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Does the use of Balance-Based Torso-Weight increase gait velocity in people diagnosed with Multiple Sclerosis?

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Does the use of Balance-Based Torso-Weight increase gait velocity in people diagnosed with Multiple Sclerosis?

Disciplines

Physical Therapy

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Title: Does the use of Balance-Based Torso-Weight increase gait velocity in people diagnosed with Multiple Sclerosis?

Clinical Scenario: The patient who led us to pursue this question is a 52 y/o female diagnosed with Multiple Sclerosis (MS). Physical therapy treatment to date has included balance training and strengthening programs for lower extremities and core musculature. The patient's main functional complaint was an inability to keep up with family on walks. Contributing impairments to this functional limitation include balance deficits, decreased endurance, decreased strength, gait ataxia and decreased gait velocity.

Brief introduction: In a recent clinical internship, patients diagnosed with MS received the therapeutic intervention of Balance-Based Torso-Weight (BBTW). Patients diagnosed with MS often present with impairments of balance deficits decreased endurance, decreased strength, gait ataxia and decreased gait velocity. We are interested to learn if this intervention is well supported in the research literature. This clinical question is also of interest because the company, Motion Therapeutics, which produces BBTW, supplied the PT clinic with promotional information. This suggested such an intervention would benefit the patient population diagnosed with MS. Motion Therapeutics claims BBTW can help patients diagnosed with MS, Parkinson's, stroke or scoliosis. Research of BBTW has currently only been conducted on patients diagnosed with MS.

Clinical question: Does the use of Balance-Based Torso-Weight increase gait velocity in people diagnosed with Multiple Sclerosis?

Clinical Question PICO:

Population – Subjects with Multiple Sclerosis and balance difficulties

Intervention - Balance-based torso-weighting

Comparison - No treatment

Outcome - Gait velocity

Overall Clinical Bottom Line: Based on outcome results from Gorgas et al., Widener et al. (October, 2009) and Widener et al. (April, 2009) we recommend a trial of BBTW for patients with MS who wish to improve gait velocity. Statistically significant improvements using the BBTW vest were recognized with an average gait velocity change by Gorgas, et al. (6.9 cm/sec) and Widener et al. (October, 2009) (10.1 cm/sec). Both gait velocities also met the clinically significant difference in gait velocity for patients with MS as suggested by Morris, et al. (2002). Widener et al. (April, 2009) did not find a difference in gait velocity between conditions. However, the number of subjects included in this study did not meet a sufficient power to determine a difference, even if one did exist. Gorgas, et al. found a small effect size and Widener, et al. (October 2009) found a small to medium effect size. Although this is not a large effect, for a patient population with MS, this could make a significant impact on quality of life and daily function. Even a small difference is important for populations with MS because fatigue is often the greatest limiting factor in daily life.

Validity of all studies in this analysis was good with only minor threats. Threats included lack blinding and multiple treatment interference. The vest cost is \$795, which is a significant expense and may not be covered by insurance. It

is feasible patients would pay this price if they experienced significant improvement in their gait velocity after a trial with the BBTW vest in clinic. The majority of study subjects were women which mirrors the established higher prevalence of women diagnosed with MS (Gorgas et al., 2014). Therefore, results can be confidently generalized to adult women diagnosed with MS. Caution should be taken when generalizing the results to men diagnosed with MS.

Research regarding the intervention of BBTW vests in populations diagnosed with MS is limited. There is a need for an increased body of research that encompasses more impairment based items such as balance, endurance and efficiency of gait. This could be done by using the following outcome measures: Berg balance scale, Dynamic Gait Index, Romberg, Timed Up and Go and motion analysis to assess efficiency of gait. Additionally, researchers should recruit subjects in lower functional base line status to determine the influence of the BBTW vest on gait velocity in this population. Dosage and longer term effects of BBTW usage would also be of interest for future research to better determine the intervention value.

Search Terms: gait velocity, balance-based torso-weighting, multiple sclerosis

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Rationale for your chosen articles

To find our chosen articles we searched the following databases: PubMed, CINHALL, Web of Science, SPORTdiscus, AgeLine. We chose the articles to critique based on their relevance to our clinical question. We wanted to find out if BBTW would increase gait velocity in adult patients with MS. Available research is limited at this time, however three studies were found where researchers analyzed gait velocity measured for 25 to 26 feet in subjects with MS. See Table 1 below for a PEDro score comparison.

PEDro score for Widener, et. al. was found in the PEDro database to be a 7/10.

Table 1. Comparison of PEDro Scores

	Gorgas <i>et al.</i>	Widener <i>et al.</i> ; October, 2009	Widener <i>et al.</i> ; April, 2009
Random		x	
Concealed allocation		x	
Baseline	x	x	x

comparability			
Blind Subjects			x
Blind Therapists			
Blind Assessors		x	x
Adequate Follow-up	x	x	x
Intention-to-Treat			
Between Group			
Point Estimates & Variability	x	x	x
Total Score	3/10	6/10	5/10

(1) Gorgas, AM, Widener, GL, Gibson-Horn, C & Allen, DD. Gait changes with balance-based torso-weighting in people with multiple sclerosis. *Physiother. Res. Int.* June 14, 2014; doi: 10.1002/pri.1595.

