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JOURNAL OF NEUROLOGY AND NEUROSCIENCE
ISSN 2171-6625

2015
Vol. 6 No. 2:7

The Validation of the Interactive Metronome: A Pilot Study Prior to Implementation for Post Deployment Service Members

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Abstract

The purpose of this study was to validate the protocols created for the Interactive Metronome ™ (IM) used in conjunction with the TRX® System for returning post deployment service members diagnosed with mild traumatic brain and/or Post-Traumatic Stress Disorder. This was done using a pilot population similar in age and physical status as active duty military, but within a college setting. The pre-established protocols were pilot tested on two male and two female participants. The data collected was from the IM Long Form, Nine Hole Peg Test, Canadian Occupational Performance Model and the Test of Everyday Attention. In a comparative analysis of pre- and post- status it was determined that the IM along with TRX® system would potentially benefit returning post deployment service members using this series of treatment interventions.

Keywords: Interactive metronome protocol development; Validating assessments; Innovative neurological intervention; Interactive metronome; Post traumatice stress interventions

Introduction

It has become common knowledge that the "Signature Injury" of the ongoing Iraq and Afghanistan Wars is that of traumatic brain injury (TBI) [1]. Blast exposure is reportedly the most common cause of TBI through multiple delivery systems, but most often from improvised explosive devices or IEDs. Returning service members describe situations of being exposed to explosive device detonations in the field of operations, and soldiers often walk away seemingly unscathed. This is a repeated and standard event; however, it is now felt that this is where sustained serious injuries, which are not readily detectable are occurring. The most common and still most overlooked war-related afflictions is traumatic brain injury [2]. As occupational therapists, we are keenly aware of the serious symptoms of TBI's with its deceptive and inconspicuous nature. It is a long term debilitating injury and should receive the full attention as with any other debilitating disease. Often associated with repeated TBI and mild traumatic brain injuries (mTBI) is the secondary affect from placement in a war time theater is that of Post-Traumatic Stress Disorder or PTSD. The nature of war time injuries and constant exposure to threats on one's life creates the realization that those who have gone through a battlefield mTBI and/or blast related concussion will have elements of PTSD. This paper and research recognizes the duality that exists when discussing mTBI the inclusion of those PTSD elements is included as part of the challenges being faced by post-deployment service members [3-5].

Due to the increased involvement of the US military in war-time operations, in the past decade, there has been a significant rise in the prevalence of TBI [6]. According to the Defense and Veterans Brain Injury Center [3], military members are more at risk for TBI because of the physically demanding environment and high exposure to IEDs, suicide bombers, land mines, mortar rounds, and rocket-propelled grenades. From the beginning of the year 2000 to May 20, 2010, there have been 178,876 recorded TBIs in the military population [3]. The recovery process for military personnel with combat-acquired TBI is complicated by the physically and emotionally traumatic circumstances in which the injury was obtained, the potential for repeated injuries during active duty, the high incidence of comorbid mental health conditions, and the difficulty in following recommended care due to the physical nature of the job [4].

The most commonly reported symptoms of TBI by patients and caregivers are attention and memory deficits [7]. According to Chan [7], attentional deficits are also the most persisting symptoms of TBI and can affect the individual years after the brain injury was acquired. Depending on the cause, severity, and location of the injury, deficits in executive functioning can cause significant negative impacts on daily activities and occupational performance. The returning post-deployment military members may not initially identify associated problems, because of the survival mode on the battlefield, but may later self identify these residual symptoms.

Mild traumatic brain injuries affect the executive and orienting components of attention [8]. According to Tipton-Burton et al. [9], individuals who exhibit clinical signs following a mTBI should be classified as post-concussion symptoms (PCS). Many PCS are related to executive functioning, such as impaired concentration and attention, slowness and inefficiency of thought and action, and learning and memory problems [5]. The executive component of attention, which allows individuals to make use of relevant stimuli or ignore irrelevant stimuli when preparing for an activity, is particularly susceptible to the effects of mTBI [8]. The disruption of attentional orientation affects one's ability to "move attention from the central fixation point, search alternate locations for the target point and re-engage attention at the appropriate location to respond to the target stimulus" [8] p.1032. In a review of attentional deficits in patients with post-concussion symptoms, the main impairments identified were in sustained attention, selective attention, divided attention, and attentional control processing [7]. Sustained attention is the ability to direct and focus cognitive activity on specific stimuli [10]. When multiple external sensory inputs are present, the process of dedicating cognitive and perceptual resources to one type/set of input and attenuating receptiveness to other inputs is known as selective attention [10]. Divided attention is defined as the process by which an individual can perform multiple non-automatic tasks at the same time [10]. Attentional control processing is responsible for the higher voluntary forms of attention, such as planning, programming, regulation, and verification [7].

