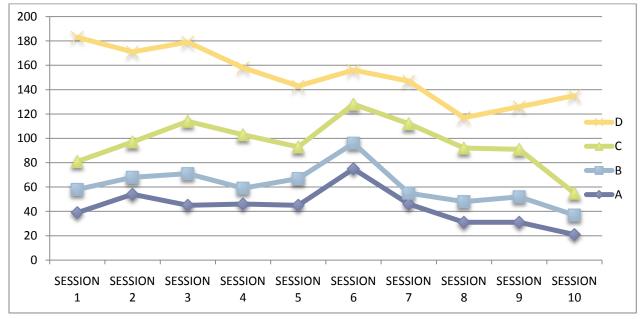




Clinical Trends of all Participants

When observed all together visually, the participants had similar trends in their data. This raw data seen in Figure 8: *Clinical Trends of IM*® *Short Form of all Participants* below, visually explains what was stated above. Although the participants all had varying scores throughout the ten sessions, the trends of each participant's scores on the IM® Short Form seem to be very similar, as evidence by the steady decline in scores over the ten sessions and the slight peak in session six. This peak during session six can be explained by a highly stressful event that was occurring following the day of this particular session. The two female participants were being expected to present information in front of a large group of peers, faculty and mentors from the University of East Carolina and the two male participants were expected to attend the presentations while preparing for six exams that were beginning the day following the presentations. All participants expressed that this was a very high stress time to focus on completing the IM® and TRX® protocols, which could explain the peak in session six for all participants. During session nine, participant's scores also plateau. This could again, be explained by the stressful environment of being evaluated with exams that the participants seemed to slightly increase or stay the same. During the entire time that research was being conducted, all participants verbally expressed feeling stressed and overwhelmed with participating in this research along with the typical expectations of their high education degree. Figure 8





IM® Long Form Assessment

The IM® Long Form results were generally positive, with three participants having scores of about 30% of change (indicating a positive improvement in score) while one

participant with a negative percentage of change of -26.20%. The mean percentage of change was 16.55% (SD = 0.29). This was a surprising result, as this participant continued to decrease the time average in ms over each session. The data noted from the IM® Short Form shows more positive results. Therefore, the expectation for this participant to decrease in the overall IM® Long Form score was not succeeded, and this could be due to many reasons. One reason could be the time of year that this participant completed the protocol sessions; it being the week before final exams could produce unnecessary stress on a student which could transfer over into other areas of life, such as participating in this research. Although the times of each session were mutually chosen by the participants and the investigators, there are particular constraints, such class times and other research projects occurring. This particular day or time could have been a bad time for this participant to complete their sessions, which affected their score. The paired, two-tailed *t*-tests produced a p-value of 0.28 for all participants combined, which demonstrates that this data is not clinically significant. Once again, because of the initial wellness and healthy nature of the participants, significant data was not expected or warranted for these pilot participants.

Implications for Future Research & Limitations

As previously stated in the literature review, the need for further research is clear. Due to the fact this was not a controlled study, one cannot assert that the IM® and TRX® protocols contributed to the observed changes in the participants. The IM® training itself is complex and multifaceted and when combined with the TRX® training, the specific protocols created are novel and need review and revision. The information provided through this pilot study will lead further research more effectively and efficiently, for the reason that specific flaws in the protocols have been observed and can be revised prior to beginning additional research. Examples of the minor blemishes in the study mainly pertain to the IM® Software and can easily be corrected. These flaws include the software retaining an individual days "best millisecond average task score" for the same exercise instead of every score obtained. This was only affected when an individual performed the same exercise within the same session, which did not skew the data, but could have provided more data for more in-depth analysis if it had been available. Further investigation with a specific military population is preferred, in order to provide data for which the protocols were constructed. Such research will help clarify the relationship between the IM® and TRX® protocols and the behavioral changes, including those which are motoric, affective and organizational.

Conclusion

The data results that were collected were expected from the investigators. This pilot study provides clinical evidence that these protocols are valid enough to be applied and delivered safely in conjunction with healthy participants. This intervention of the specific protocols also appears to be associated with the positive scores on assessments and behaviors in aggression as evident by the clinical measures. Although all reported data was not clinically significant for these four participants, the overall purpose of the study, to validate the protocols created for the IM® and TRX® developed for clients with mild TBI and PTSD, was attained and verified. In addition to forging an improved understanding of the effects of the IM® and TRX® protocols created, it will be important to determine the effects in the Military population. This research can be used as a catalyst to further the knowledge of the behavioral course of the Military population who suffer with mild TBI and PTSD and help occupational therapists better understand how to treat these individuals and symptoms.

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Acknowledgments

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APPENDIX A: East Carolina University International Review Board



EAST CAROLINA UNIVERSITY University & Medical Center Institutional Review Board Office 1L-09 Brody Medical Sciences Building• 600 Moye Boulevard • Greenville, NC 27834 Office 252-744-2914 • Fax 252-744-2284 • www.ecu.edu/irb

TO: Michelle McBride, Student, C/O Leonard Trujillo, PhD, Dept of Occupational Therapy, ECU

FROM: UMCIRB

DATE: April 21, 2011

RE: Expedited Category Research Study

TITLE: "The Effects of the Interactive Metronome as an Intervention Tool on Decreasing Level of Aggression and Improving Life Satisfaction with Traumatic Brain Injury and Post Traumatic Stress Disorder Clients: A Pilot Study on Protocols"

UMCIRB #11-0223

This research study has undergone review and approval using expedited review on 4.13.11. This research study is eligible for review under an expedited category number 7. The Chairperson (or designee) deemed this Interactive Metronome® sponsored 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 **4.13.11** to **4.12.12**. The approval includes the following items:

- Internal Processing Form (dated 3.3.11)
- Canadian Occupational Performance Measure (received date 4.5.11)
- Overt Aggression Scale (received date 4.5.11)
- Interactive Metreonome Proposed Protocol (received date 3.25.11)
- Informed Consent (received date 4.7.11)

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

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.

CONSENT DOCUMENT

Title of Research Study: "The Effects of the Interactive Metronome® as an Intervention Tool on Decreasing Level of Aggression and Improving Life Satisfaction with Traumatic Brain Injury and Post Traumatic Stress Disorder Clients: A Pilot Study on Protocols"

Principal Investigator: Michelle McBride, OT MS Student Institution: East Carolina University Address: Health Sciences Building, Occupational Therapy, Room 3305- H Telephone #: (252)744-6195

INTRODUCTION

You have been asked to participate in a research study being conducted by Leonard G. Trujillo, PhD OTR/L. This research study is a pilot study to test the effectiveness of a specific set of protocols established by the researchers. The protocols are designed understand if participating in occupational therapy intervention of treatment can make a positive change in the levels of aggression and life satisfaction in occupational performance. The information from this study will provide therapists with specific protocols that can be used with mild traumatic brain injured clients and/or individuals with post-traumatic stress disorder symptoms. Results of this study will also be valuable for therapists working with military populations.