PEDro Score 3/10

Patient: Included subjects who were similar to our patient

Intervention: BBTW vest with individualized weight placement

Comparison: No BBTW vest and healthy population without MS with and without BBTW vest

Outcome Measures: Average gait velocity out of 3 trial in cm/sec, step length, cadence, between-foot support base, and the percentage of gait cycle spent in single-limb support and double-limb support

(2) Widener GL, Allen, DD & Gibson-Horn C. Randomized clinical trial of balance-based torso weighting for improving upright mobility in people with multiple sclerosis. *Neurorehabilitation and Neural Repair* 2009; 23(8): 784-791.

PEDro Score 6/10

Patient: Included subjects who were similar to our patient

Intervention: BBTW with individualized weight placement of approximately 1.5% body weight

Comparison: No BBTW and Standard Weight Placement

Outcome measures: Timed 25-foot walk, Sharpened Romberg with eyes open and closed, Timed Up & Go, 360 degree turns and computerized platform posturography.

(3) Widener, GL, Allen, DD & Gibson-Horn, C. Balance-based torso-weighting may enhance balance in persons with multiple sclerosis: Preliminary evidence. *Arch Phys Med Rehabil.* April, 2009; 90: 602-609.

PEDro Score 5/10

Patient: Included subjects who were similar to our patient

Intervention: BBTW with individualized weight placement, up to 1.5% of subject's body weight and Non-weighted vest

Comparison: No BBTW vest

Outcome measures: Sharpened Romberg, eyes open and Sharpened Romberg eyes closed, computerized dynamic platform posturography, Timed Up & Go and the Timed 25-foot walk

Article: Gorgas, AM, Widener, GL, Gibson-Horn, C & Allen, DD. Gait changes with balance-based torso-weighting in people with multiple sclerosis. *Physiother. Res. Int.* June 14, 2014; doi: 10.1002/pri.1595

Clinical Bottom Line: The balance-based torso-weighting (BBTW) vest can be beneficial at improving gait velocity for individuals that meet the inclusion criteria of this study. Subjects diagnosed with MS were included with the following inclusion criteria: ability to speak and read English, walk 25 feet with or without a cane, withstand perturbations without pain, exhibited difficulty with balance and mobility and had not had an exacerbation of symptoms in the last 2 months. Gorgas et al. excluded subjects with other neurological pathologies, musculoskeletal conditions or experienced pain with perturbation. Twenty subjects diagnosed with MS and meeting criteria were recruited and served as their own controls. Study subjects were asked to walk 26 feet 3 times with and without the BBTW vest with a mandatory 30 minute rest period between trials. Subjects' gait velocities were measured in centimeters per second. The authors reported a clinically significant difference in mean (6.9 cm/sec) gait velocity between wearing the BBTW vest and not wearing the vest. The effect size for within subjects was 0.17, which is considered to be small. We would highly recommend a trial use of the BBTW before individual patient purchase. One minor and one major threat to internal validity included a lack of randomization of treatment order and lack of subject blinding. A multiple treatment interference, with subjects asked to perform the entire treatment in one day, was a minor threat to external validity: This is only a minor threat because subjects were allowed rest time to achieve recovery between conditions. GAITRite cost may be higher than some clinics are able to afford, however measurement of gait speed is easily accomplished with substitution of a stopwatch and measured course in a clinic. The BBTW vest is also expensive and unlikely to be covered by insurance. Patients must be fitted by a BBTW trained clinician prior to purchasing equipment. Overall, there was a significant improvement in gait velocity with the use of BBTW and this met the 3.3 cm/sec claimed by Morris et al. to be clinically significant for patients with MS, indicating increased functional mobility (2002). Even though there is a small effect size, this could make a great difference for a patient with MS who is experiencing fatigue throughout the day.

Article PICO:

Population – Adult females diagnosed with Multiple Sclerosis

Intervention - Balance-Based Torso-Weighting (BBTW)

Comparison - No BBTW vest and healthy population without MS with and without BBTW vest

Outcome - Average velocity, cadence, step length, between-foot support base and the percentage of the gait cycle spent in single-limb and double-limb support

Blinding: Subjects were not blinded to the treatment condition. This was a major threat because there could have been a potential placebo effect, which can impact the subject's gait velocity. The clinician providing the intervention was not blinded because he/she needed to analyze subjects for weight placement in the BBTW vest and is not a considered a threat.

Controls: Subjects performed gait velocity tests with and without BBTW and therefore served as their own control.

Randomization: The order of gait velocity administration, either with or without BBTW, was not randomized. This was a minor threat, but it was done intentionally by the authors to prevent potential carry over effect of the BBTW vest.