Significance to occupational therapy

All areas of occupation, as identified in the Occupational Therapy Practice Framework, are affected by mild traumatic brain injury and post-traumatic stress disorder [11]. Individuals may have difficulty with activities of daily living (ADL), instrumental activities of daily living (IADL), education, work, play, leisure, and/or social participation due to impairments of attention. Attentional deficits significantly impact an individual's ability to perform ADLs and IADLs, such as self-care and grooming tasks, job performance, caring for others, financial management, and leisure and social participation. Occupational gaps occur when there is a disparity between what individuals can do and what they want and need to do [12]. A study by Ericksson et al. [12], found the number of occupational gaps increased after a mTBI from 46% to 71%. The difficulties in attention, concentration, memory, and processing speed greatly impacted the ability to perform daily routines, complete work-related tasks, and maintain a social life.

Individuals who suffer from mTBI and/or PTSD often experience similar residual symptoms [5]. In a study conducted in 1997 by Beckham et al. [13], 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 mTBI [13]. Patients and families most often described the neurobehavioral symptoms of mTBI and associated PTSD to be the most difficult to deal with as they re-integrate into family living. These, along with alienating family members and negatively impacting the social support networks are presented by individuals diagnosed with mTBI may have otherwise had [14,15]. For example, the symptoms of aggression, often interferes in every aspect of the individual's life, including activities of daily living; thus, limiting the veteran's ability to receive the full benefits from additional therapies or achieve recovery in other areas that are also affected in the lives. Giving attention to the individual's specific needs during the recovery process can lead to greater engagement and motivation on the part of the post- deployed service member, and therefore, improve their satisfaction and intervention outcomes [16].

A significant challenge as viewed by an "outsider to Military Medicine delivery is that protocols and treatments provided to military service members must have a least demonstrated a level of effectiveness, before being implemented with the service member seeking medical care. Military treatment centers, while advocating for innovative treatment approaches for post-deployed service members, want to ensure the treatment intervention provides the outcomes expected and are not experimental in nature. Thus, in preparation this study demonstrating the effectiveness of the protocols developed for use with post deployment service members was established. The pilot study using healthy college students and their outcomes is presented here in.

Method

After obtaining approval from the Institutional Review Board participants were recruited, selected, and given verbal and written information of the study. Intervention sessions were conducted in multiple settings for convenience of the participants. These settings include the Clinic Lab setting and home apartments of two of the participants, which mirrored anticipated implementation of the study to a larger population.

Prior to implementation, the researchers had designed a specific set of protocols based on protocols developed by the Interactive Metronome™ (IM) and exercises provided by TRX®. The IM protocol template that influenced the protocols designed for this study was for individuals with attention-deficit hyperactivity disorder (ADHD), which is effective at improving attentional deficits [17]. Based on these two sources, and trial runs with individuals of similar ages and genders, the researchers developed a 12-session intervention plan, with the first and last session consisting of pre- and post-testing evaluations. The remaining ten sessions were designed to include 1350-1512 repetitions with the IM per session, which is the number of repetitions needed for effective treatment [17]. Each session had a variety of IM routines which were paired with a similar exercise using the TRX®. Due to the demanding physical nature of TRX®,

exercises with the TRX® equipment were performed in 30 second increments with 30 seconds of break between each interval. Each session lasted a maximum of an hour and a half. The design of the study suggested that no more than three sessions be performed per week. The intervention plan was designed so that two participants could be treated simultaneously; this was done to encourage motivation and competition during the treatment sessions. When one participant was completing the proposed IM routine, the other participant would be completing the paired TRX® exercise. Researchers completed pre-test evaluations on all participants using the Canadian Occupational Performance Measure (COPM), Test of Everyday Attention (TEA), Interactive Metronome (IM) Long Form assessments, and the Nine-Hole Peg Test (NHPT). This session was also used to familiarize participants with the TRX® as well as the IM.

A non-probability sampling method was utilized due to its convenience and purposive nature. Participants were recruited from an occupational therapy program based on their willingness to participate, good health status, and availability of time. Two males and two females were recruited by the primary investigator. All four students were graduate students attending the same university and graduate program. They all reported to be in good health with no known physical or mental challenges. Their average age was 24 and they completed their sessions in the later third of the semester extending into final exam week.

Instrumentation

For this pilot study, four standardized assessments were used to collect data. These assessments were the Canadian Occupational Performance Measure (COPM), Test of Everyday Attention (TEA), Interactive Metronome (IM) Long Form assessments, and the Nine-Hole Peg Test (NHPT).