PLAN AND PROCEDURES

You will be one of four participants in the study. This research will be initiated and concluded at East Carolina University Occupational Therapy Department. The actual therapy sessions, if you agree to participate, will be conducted on the East Carolina University Allied Health Sciences Campus in the OT Department's Lab for the Skills of Living. If you agree to participate in this study, you will complete four standard evaluations. The Interactive Metronome® will be used to gather data using the Long form and Short form assessments. The Overt Aggression Scale (OAS) will be used to assess the levels aggression exhibited by participants in the previous week. The Canadian Occupational Performance Measure (COPM) measures the participant's self-perception of change in occupational performance and satisfaction over time. These evaluations will help the researchers to evaluate how the intervention protocols are affecting aggression and life satisfaction throughout the study.

Once you have completed the standard evaluations, you will complete six protocol sessions involving the Interactive Metronome® and the TRX® Suspension Training exercise equipment. Sessions will be approximately an hour and a half, three times a week. Sessions will never last longer than 3 hours. Sessions will begin with the Interactive Metronome® for a maximum of six minutes, then perform the proposed TRX® exercise for no longer than six minutes. Due to the physical nature of the TRX®,

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participants will perform the exercise for 30 seconds, and then take a 30 second break before beginning the movement again. The TRX® will be suspended from a secure position and researchers will ensure the equipment and participant are positioned properly throughout all exercises. A sub-investigator will also be present during all sessions. After session six, the midpoint of the study, participants will be evaluated again with the Interactive Metronome® Long form and Short form assessments, OAS, and COPM. You will complete six more treatment sessions involving the Interactive Metronome® and TRX®. Upon completion of these sessions, you will be asked to return to the lab for post-test evaluation that will be of the same nature of the pre-test and interim test, with the Interactive Metronome® Long form and Short form assessments, TEA, and COPM.

POTENTIAL RISKS AND DISCOMFORTS

Some individuals experience some anxiety during rehabilitation evaluations. Sometimes this is due to the stress of knowing you are being evaluated. Also some people become anxious because they do not perform as well on the evaluation as they would have preferred. In either case, the research staff will always be available to answer questions and reassure you on your performance.

Because the Interactive Metronome® is new to most individuals, they are having to learn a new skill and may experience some anxiety about doing it correctly. Learning times are built into the process and these can be extended to allow you to increase your comfort with the process.

The number of repetitions in performing the Interactive Metronome® activities may become challenging for some individuals and some may not have the endurance to complete the full number of repetitions outlined in the protocols designed. However, Interactive Metronome® training provides options to lower this to a successful number to meet the capabilities of each individual.

POTENTIAL BENEFITS

You may experience a decrease of aggression and an improvement in life satisfaction from completing this study. However, you may receive no benefit from this study. It is anticipated that many will improve their sense of coordination, smoothness in movement and fluid motor patterns.

SUBJECT PRIVACY AND CONFIDENTIALITY OF RECORDS

You will not be personally identified in any reports or publications that may result from this study. Any personal information about you that is gathered during this study will remain confidential to every extent of the law. A special number will be used to identify you in the study. All information from this study will be kept in a locked file cabinet within a locked office or within a password protected computer. Only the investigators and sub-investigators will have access to the files.

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COSTS OF PARTICIPATION

There are no costs to you for your participation in this study.

VOLUNTARY PARTICIPATION

Participating in this study is voluntary. If you decide not to be in this study after it has already started, you may stop at any time without losing benefits that you should normally receive. You may stop at any time you choose without penalty.

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 Primary Investigator: Leonard G. Trujillo PhD, OTR/L at 252-744-6195 or the sub investigators: Kelly Ridenhour, OTS at 704-612-1374; Michelle McBride, OTS at 440-668-6495; and Jamie Joyner, OTS at 336-413-2984. If you have questions about your rights as a research subject, you may call the Chair of the University and Medical Center Institutional Review Board at phone number 252-744-2914 (days) and/or the ECU Risk Management Office at 252-328-6858.

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CONSENT TO PARTICIPATE

<u>**Title of research study:</u></u> : "The Effects of the Interactive Metronome® as an Intervention Tool on Decreasing Level of Aggression and Improving Life Satisfaction with Traumatic Brain Injury and Post Traumatic Stress Disorder Clients: A Pilot Study on Protocols"</u>**

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

| Participant's Name (PRINT) | Signature | ta 38a | Date | Time |
|----------------------------|-----------|--------|------|------|
| If applicable: | | N | | 81 |
| Guardian's Name (PRINT) | Signature | | Date | Time |

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

| Person Obtaining consent (PRINT) | Signature | Date |
|----------------------------------|-----------|------|
| 81. | | |
| Principal Investigator (PRINT) | Signature | Date |

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Continuing Review/Closure Obligation

****IMPORTANT INFORMATION**

As a investigator you are required to submit a continuing review/closure form to the UMCIRB office in order to have your study renewed or closed before the date of expiration as noted on your approval letter. This information is required to outline the research activities since it was last approved. You must submit this research form even if you there has been no activity, no participant s enrolled, or you do not wish to continue the activity any longer. The regulations do not permit any research activity outside of the IRB approval period. Additionally, the regulations do not permit the UMCIRB to provide a retrospective approval during a period of lapse. Research studies that are allowed to be expired will be reported to the Vice Chancellor for Research and Graduate Studies, along with relevant other administration within the institution. The continuing review/closure form is located on our web site at <u>www.ecu.edu/irb</u> under forms and documents. The meeting dates and submission deadlines are also posted on our web site under meeting information. Please contact the UMCIRB office at 252-744-2914 if you have any questions regarding your role or requirements with continuing review. <u>http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.htm</u>

Required Approval for Any Changes to the IRB Approved Research

As a research investigator you are required to obtain IRB approval prior to making any changes in your research study. Changes may not be initiated without IRB review and approval, except when necessary to eliminate an immediate apparent hazard to the participant. In the case when changes must be immediately undertaken to prevent a hazard to the participant and there was no opportunity to obtain prior IRB approval, the IRB must be informed of the change as soon as possible via a protocol deviation form. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.103

Reporting of Unanticipated Problems to Participants or Others

As a research investigator you are required to report unanticipated problems to participants or others involving your research as soon as possible. Serious adverse events as defined by the FDA regulations may be a subset of unanticipated problems. The reporting times as specified within the research protocol, applicable regulations and policies should be followed.

http://www.hhs.gov/ohrp/policy/AdvEvntGuid.htm

APPENDIX B: Overt Aggression Scale

Overt Aggression Scale (OAS)

Stuart Yudofsky, M.D., Jonathan Silver, M.D., Wynn Jackson, M.D., and Jean Endicott, Ph.D.

Identifying Data

Name of patient:

Name of rater:Sex of patient: 1 male 2 femaleDate:/Shift: 1 night2 day3 evening

□ No aggressive incident(s) (verbal or physical) against self, others, or objects during the shift (check here).