Instrumentation: Canadian occupational performance measure

The COPM [18] is based on a client-centered approach for the purpose of establishing treatment goals and assessing changes in perceived performance and satisfaction with occupational performance over time [19]. The COPM, is well established and accepted in occupational therapy practice. Baseline scores were used to compare with the re-assessment. The re-assessment follows the intervention or treatment [20]. The COPM is a stable and sensitive measure to use with individuals with mild traumatic injuries in a community-based rehabilitation setting. This evaluation allowed for the researchers to measure the client's affect, valued activities or occupations and what specific everyday tasks the individual might identify as frustrating or difficult.

Instrumentation: Test of everyday attention

The Test of Everyday Attention (TEA) was used to assess changes in attention. The TEA is an evaluation tool that measures selective attention, sustained attention, attentional switching, and divided attention [21]. This instrument was used as a pre- and post-test evaluation tool and took approximately 45 minutes to administer. Within this assessment tool, there are eight subtests designed to mimic everyday tasks and help to assess how individuals perform these activities with attentional problems. Visual selective attention, auditory selective attention, auditory-verbal working memory, attentional switching, divided attention, and sustained attention are measured with one or more of the eight subtests of the TEA. The eight subtests include: map search, elevator counting, elevator counting with distraction, visual elevator, auditory elevator with reversal, telephone search, telephone search dual task, and lottery. Reliability and validity data of the TEA are based on a sample of normal individuals and sample of individuals diagnosed with stroke. Versions A and B of the TEA have test-retest reliability ranging from 0.59 to 0.86, from a normative sample of 118 people, ages 18-80 [21].

Instrumentation: The Interactive Metronome™ (IM)

The Interactive Metronome™ is a treatment tool that has been shown to improve neurological functions of motor planning and sequencing [17]. According to IM, it has been shown to improve attention, concentration, cognitive speed, memory, and a variety of other skills. Additionally, it may help clients with the diagnoses of attention deficit hyperactivity disorder, cerebral palsy, epilepsy, traumatic brain injury, and more [17]. The IM was selected for this pilot study because of the promising neurological effects it has had in past studies regarding attention and concentration.

The IM is a computerized software system with special hand and foot switches that provide a synchronized, rhythmic reoccurring tone that the user in turn, attempts to hit the hand and/or foot switch at the same time as the synchronized tone. The software provides the user instant feedback of the milliseconds one is either slower than the reoccurring sound or faster than the rhythm pace presented. It provides both visual and auditory feedback to allow the user to adjust accordingly.

Research with animals has shown that after brain injuries occur, there are structural changes that take place in the brain [22]. This research suggests that strategies that enhance plasticity in the motor cortex can lead to gains in functional abilities. The IM operates on the concept of neural plasticity and may be a strategy that allows the brain to build and strengthen connections through the repetitive exercises regardless of the premorbid status of the user.

The IM, particularly the home system, is convenient and can be done in the home on a client's own time. Furthermore, although it utilizes a bottom-up design, the benefits gained from the IM may provide positive carry over into other areas of occupation. In this study the IM Short Form and IM Long Form evaluations were used to compare changes and anticipated improvements in using the IM. The IM Short Form is a short brief evaluation intended to provide the IM Provider a brief insight to the possible status of the client just prior to starting the session. The IM Long Form is an assessment that uses the 14 different IM tasks and establishes a baseline. It is used at the onset, and again at the conclusion of the protocol series being followed providing a comparison between the before and after scores. It records the timing and number of "Super Right On" hits (perfect score hits) and estimates percentages of number of hits that fall within the desired areas [17].

Instrumentation: Nine-Hole Peg Test

The Nine-Hole Peg Test (NHPT) is an instrument commonly used by occupational therapists to quickly and accurately assess finger dexterity [23,24]. The NHPT was used as a secondary measure primarily because the IM purports to affect changes in more than one specific area of an individual, and was used as a control measure. The returning wounded warriors must demonstrated efficient dexterity skills in order to maintain their worldwide ready for duty status.

TRX Apparatus

The TRX® Suspension Training 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. The TRX® allows the user to perform hundreds of functional exercises that build strength, flexibility, core stability and endurance [25]. This piece of exercise equipment was used to supplement the IM during the treatment protocols, by mimicking the same exercises and body movements of those used with the IM.

Procedure

Intervention sessions of the protocol were carried out over the course of three weeks. The two male participants performed each session together, as did the two female participants. Each session began with one participant completing the short form assessment of the IM® and the other participant stretching with the TRX®. Approximately nine other exercises were performed during each session i.e. nine IM® routines, complemented by nine TRX® exercises

During the first and last intervention sessions, the standardized assessment tests were completed. These included the COPM, TEA, and the NHPT along with the IM Long Form and IM Short Form assessments. Once all data were collected it was compiled for analysis and review.