Aggressive Behavior (check all that apply)

Verbal aggression

- □ Makes loud noises, shouts angrily
- □ Yells mild personal insults (e.g. "You're stupid!")
- Curses viciously, uses foul language in anger, makes moderate threats to others or self

□ Makes clear threats of violence toward others or self ("I'm going to kill you.) or requests to help to control self

Physical aggression against self

□ Picks or scratches skin, hits self, pulls hair (with no or minor injury only)

□ Bangs head, hits fist into objects, throws self onto floor or into objects (hurts self without serious injury)

□ Small cuts or bruises, minor burns

 $\hfill\square$ Mutilates self, makes deep cuts, bites that bleed, internal injury, fracture, loss of consciousness, loss of teeth

Physical aggression against objects

- □ Slams door, scatter clothing, makes a mess
- □ Throws objects down, kicks furniture without breaking it, marks the wall
- □ Breaks objects, smashes windows
- □ Sets fires, throws objects dangerously

Physical aggression against other people

- □ Makes threatening gesture, swings at people, grabs at clothes
- Strikes, kicks, pushes, pulls hair (without injury to them)
- Attacks others, causing mild to moderate physical injury (bruises, sprain, welts)

□ Attacks others, causing severe physical injury (broken bones, deep lacerations, internal injury)

Time incident began _____: ____ am/pm Duration of incident: _____: ____ hours/minutes

Intervention (check all that apply)

- □ None
- □ Talking to patient
- □ Closer observation
- □ Holding patient
- □ Immediate medication given by mouth
- □ Immediate medication given by injection
- □ Isolation without seclusion (time out)
- □ Seclusion
- Use of restraints
- □ Injury requires immediate medical treatment for patient
- □ Injury requires immediate treatment for other person

Comments:

Copyright, Stuart C. Yudofsky, M.D.

CANADIAN OCCUPATIONAL PERFORMANCE MEASURE

Authors: Mary Law, Sue Baptiste, Anne Carswell, Mary Ann McColl, Helene Polatajko, Nancy Pollock

The Canadian Occupational Performance Measure (COPM) is an individualized measure designed for use by occupational therapists to detect self-perceived change in occupational performance problems over time.

| Client Name: | | |
|-----------------------------|----------------------------------|-----------------------|
| Age: | Gender: | ID#: |
| Respondent (if not client): | | |
| Date of Assessment: | Planned Date of Reassessment: | Date of Reassessment: |
| Therapist: | | |
| Facility/Agency: | | |
| Program: | | |

Published by CAOT Publications ACE © M. Law, S. Baptiste, A. Canwell, M.A. McColl, H. Polatojko, N. Pollock, 1998 Printed in Canada

STEP 1: IDENTIFICATION OF OCCUPATIONAL PERFORMANCE ISSUES

To identify occupational performance problems, concerns and issues, interview the client, asking about daily activities in self-care, productivity and leisure. Ask clients to identify daily activities which they want to do, need to do or are expected to do by encouraging them to think about a typical day. Then ask the client to identify which of these activities are difficult for them to do now to their satisfaction. Record these activity problems in Steps 1A, 1B, or 1C.

STEP 2: RATING IMPORTANCE

Using the scoring card provided, ask the client to rate, on a scale of 1 to 10, the importance of each activity. Place the ratings in the corresponding boxes in Steps 1A, 1B, or 1C.

| STEP 1A: Self-care | IMPORTANCE |
|---|------------|
| Personal Care e.g., dressing, bathing, leeding, hygiene) | |
| Functional Mobility (e.g., transfers, ndoor, outdoor) | |
| Community Management (e.g., transportation, shopping, finances) | |
| STEP 1B: Productivity | |
| Paid/Unpaid Work (e.g., finding/keeping a job, volunteering) | |
| Household Management (e.g., cleaning, laundry, cooking) | |
| | |

| STEP 1C: Leisure | | IMPORTANCE |
|---|---------|------------|
| Quiet Recreation (e.g., hobbies, crafts, reading) | CANADIA | |
| Active Recreation (e.g., sports, outings, travel) | | |
| Socialization (e.g., visiting, phone calls, parties, correspondence) | | |

1

STEPS 3 & 4: SCORING - INITIAL ASSESSMENT and REASSESSMENT

Confirm with the client the 5 most important problems and record them below. Using the scoring cards, ask the client to rate each problem on performance and satisfaction, then calculate the total scores. Total scores are calculated by adding together the performance or satisfaction scores for all problems and dividing by the number of problems. At reassessment, the client scores each problem again for performance and satisfaction. Calculate the new scores and the change score.

| Initial Assessment: | | | Reassessmen | t: |
|--|------------------------|----------------|-------------------------|----------------|
| OCCUPATIONAL PERFORMANCE PROBLEMS: | PERFORMANCE 1 | SATISFACTION 1 | PERFORMANCE 1 | SATISFACTION 1 |
| L | | | | |
| 3 4 5 | | | | |
| SCORING: Total performance or satisfaction score = scores # of problems | PERFORMANCE SCORE 1 | | PERFORMANCE SCOPIE 2 | |
| CHANGE IN PERFORMANCE = Perfor | | | ance Score 1 | = |

ADDITIONAL NOTES AND BACKGROUND INFORMATION

Initial Assessment:

Reassessment:

| | Interactive Metronome® Proposed Protocol | TRX® |
|-----------|---|---|
| Session 1 | Initial Evaluation: Short form IM test COPM Overt TEA 9 Hole Peg Test Long form IM test | (During sessions-30 seconds on, 30 seconds off) |
| Session 2 | Short form test Exercise 1: Both Hands (216 Reps, 4 Min) Exercise 5: Right Toe (162 Reps, 3 Min) Exercise 2: Right Hand (162 Reps, 3 Min) Exercise 1: Both Hands (162 Reps, 3 Min) Exercise 6: Left Toe (162 Reps, 3 Min) Exercise 3: Left Hand (162 Reps, 3 Min) Exercise 3: Left Hand (162 Reps, 3 Min) Exercise 1: Both Hands (324 Reps, 6 Min) <i>Total: 1350 Reps, 25 Minutes</i> | TRX Stretching Chest Press toward Midline Single leg squat right leg only-between 2 progressions Hand on Hip-Lateral Stance bicep pull- first-second-second exercise-3 rd -first TRX Stretching Single leg squat left leg only Face TRX, wide stance, rotate trunk, swing specified hand to TRX-15 sec break-do 1 st exercise Low Row (Bicep pull) |
| Session 3 | Short form test Exercise 1: Both Hands (216 Reps, 4 Min) Exercise 4: Both Toes (162 Reps, 3 Min) Exercise 10: Right Hand, Left Toe (162 Reps, 3 Min) Exercise 9: Left Heel (162 Reps, 3 Min) Exercise 1: Both Hands (162 Reps, 3 Min) Exercise 8: Right Heel (162 Reps, 3 Min) Exercise 11: Left Hand, Right Toe (162 Reps, 3 Min) Exercise 11: Left Hands (324 Reps, 6 Min) <i>Total: 1512 Reps, 28 Minutes</i> | TRX Stretching Chest Press toward Midline Single leg squat, alternating legs Chest press facing away from TRX, lunge backward Sprinter start backward lunge; left leg only (Progression 1) TRX Stretching Sprinter start backward lunge; right leg only (Progression 1) Chest Press facing away from TRX, lunge backward, alternating legs Low Row (Bicep Pull) |
| Session 4 | Short form test Exercise 1: Both Hands (216 Reps, 4 Min) Exercise 4: Both Toes (162 Reps, 3 Min) Exercise 2: Right Hand (162 Reps, 3 Min) Exercise 10: Right Hand, Left Toe (162 Reps, 3 Min) Exercise 1: Both Hands (162 Reps, 3 Min) | TRX Stretching Chest Press towards Midline Single Leg Squat, alternating legs Hand on Hip-Lateral stance bicep pull Chest Press facing away from TRX, then lunge backward, alternating TRX Stretching |

APPENDIX D: IM® and TRX® Protocol Overview

| | Exercise 3: Left Hand (162 Reps, 3 Min) | Face TRX, wide stance, rotate trunk, |
|------------|--|---|
| | | swing specified hand to TRX |
| | Exercise 11: Left Hand, Right toe (162 Reps, 3 | Chest Press facing away from TRX, then |
| | Min) Exercise 1: Both Hands (324 Reps, 6 Min) | lunge backward, alternating Low Row (Bicep Pull) |
| Session 5 | Total: 1512 Reps, 28 Minutes | Low Row (Bicep Pull) |
| 56351011 5 | 10tul. 1912 https, 20 Winutes | |
| | Short form test | TRX Stretching |
| | Exercise 1: Both Hands (216 Reps, 4 Min) | Chest Press towards Midline |
| | Exercise 3: Left Hand (162 Reps, 3 Min) | Hand on Hip-Lateral stance bicep pull |
| | | Sprinter start, backward lunge; alternate |
| | Exercise 7: Both Heels (162 Reps, 3 Min) | feet (Progression 1) |
| | | |
| | Exercise 13: Balance Left Foot (162 Reps, 3 | |
| | Min) | TRX Stretching |
| | Exercise 1: Both Hands (162 Reps, 3 Min) | Chest Press facing away from TRX, |
| | Exercise 12: Balance Right Foot (162 Reps, 3 Min) | then lunge backward, alternating sides |
| | Exercise 11: Left Hand, Right Toe (162 Reps, 3 | Low Row (Bicep Pull) |
| | Min) | |
| | Exercise 1: Both Hands (324 Reps, 6 Min) | |
| Session 6 | Total: 1512 Reps, 28 Minutes | |
| | | |
| | Short form test | TRX Stretching |
| | Exercise 1: Both Hands (216 Reps, 4 Min) | Chest Press towards Midline |
| | Exercise 5: Right Toe (162 Reps, 3 Min) Exercise 13: Balance Left Foot (162 Reps, 3 | Single leg square right leg only |
| | Min) | Single leg square right leg only |
| | Exercise 1: Both Hands (162 Reps, 3 Min) | TRX Stretching |
| | Exercise 12: Balance Right Foot (162 Reps, 3 | |
| | Min) | Single leg squat left leg only |
| Session 7 | Exercise 6: Left Toe (162 Reps, 3 Min) | Low Row (Bicep Pull) |
| | Exercise 1: Both Hands (324 Reps, 6 Min) | |
| | Total: 1512 Reps, 28 Minutes | |
| | Chart farma hash | |
| | Short form test Exercise 1: Both Hands (216 Reps, 4 Min) | TRX Stretching Chest Press towards Midline |
| | Exercise 2: Right Hand (162 Reps, 3 Min) | Hand on Hip-Lateral Stance, bicep pull |
| | Exercise 2. Aight Hund (102 Acps, 5 Min) | Face TRX, wide stance, rotate |
| | Exercise 12: Balance Right Foot (162 Reps, 3 | trunk swing specified hand to TRX |
| | Min) | |
| | Exercise 3: Left Hand (162 Reps, 3 Min) | |
| | | TRX Stretching |
| | Exercise 1: Both Hands (162 Reps, 3 Min) | |
| | | Cheet Drees facing over from TDV |
| | | Chest Press facing away from TRX, lunge |

| | Exercise 11: Left Hand/Right Toe (162 Reps, 3 | backward, alternating |
|------------|---|--|
| | Min) | |
| | Exercise 13: Balance Left Foot (162 Reps, 3 | |
| | Min) | Low Row (Bicep Pull) |
| | Exercise 1: Both Hands (324 Reps, 6 Min) | |
| | Total: 1512 Reps, 28 Min | |
| | | TRX Stretching |
| Session 8 | Short form test | Chest Press towards Midline |
| | Exercise 1: Both Hands (216 Reps, 4 Min) | Face TRX, wide stance, rotate trunk, swing |
| | Exercise 3: Left Hand (162 Reps, 3 Min) | specified hand to TRX |
| | | Single leg squat left leg only |
| | Exercise 6: Left Toe (162 Reps, 3 Min) | TRX Stretching |
| | Exercise 1: Both Hands (162 Reps, 3 Min) | Right hand on hip; lateral stance |
| | Exercise 2: Right Hand (162 Reps, 3 Min) | bicep pull |
| | | Single leg squat right leg only |
| | Exercise 5: Right Toe (162 Reps, 3 Min) | Chest Press facing away from TRX; lunge |
| | Exercise 10: Right Hand/Left Toe (162 Reps, 3 | backward, alternating |
| | Min) | |
| | | Low Row (Bicep Pull) |
| | Exercise 1: Both Hands (324 Reps, 6 Min) | |
| | Total: 1512 Reps, 28 Min | |
| Session 9 | | |
| | | TRX Stretching |
| | Short form test | Chest Press towards Midline |
| | Exercise 1: Both Hands (216 Reps, 4 Min) | Single leg squat, alternating legs |
| | Exercise 5: Right Toe (162 Reps, 3 Min) | |
| | Exercise 13: Balance Left Foot (162 Reps, 3 | Sprinter start backwards; Alternating feet |
| | Min) | (Progression one) |
| | Exercise 7: Both Heels (162 Reps, 3 Min) | |
| | | TRX Stretching |
| | Exercise 1: Both Hands (162 Reps, 3 Min) | Single leg squat left leg only |
| | Exercise 6: Left toe (162 Reps, 3 Min) | |
| | Exercise 12: Balance Right Foot (162 Reps, 3 | |
| | Min) | Low Row (Bicep Pull) |
| Session 10 | Exercise 1: Both Hands (324 Reps, 6 Min) | |
| | Total: 1512 Reps, 28 Min | |
| | | TRX Stretching |
| | Short form test | Chest Press towards Midline |
| | Exercise 1: Both Hands (216 Reps, 4 Min) | Sprinter start backward lunge-Right leg only |
| | Exercise 8: Right Heel (162 Reps, 3 Min) | (Progression 1) |
| | | Chest Press facing away from TRX, lunge |
| | Exercise 10: Right Hand/Left Toe (162 Reps, 3 | backward, alternating |
| | Min) | |
| | | TRX Stretching |
| | Exercise 1: Both Hands (162 Reps, 3 Min) | Sprinter start backward lunge-Left leg only |
| | Exercise 9: Left Heel (162 Reps, 3 Min) | (Progression 1) |