Data analysis

The instruments utilized in this study produced measurable, numerical data. To analyze the data, the researchers found percentages of change from pre- to post-test. t-Tests were then calculated using SPSS [26] to determine whether there were significant differences between pre- and post-test scores at a 0.05 level.

Canadian Occupational Performance Measure

During the pre-test administration of the Canadian Occupational Performance Measure (COPM), each of the four participants identified specific areas of concern that were impacting the performance of self-care, productivity, and leisure occupations. **Table 1** reflects the identified areas of concern per participant, pre- and post-test scores, and the amount of change observed.

When grouped together the changes identified showed significance based on t-Test outcomes demonstrating notable *p* values with the Performance area changes having a *p* value of 0.015 and the Satisfaction *p* value of 0.023. These are significant in identifying changes as identified by the participants. The importance is that of the identification by the individual and their view of change over time.

Test of Everyday Attention

The following results are four of the nine subtests in the Test of Everyday Attention (TEA). The raw scores were translated to scaled-scores using the TEA manual according to the age of the participant [21]. These were then compiled and independent t-Test indications where changes and improvements were made as a group. An average of 14.24% of change was made with the ranges 8.5% to 24.5%. Given the small population and pre morbid skill levels of the students

The four areas being presented were notable scores obtained and t-Tests scores were determined. These included the following areas: Subtest #3: Elevator Counting with Distraction, Subtest #4: Visual Elevator, Subtest #5: Elevator Counting with Reversal and Subtest #8: Lottery. The t test *p* values obtained were Elevator Counting with Distraction .063 (a notable change); Visual Elevator *p* value .006 (statistically significant), Elevator Counting with Reversal *p* value of .08 (a notable change); and Lottery for a *p* values of .0006 again a notable statistical significant score.

Interactive Metronome Long Form Assessment and TRX

This study set out to examine the effectiveness of the IM and TRX® as a combined intervention. In piloting this the outcomes of those involved in the pilot are significant as well. **Table 2** shows the adjusted millisecond averages and percentage of change from pre- to post-test for all participants using the Long Form assessment of the Interactive Metronome. Participant A and B, and Participants C and D all showed negative percentages of change, meaning they showed decreases in milliseconds averages from pre- to

	Participant A		Participant B		Participant C		Participant D	
	Performance	Satisfaction	Performance	Satisfaction	Performance	Satisfaction	Performance	Satisfaction
Pre-test	5.75	4.25	3.75	3.0	6	5.0	6.25	7.5
Post-test	6.5	5.0	5.0	5.0	6.5	6.0	7.0	8
Change	0.75	0.75	1.25	2.0	.5	1.0	1.25	1.0
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, leisure time for self and socializing with friends		Time management skills, managing stress levels, budgeting finances, cooking, participating in leisure/ social activities		Balance and coordination, organization of finances, organization related to work, motivation and endurance during exercise	

Table 1 Pre- and post-test COPM scores of all participants.

	Pre-test	Post-test	Percentage of Change
Participant A	58.6	40.6	-30.8%
Participant B	24.4	17.2	-29.7%
Participant C	46.53	36.8	-20.8%
Participant D	158.9	108.3	-31.9%

Table 2 IM long form adjusted ms averages and percentage of change for all participants.

post-test. Therefore, a negative percentage of change indicates improved performance. Participant A showed a 30.8% decrease from pre- to post-test. Participant B also decreased in millisecond average, with a percentage of change of -29.7%. Participant C also decreased in millisecond average, with a percentage of change of -20.8%. Finally, participant D showed a larger decrease in average with a change of -31.9%.

An independent-samples 2 tailed t-Test was conducted to compare pre-test Long Form assessment scores to post-test Long Form assessment scores of all participants. There were noted significance differences in the pre- and post-test scores at the .05 level. The average percentage of change was 28.3%. In clinical trials, evaluation using an anchor-based approach for a determinate level of success. The change is a 100% and based on those standards should be found to be acceptable for implementation [27].

No measurements pertaining to the TRX® and its use were taken with the exception of anecdotal notations, most of which revolved around how the routines became more obtainable as they progressed through the protocols.

Nine-Hole Peg Test

The Nine-Hole Peg Test (NHPT) generated right and left hand results from all four participants. Given all participants were right hand dominant the findings for the right hand changes are presented in **Table 3**. Of note all participants were well within norms before participating in the study and while the percentage of change is not statistically significant improvements upon an already acceptable level are worth taking note on their changes. Improvement in hand dexterity is indicated by a decrease in the amount of time it takes to perform the NHPT. Therefore, negative percentage of change reflects improved performance.