| Chest press facing away from TRX, thenExercise 11: Left Hand/ Right Toe (162 Reps, 3Min)Exercise 4: Both Toes (162 Reps, 3 Min)Exercise 4: Both Toes (162 Reps, 3 Min)Exercise 1: Both Hands (324 Reps, 6 Min)Total: 1512 Reps, 28 MinTRX Stretching |
|--|
| Min)Single Leg Squat, alternating legsExercise 4: Both Toes (162 Reps, 3 Min)Low Row (Bicep Pull)Exercise 1: Both Hands (324 Reps, 6 Min)Total: 1512 Reps, 28 Min |
| Exercise 4: Both Toes (162 Reps, 3 Min) Low Row (Bicep Pull) Exercise 1: Both Hands (324 Reps, 6 Min) Total: 1512 Reps, 28 Min |
| Exercise 1: Both Hands (324 Reps, 6 Min) Total: 1512 Reps, 28 Min |
| Total: 1512 Reps, 28 Min |
| |
| |
| The stretching |
| Session 11 Short form test Chest Press towards Midline |
| Exercise 1: Both Hands (216 Reps, 4 Min) |
| Exercise 12: Balance Right Foot (162 Reps, 3 Face TRX, wide stance, rotate trunk, swing |
| Min) specified hand to TRX |
| Exercise 3: Left Hand (162 Reps, 3 Min) Single leg squat; right leg only |
| Exercise5: Right Toe (162 Reps, 3 Min) TRX Stretching |
| Exercise 1: Both Hands (162 Reps, 3 Min) |
| Exercise 13: Balance Left Foot (162 Reps, 3 Hand on Hip-Lateral stance bicep pull |
| Min) |
| Exercise2: Right Hand (162 Reps, 3 Min) Low Row (Bicep Pull) |
| Exercise 1: Both Hands (324 Reps, 6 Min) |
| Total: 1512 Reps, 28 Min |
| Session 12 |
| Final Evaluation: |
| Short form IM test |
| СОРМ |
| Overt |
| TEA |
| 9 Hole Peg Test |
| Long form IM test |
| |
| |

APPENDIX E: Detailed IM® and TRX® Protocols Session-by-Session

Interactive Metronome[®] Research Protocols Session One *Initial Evaluation:* Short form IM test **1-Both Hands** 2-Repeat #1 with Guide Sounds COPM Total Score Overt TEA 9 Hole Peg Test Left Hand Right Hand _____ Long form IM test 1-Both Hands 2-Right Hand 3-Left Hand **4-Both Toes** 5-Right Toe 6-Left Toe 7-Both Heels 8-Right Heel 9-Left Heel 10-Right Hand/Left Toe 11-Left Hand/Right Toe 12-Balance Right Foot/Tap Left Toe 13-Blanace Left Foot/Tap Right Toe

TRX Basic Training-Getting to know the Suspension set

To Shorten the TRX:

Hold one strap of the TRX

Dress the cam buckle on that strap with your thumb and grasp the yellow adjustment tab with your other hand.

Simultaneously press the cam buckle and push the adjustment tab up along the strap Repeat with the other strap

To Lengthen the TRX:

Simultaneously depress both cam buckles and pull downward, away from anchor point How to make TRX Exercises harder or easier:

Modify your body angle-Make most of the standing exercises harder by adopting a steeper body angle. Move feet towards the anchor point to increase challenge and vice versa. Widen or narrow your base of support-Make most standing exercises harder by narrowing your base of support. For instance, you can bring your feet together or extend one leg forward, backward, or to the side.

Offset your feet-Make some standing exercises easier by moving one foot slightly forward and supporting some bodyweight with it. An offset stance will also provide more stability.

Dos and Don'ts:

Engage your core and keep hips, shoulders, and ears aligned at all times

TRX straps should never go slack during exercises-keep tension on TRX at all times Do not perform sawing motions of the straps. Keep equal pressure on both handles at all times.

Do not allow straps to rub against arms. Stabilizing the TRX in this fashion makes the exercise less effective. Move hands higher to prevent rubbing.

Recommended TRX Length Explanations:

Length Long-Fully Lengthen the TRX so that the bottom of the foot cradles are about 3 inches off the ground.

Length Mid-Calf-Adjust the TRX so that the bottom of the foot cradles are at a mid-calf level, roughly 8 inches off the ground.

Mid-Length-Adjust the TRX to mid-length by positioning the yellow adjustment tabs at the double yellow marks that are swen midway up the black TRX strap.

Length Short-Fully shorten the TRX by positioning the yellow adjustment tabs at the upper set of yellow marks on the black TRX strap.

Session Two

Note: Participant may choose to use guide sounds or turn sounds off. If the guide sounds are on, the participant should focus on achieving the cowbell sound. Images from the Interactive Metronome® can be set according to the preference of the participants. Remind the participant that during all tasks, s/he should try to avoid quick, ballistic, jerky movements. All motions should be continuous and fluid. Remind the participant that it is alright to miss a beat, but if one is missed, keep going because the IM® program will calculate only the registered trigger hits.

Session 2: Approximately 50 Min Total (25 Minutes IM®/1350 Reps, 25 Minutes TRX)

| Short form testing | |
|--|--|
| 1-Both Hands (54 Reps, 1 Min) | ms avg |
| 2-Repeat #1 with Guide Sounds (54 Reps, 1 Min) | ms avg. |
| Regular Training (with/out guide sounds) Exercise 1: Both Hands (216 Reps, 4 Min) Exercise 5: Right Toe (162 Reps, 3 Min) Exercise 2: Right Hand (162 Reps, 3 Min) Exercise 1: Both Hands (162 Reps, 3 Min) Exercise 6: Left Toe (162 Reps, 3 Min) Exercise 3: Left Hand (162 Reps, 3 Min) Exercise 1: Both Hands (324 Reps, 6 Min) | ms avg ms avg ms avg ms avg ms avg ms avg ms avg |
| Date:// Reps/Minutes compl | eted to-date:/ |

TRX Training should be completed while the partner is performing the IM®. Make sure to focus on position of the feet and posture of the body as each exercise is completed. Participants should perform each exercise for 30 seconds, take a break, and continue until the partner has stopped the IM® protocols.

During Short Form Testing: TRX Stretching (Straps at Mid-Length)

<u>TRX Lower Back Stretch</u>-Stand facing the TRX, extend arms forward. Bend at the hips and drop tailbone toward ground, knees slightly bent and hold. Straighten the left knee, rotate shoulders to the left and hold. Return to the center, and do same stretch on the right side. Return to the center and breathe deeply while keeping your back flat. To increase the intensity, lean into hip of straightened leg while flexing your quad.

<u>TRX Long Torso Twist</u>-Stand facing the TRX, arms extended, and cross right leg over the left, turn hips to the left. Drop the left hip toward the ground and let the torso and arms rotate toward the TRX, hold. Rotate chest to the left, hold, then to the right and hold. Return to the start position and repeat the exercise. Breathe deeply. Adjust your body position to release tight muscles.

<u>TRX Chest and Torso Stretch</u>-Stand facing away from the TRX. Have arms in a "T" position with your feet offset. Press your chest forward, and feel stretch in chest and arms. Reach overhead with left arm, rotate chest to right, look back, eyes on right hand. Tuck pelvis, reach overhead with right arm, rotate chest to left, look back and eyes on left hand. Return to the

start position and switch legs to repeat. Breathe deeply. Press rear heel into ground, bend rear knee and contract rear-leg glute to stretch hip flexor and calf.

Exercise 1: Chest Press toward Midline (Straps are Length Long)

(30 Seconds on, 30 Seconds rest for 4 minutes) Face away from the TRX,

perform exercise with feet beyond shoulder-width. Lower the chest in push-up motion and return to start position.

Exercise 5: Single Leg Squat, right leg only (Straps at Mid-Length)

(30 Seconds on, 30 Seconds rest for 3 Minutes) Face the TRX, elbows bent at sides. Extend the left leg forward, with the heel on the floor. Bend at the knees for a 90 degree angle. Return to start position. Continue for 30 seconds and then take a break. Participant can alternate between easy and hard progressions by holding the left leg in the air while squatting down.

Exercise 2: 1-Arm Bicep Pull/Swinging Hand (Straps at Mid-Length)

(30 Seconds on, 30 Seconds off for 3 Minutes) Intertwine handles to make one strap. Stand perpendicular to TRX while holding the handle with the right hand. The participant should have left hand on hip in a lateral stance, right arm bicep pull for the first 30 seconds. After rest, participant should face TRX with a wide stance, rotate trunk, and swing right hand to TRX

Exercise 1: TRX Stretching (Same as above) (30 Seconds on, 30 Seconds off for 3 Minutes) TRX Lower Back Stretch TRX Long Torso Twist TRX Chest and Torso Stretch

Exercise 6: Single Leg Squat, Left leg only (Straps at Mid-Length)

(30 Seconds on, 30 Seconds rest for 3 Minutes) Face the TRX, elbows bent at

sides. Extend the right leg forward, heel on the floor. Bend at the knees until a 90 degree angle. Return to start position. Continue for 30 seconds and then take a break. Participant can alternate between easy and hard progressions by holding the left leg in the air while squatting.

Exercise 3: 1-Arm Bicep Pull/Swinging Hand (Straps at Mid-Length)

(30 Seconds on, 30 Seconds off for 3 Minutes) Intertwine handles to make one strap. Stand perpendicular to TRX while holding the handle with the left hand. The participant should have right hand on hip in a lateral stance, left arm bicep pull for the first 30 seconds. After rest, participant should face TRX with a wide stance, rotate trunk, and swing left hand to TRX

Exercise 1: Low Row (Straps at Length-Short)

(30 Seconds on, 30 Seconds rest for 6 Minutes) Face TRX with feet together, extend arms forward and lean back. Pull chest forward and squeeze back muscles. Return to the start position. Participant can make harder by leaning at a larger angle, or easier buy widening stance or offsetting feet.

Session Three

Date: / /

Note: Participant may choose to use guide sounds or turn sounds off. If the guide sounds are on, the participant should focus on achieving the cowbell sound. Images from the Interactive Metronome® can be set according to the preference of the participants. Remind the participant that during all tasks, s/he should try to avoid quick, ballistic, jerky movements. All motions should be continuous and fluid. Remind the participant that it is alright to miss a beat, but if one is missed, keep going because the IM® program will calculate only the registered trigger hits.

Session 3: Approximately 56 Min Total (28 Minutes IM®/1512 Reps, 28 Minutes TRX)

| Short form testing 1-Both Hands (54 Reps, 1 Min) 2-Repeat #1 with Guide Sounds (54 Reps, 1 Min) | ms avg ms avg |
|--|--|
| Regular Training (with/out guide sounds) Exercise 1: Both Hands (216 Reps, 4 Min) Exercise 4: Both Toes (162 Reps, 3 Min) Exercise 10: Right Hand, Left Toe (162 Reps, 3 Min) Exercise 9: Left Heel (162 Reps, 3 Min) Exercise 1: Both Hands (162 Reps, 3 Min) Exercise 8: Right Heel (162 Reps, 3 Min) Exercise 11: Left Hand, Right Toe (162 Reps, 3 Min) Exercise 1: Both Hands (324 Reps, 6 Min) | ms avg ms avg ms avg ms avg ms avg ms avg ms avg ms avg |

TRX Training should be completed while the partner is performing the IM®. Make sure to focus on position of the

Reps/Minutes completed to-date: /

feet and posture of the body as each exercise is completed. Participants should perform each exercise for 30 seconds, take a break, and continue until the partner has stopped the IM® protocols.

During Short Form Testing: TRX Stretching (Straps at Mid-Length)

<u>TRX Lower Back Stretch</u>-Stand facing the TRX, extend arms forward. Bend at the hips and drop tailbone toward ground, knees slightly bent and hold. Straighten the left knee, rotate shoulders to the left and hold. Return to the center, and do same stretch on the right side. Return to the center and breathe deeply while keeping your back flat. To increase the intensity, lean into hip of straightened leg while flexing your quad.

<u>TRX Long Torso Twist</u>-Stand facing the TRX, arms extended, and cross right leg over the left, turn hips to the left. Drop the left hip toward the ground and let the torso and arms rotate toward the TRX, hold. Rotate chest to the left, hold, then to the right and hold. Return to the start position and repeat the exercise. Breathe deeply. Adjust your body position to release tight muscles.

<u>TRX Chest and Torso Stretch</u>-Stand facing away from the TRX. Have arms in a "T" position with your feet offset. Press your chest forward, and feel stretch in chest and arms.

Reach overhead with left arm, rotate chest to right, look back, eyes on right hand. Tuck pelvis, reach overhead with right arm, rotate chest to left, look back and eyes on left hand. Return to the start position and switch legs to repeat. Breathe deeply. Press rear heel into ground, bend rear knee and contract rear-leg glute to stretch hip flexor and calf.

Exercise 1: Chest Press toward Midline (Straps at Length Long)

(30 Seconds on, 30 Seconds rest for 4 minutes) Face away from the TRX; perform exercise with feet beyond shoulder-width. Lower the chest in push-up motion and return to start position.