Discussion of findings

This pilot study was developed to demonstrate the effectiveness of the protocols established specific to the use of the Interactive Metronome and TRX® in improving life satisfaction and reducing loss of attention in a normal and well population. The expectations are that these findings can be transferred to military service members returning to active duty post-deployment who may have suffered mTBI and PTSD.

Changes were observed and recorded using a variety of instruments. The Canadian Occupational Performance Measure, Test of Everyday Attention, IM Long Form assessment, and the Nine-Hole Peg Test were administered during pre- and post-test evaluations. The results collected demonstrated positive results. These results though not significant in all areas are highly notable

	Pre-test	Post-test	Percentage of Change
Participant A	17	16.5	-3%
Participant B	16.7	14.9	-11%
Participant C	20.8	15.6	-25%
Participant D	18.5	18.	-1.7%
Significance at 0.05			

Table 3 NHPT right hand results and percentage of change for all participants.

especially given the premorbid normal status of the participants who then made measureable positive changes.

This normal premorbid status might best be the reason behind the outcomes noted on the Test of Everyday Attention (TEA). The high scores obtained by the participants on their initial scores may have lead to the inability to measure changes in attention for the four participants, but important observations were made throughout this study that qualitatively could have been noted.

The Canadian Occupational Performance Measure (COPM) was used to assess the participants' perception of occupational performance and satisfaction before and after intervention. In this pilot study, it was expected that if the loss of attention was reduced, individuals would begin to report higher levels of life satisfaction. While there were not significant changes, positive outcomes and anecdotal comments collected support the sense this level of change. By using a well-population, it was not expected that attention would improve as these individuals did not have attentional impairments to measure change against. This could be explained by the physical nature of the protocol and instruments. The IM and TRX® are designed to provide individuals with exercise and movement to improve coordination, balance, timing, and motor ability. By completing a 10-session protocol, individuals may report improvements in satisfaction with occupations due to the physical nature of these pieces of equipment.

The Interactive Metronome Long Form assessment did not show evidence of statistically significant change in timing after the specific protocols were performed. However, all four participants did show improvements in adjusted millisecond averages. The percentages of change are very similar and should be give strong consideration when the average percentage of change is closing in on 30% (28.3%). This average if presented to caseworker review boards would find the outcomes substantial and acceptable resulting in approval for payment or continued use as a treatment modality. Participants reported that they found the IM a reassuring; especially at the end of the academic day. Anecdotally, the participants reported that it was a "happy place to go to" during their final exams and relieved some of the sense of stress.

Summary and Conclusion

Though the results of this pilot study provided moderate areas of significance, the observed changes demonstrate the positive effects of the designed and implemented Interactive Metronome and TRX® protocol series. The most pertinent information can be seen in the areas of attention and life satisfaction.

The intervention sessions of the designed protocol series affected

attention skills and life satisfaction of the normal, young adult participants of the pilot study population. Change was observed using a variety of evaluation tools. The Test of Everyday Attention and the Canadian Occupational Performance Measure showed improvements in attention skills and life satisfaction of the four participants. It may be concluded that the protocols series using the IM and TRX® is effective at producing positive change in such areas, and may be applied to post-deployed military personnel individuals with mild traumatic brains injuries and/or post-traumatic stress disorder symptoms.

Implications for practice

Future research is strongly encouraged to further investigate the findings of this pilot study. This study was conducted in preparation for implementation with a population of post-deployed service members with mTBI and/or PTSD. Further research may indicate the effects of the IM and TRX® in improving life satisfaction and reducing loss of attention. The military population experience significant occupational gaps due to the residual symptoms of mTBI and/or PTSD. Occupational therapists must be well equipped with treatment interventions and intervention strategies to assist individuals with residual symptoms of mTBI and/or PTSD. These should effectively allow them to maintain and return to living as independently as possible. With further research, occupational therapists will be able to provide evidence-based practice and make significant changes in the everyday lives of this population. As a pilot study, this research met and exceeded its goals in paving a positive avenue for treatment interventions on a population that currently has no specific intervention plan established for the complexity of injuries at hand.

Acknowledgements

The author would like to thank the Interactive Metronome ™ for providing equipment and software for this study. The author would also like to thank the participants for their devoted time and effort throughout this study. Lastly, the author would like to thank Michelle L. Foley, OTR and Kelly N. Ridenhour, OTR for their assistance and knowledge in the development and implementation of the protocol series.

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