Exercise 4: Single Leg Squat, Alternating Legs Every 30 Seconds (Straps at Mid-Length) (30 Seconds on, 30 Seconds rest for 3 Minutes) Face the TRX, elbows bent at

sides. Extend the left leg forward, with the heel on the floor. Bend at the knees for a 90 degree angle. Return to start position. Continue for 30 seconds and then take a break. Participant can alternate between easy and hard progressions by holding the left leg in the air while squatting down with the right leg. The next 30 seconds, the participant should alternate legs.

Exercise 10: Chest press facing away from TRX, Lunge Backward (Straps at Mid-Length) (30 Seconds on, 30 Seconds rest for 3 Minutes)

Exercise 9: Sprinter Start Backward Lunge-Left Leg Only (Straps at Length-Long) (30 Seconds on, 30 Seconds rest for 3 Minutes)

Exercise 1: TRX Stretching (Same as above)

(30 Seconds on, 30 Seconds off for 3 Minutes)

TRX Lower Back Stretch

TRX Long Torso Twist

TRX Chest and Torso Stretch

Exercise 8: Sprinter Start Backbard Lunge-Right Leg Only (Straps at Length-Long) (30 Seconds on, 30 Seconds rest for 3 Minutes)

Exercise 11:Sprinter Start Forward Lunge-Alternating Legs

(30 Seconds on, 30 Seconds rest for 3 Minutes)

Exercise 1: Low Row (Straps at Length-Short)

(30 Seconds on, 30 Seconds rest for 6 Minutes) Face TRX with feet together, extend arms forward and lean back. Pull chest forward and squeeze back muscles. Return to the start position. Participant can make harder by leaning at a larger angle, or easier buy widening stance or offsetting feet.

Session Four

Note: Participant may choose to use guide sounds or turn sounds off. If the guide sounds are on, the participant should focus on achieving the cowbell sound. Images from the Interactive Metronome® can be set according to the preference of the participants. Remind the participant that during all tasks, s/he should try to avoid quick, ballistic, jerky movements. All motions should be continuous and fluid. Remind the participant that it is alright to miss a beat, but if one is missed, keep going because the IM® program will calculate only the registered trigger hits.

Session 4: Approximately 56 Min Total (28 Minutes IM®/1512 Reps, 28 Minutes TRX)

| Short form testing | |
|---|---------|
| 1-Both Hands (54 Reps, 1 Min) | ms avg. |
| 2-Repeat #1 with Guide Sounds (54 Reps, 1 Min) | ms avg. |
| Regular Training (with/out guide sounds) | |
| Exercise 1: Both Hands (216 Reps, 4 Min) | ms avg. |
| Exercise 4: Both Toes (162 Reps, 3 Min) | ms avg. |
| Exercise 2: Right Hand (162 Reps, 3 Min) | ms avg. |
| Exercise 10: Right Hand, Left Toe (162 Reps, 3 Min) | ms avg. |
| Exercise 1: Both Hands (162 Reps, 3 Min) | ms avg. |
| Exercise 3: Left Hand (162 Reps, 3 Min) | ms avg. |
| Exercise 11: Left Hand, Right Toe (162 Reps, 3 Min) | ms avg. |
| Exercise 1: Both Hands (324 Reps, 6 Min) | ms avg. |
| | |

Date: ____/___/____

Reps/Minutes completed to-date: ____/___

*Follow previous Exercise explanations for instruction

Session Five

Note: Participant may choose to use guide sounds or turn sounds off. If the guide sounds are on, the participant should focus on achieving the cowbell sound. Images from the Interactive Metronome® can be set according to the preference of the participants. Remind the participant that during all tasks, s/he should try to avoid quick, ballistic, jerky movements. All motions should be continuous and fluid. Remind the participant that it is alright to miss a beat, but if one is missed, keep going because the IM® program will calculate only the registered trigger hits.

Session 5: Approximately 56 Min Total (28 Minutes IM®/1512 Reps, 28 Minutes TRX)

| Short form testing | |
|---|---------|
| 1-Both Hands (54 Reps, 1 Min) | ms avg. |
| 2-Repeat #1 with Guide Sounds (54 Reps, 1 Min) | ms avg. |
| Regular Training (with/out guide sounds) | |
| Exercise 1: Both Hands (216 Reps, 4 Min) | ms avg. |
| Exercise 3: Left Hand (162 Reps, 3 Min) | ms avg. |
| Exercise 7: Both Heels (162 Reps, 3 Min) | ms avg. |
| Exercise 13: Balance Left Foot (162 Reps, 3 Min) | ms avg. |
| Exercise 1: Both Hands (162 Reps, 3 Min) | ms avg. |
| Exercise 12: Balance Right Foot (162 Reps, 3 Min) | ms avg. |
| Exercise 11: Left Hand, Right Toe (162 Reps, 3 Min) | ms avg. |
| Exercise 1: Both Hands (324 Reps, 6 Min) | ms avg |
| | |

Date: ___/___/

Session Six

Note: Participant may choose to use guide sounds or turn sounds off. If the guide sounds are on, the participant should focus on achieving the cowbell sound. Images from the Interactive Metronome® can be set according to the preference of the participants. Remind the participant that during all tasks, s/he should try to avoid quick, ballistic, jerky movements. All motions should be continuous and fluid. Remind the participant that it is alright to miss a beat, but if one is missed, keep going because the IM® program will calculate only the registered trigger hits.

Session 6: Approximately 56 Min Total (25 Minutes IM®/ 1350 Reps, 25 Minutes TRX)

| Short form testing | |
|---|---------|
| 1-Both Hands (54 Reps, 1 Min) | ms avg. |
| 2-Repeat #1 with Guide Sounds (54 Reps, 1 Min) | ms avg. |
| Regular Training (with/out guide sounds) | |
| Exercise 1: Both Hands (216 Reps, 4 Min) | ms avg. |
| Exercise 5: Right Toe (162 Reps, 3 Min) | ms avg. |
| Exercise 13: Balance Left Foot (162 Reps, 3 Min) | ms avg. |
| Exercise 1: Both Hands (162 Reps, 3 Min) | ms avg. |
| Exercise 12: Balance Right Foot (162 Reps, 3 Min) | ms avg. |
| Exercise 6: Left Toe (162 Reps, 3 Min) | ms avg. |
| Exercise 1: Both Hands (324 Reps, 6 Min) | ms avg. |
| | |

Date: ___/___/

Session Seven

Note: Participant may choose to use guide sounds or turn sounds off. If the guide sounds are on, the participant should focus on achieving the cowbell sound. Images from the Interactive Metronome® can be set according to the preference of the participants. Remind the participant that during all tasks, s/he should try to avoid quick, ballistic, jerky movements. All motions should be continuous and fluid. Remind the participant that it is alright to miss a beat, but if one is missed, keep going because the IM® program will calculate only the registered trigger hits.

Session 7: Approximately 56 Min Total (28 Minutes IM®/1512 Reps, 28 Minutes TRX)

| Short form testing | |
|---|---------|
| 1-Both Hands (54 Reps, 1 Min) | ms avg. |
| 2-Repeat #1 with Guide Sounds (54 Reps, 1 Min) | ms avg. |
| Regular Training (with/out guide sounds) | |
| Exercise 1: Both Hands (216 Reps, 4 Min) | ms avg. |
| Exercise 2: Right Hand (162 Reps, 3 Min) | ms avg. |
| Exercise 12: Balance Right Foot (162 Reps, 3 Min) | ms avg. |
| Exercise 3: Left Foot (162 Reps, 3 Min) | ms avg. |
| Exercise 1: Both Hands (162 Reps, 3 Min) | ms avg. |
| Exercise 11: Left Hand, Right Toe (162 Reps, 3 Min) | ms avg. |
| Exercise 13: Balance Left Foot (162 Reps, 3 Min) | ms avg. |
| Exercise 1: Both Hands (324 Reps, 6 Min) | ms avg. |
| | |

Date: ___/___/

Session Eight

Note: Participant may choose to use guide sounds or turn sounds off. If the guide sounds are on, the participant should focus on achieving the cowbell sound. Images from the Interactive Metronome® can be set according to the preference of the participants. Remind the participant that during all tasks, s/he should try to avoid quick, ballistic, jerky movements. All motions should be continuous and fluid. Remind the participant that it is alright to miss a beat, but if one is missed, keep going because the IM® program will calculate only the registered trigger hits.

Session 8: Approximately 56 Min Total (28 Minutes IM®/1512 Reps, 28 Minutes TRX)

| Short form testing | |
|--|---------|
| 1-Both Hands (54 Reps, 1 Min) | ms avg. |
| 2-Repeat #1 with Guide Sounds (54 Reps, 1 Min) | ms avg. |
| Regular Training (with/out guide sounds) | |
| Exercise 1: Both Hands (216 Reps, 4 Min) | ms avg. |
| Exercise 3: Left Hand (162 Reps, 3 Min) | ms avg. |
| Exercise 6: Left Toe (162 Reps, 3 Min) | ms avg. |
| Exercise 1: Both Hands (162 Reps, 3 Min) | ms avg. |
| Exercise 2: Right Foot (162 Reps, 3 Min) | ms avg. |
| Exercise 5: Right Toe (162 Reps, 3 Min) | ms avg. |
| Exercise 10: Right Hand/Left Toe (162 Reps, 3 Min) | ms avg. |
| Exercise 1: Both Hands (324 Reps, 6 Min) | ms avg. |

Date: ___/___/

Session Nine

Note: Participant may choose to use guide sounds or turn sounds off. If the guide sounds are on, the participant should focus on achieving the cowbell sound. Images from the Interactive Metronome® can be set according to the preference of the participants. Remind the participant that during all tasks, s/he should try to avoid quick, ballistic, jerky movements. All motions should be continuous and fluid. Remind the participant that it is alright to miss a beat, but if one is missed, keep going because the IM® program will calculate only the registered trigger hits.

Session 9: Approximately 56 Min Total (28 Minutes IM®/1512 Reps, 28 Minutes TRX)

| Short form testing | |
|---|---------|
| 1-Both Hands (54 Reps, 1 Min) | ms avg. |
| 2-Repeat #1 with Guide Sounds (54 Reps, 1 Min) | ms avg |
| Regular Training (with/out guide sounds) | |
| Exercise 1: Both Hands (216 Reps, 4 Min) | ms avg. |
| Exercise 5: Right Toe (162 Reps, 3 Min) | ms avg. |
| Exercise 13: Balance Left Foot (162 Reps, 3 Min) | ms avg. |
| Exercise 7: Both Heels (162 Reps, 3 Min) | ms avg. |
| Exercise 1: Both Hands (162 Reps, 3 Min) | ms avg. |
| Exercise 6: Left Toe (162 Reps, 3 Min) | ms avg. |
| Exercise 12: Balance Right Foot (162 Reps, 3 Min) | ms avg. |
| Exercise 1: Both Hands (324 Reps, 6 Min) | ms avg |
| | |

Date: ___/___/

Session Ten

Note: Participant may choose to use guide sounds or turn sounds off. If the guide sounds are on, the participant should focus on achieving the cowbell sound. Images from the Interactive Metronome® can be set according to the preference of the participants. Remind the participant that during all tasks, s/he should try to avoid quick, ballistic, jerky movements. All motions should be continuous and fluid. Remind the participant that it is alright to miss a beat, but if one is missed, keep going because the IM® program will calculate only the registered trigger hits.

Session 10: Approximately 56 Min Total (28 Minutes IM®/1512 Reps, 28 Minutes TRX)

| Short form testing | |
|--|---------|
| 1-Both Hands (54 Reps, 1 Min) | ms avg |
| 2-Repeat #1 with Guide Sounds (54 Reps, 1 Min) | ms avg. |
| Regular Training (with/out guide sounds) | |
| Exercise 1: Both Hands (216 Reps, 4 Min) | ms avg. |
| Exercise 8: Right Heel (162 Reps, 3 Min) | ms avg. |
| Exercise 10: Right Hand/Left Toe (162 Reps, 3 Min) | ms avg. |
| Exercise 1: Both Hands (162 Reps, 3 Min) | ms avg. |
| Exercise 9: Left Heel (162 Reps, 3 Min) | ms avg. |
| Exercise 11: Left Hand/Right Toe (162 Reps, 3 Min) | ms avg. |
| Exercise 4: Both Toes (162 Reps, 3 Min) | ms avg. |
| Exercise 1: Both Hands (324 Reps, 6 Min) | ms avg. |
| | |

Date: ___/___/

Session Eleven

Final Evaluation: Short form IM test 1-Both Hands 2-Repeat #1 with Guide Sounds COPM Total Score Overt TEA 9 Hole Peg Test Left Hand _____ Right Hand _____ Long form IM test 1-Both Hands 2-Right Hand 3-Left Hand **4-Both Toes** 5-Right Toe 6-Left Toe 7-Both Heels 8-Right Heel 9-Left Heel 10-Right Hand/Left Toe 11-Left Hand/Right Toe 12-Balance Right Foot/Tap Left Toe 13-Blanace Left Foot/Tap Right Toe

APPENDIX F: Corresponding IM® and TRX® Movements

| Interactive Metronome | TRX |
|---------------------------|--|
| Both hands, easy clapping | Chest press towards midline |
| | Low Row (Bicep pull) |
| Right hand (on hip) | Lateral stance bicep pull |
| Left hand | Face TRX, feet hip-width apart, rotate trunk, swing specified hand to TRX |
| Both toes | Single leg squat, alternating legs |
| Right toe | Single leg squat right leg only |
| Left toe | Single leg squat left leg only |
| Both heels | Sprinter start backward lunge (Progressio 1); alternate feet |
| Right heel Left heel | Sprinter start backward lunge (Progressio 1) right leg only |
| | Sprinter start backward lunge (Progression 1) Sprinter start backwar |
| Right hand/Left toe | Chest press facing away from TRX, then |
| Left hand/Right toe | lunge backward Alternate legs |