Study: Twenty women with MS and twenty healthy women, matched for age within 7 years, height within 5 inches and weight within 20 lbs., were recruited for the study. The inclusion criteria for subjects with MS were ability to speak and read English, walk 25 feet with or without a cane, difficulty with balance or mobility, no symptom exacerbation in the last 2 months and ability to withstand perturbations without pain. Subjects in the MS group and the healthy control group walked three trials at a self-selected fast speed without BBTW and then with BBTW for 26 feet. A perturbation assessment was done by a clinician to determine BBTW placement and was individualized for each subject.

Outcome measures: The outcome measure most relevant to our clinical question was gait velocity in cm/sec. Measurements of gait velocity were taken on the same day first without BBTW and then, after a mandatory resting period, with the BBTW. Reliability and validity for the GAITRite system has been documented by McDonough et al. (2001) and Youdas, et al. (2006). Morris et al. have claimed a change in gait velocity of 3.3 cm/sec or more to be clinically significant for subjects with MS (Morris, et al., 2002). The 26-foot walk test has face validity as a measure for gait velocity. All subjects were instructed with the same verbal cues, which indicated good construct validity.

Study losses: Two subjects were lost, one due to power outage and the other to a diagnosis change post data collection.

Summary of internal validity: Internal validity was considered good with one minor and one major threat. Subjects were not randomized in the order in which treatment was administered. We believe this to be a minor threat. The authors chose to perform the BBTW trial second based upon research that showed a carry over effect of BBTW (Widener et al., October, 2009). Subjects were not

blinded to treatment condition, which could have caused a placebo effect making them feel more confident to walk faster. This should be a major threat because placebo effect can impact a subject’s gait velocity. Subjects were not randomized into groups because the authors wished to compare a healthy population to a population with MS. Therefore, we do not consider this to be a threat. The authors conducted a power analysis in which 17 subjects were needed to note a significant difference. This requirement was met with recruitment of 22 subjects, 20 completing the full study course. Groups were determined to be similar in age, height and weight.

Evidence:

Twenty adult females with Multiple Sclerosis participated in both a Balance-Based Torso-Weight (BBTW) condition and a non-BBTW condition. The condition without BBTW was completed first. The average of three trials was taken for each condition. A statistically significance difference was found between treatment conditions ($p < 0.05$). Gait velocity measurements were taken using the GAITRite on a 26-foot course. Weighting for the BBTW was individualized for each subject. Average gait velocity without the BBTW vest was 160.8 cm/sec and with the BBTW was 167.7 cm/sec for subjects with MS. The mean difference was 6.9 cm/sec. The within group effect size was 0.17. The mean difference between conditions was clinically significant, as it is greater than 3.3 cm/sec (as claimed by Morris et al., 2002). The effect size is small (0.17), therefore, we can say there is a relationship between the use of the BBTW vest and gait velocity in people with MS. This is comparable to a difference in tenths of a second in a 26-foot walk test. A confidence interval was not calculated for effect size because it was a within group study. Calculations presented in Table 1 were calculated by Sarah Tomscha and Christina Dodini-Marquez.

Table 1. Average Gait Velocity of Subjects with Multiple Sclerosis (MS) without and with Balance-Based Torso-Weight (BBTW).

	Overall Velocity Change without BBTW (cm/sec)	Overall Velocity Change with BBTW (cm/sec)	Overall Velocity Change (cm/sec)	P-value
Subjects with MS	160.8	167.7	6.9	P < 0.05

Applicability of study results:

Benefits vs. Costs: The subjects, on average, showed a statistically significant difference of increased velocity within the same treatment day after applying the BBTW. There was a statistically significant improvement in velocity within the same day, which indicates that BBTW could be beneficial for increasing gait speed in some individuals. With improved gait speed, patients would improve in community ambulation, which includes activities such as crossing crosswalks efficiently and keeping up with peers for social interaction. The fitting of the vest would take minimal clinician and patient time. Currently, no adverse events due

to treatment have been reported. The cost of the BBTW vest is \$795.00 for a non-rigid model (the same version used in the study), which currently is not covered by insurance. (Frequently asked, 2013).

Feasibility of treatment: The BBTW vests are easily accessible to clinicians and are within a reasonable price range allowing for clinical setting use. Motion Therapeutics, the manufacturer of BBTW vests, recommends that clinicians take coursework specific to the BBTW vest prior to fitting patients. If a therapist does not have access to a training facility, the individualized weight placement for the BBTW vest may be difficult to reproduce. Additionally, many outpatient settings would not have a GAITRite due to costs. However, the study could be easily replicated by using a stopwatch and a set distance in order to quantify velocity from which changes with intervention can be determined. It is reasonable the fitting and trial of a BBTW vest could occur in one physical therapy session that would likely be covered by insurance.

This treatment is feasible for patients diagnosed with MS. The authors of the study did not address the possible changes over time, adherence or dosage. For this reason, it is impossible to state long term benefits, patient compliance with vest wearing, or the necessary treatment dosage.

Summary of external validity: External validity was considered as good, as there was only one minor threat, that of multiple treatment interference. This was due to completing the entire study in the same day, which had potential to cause subject fatigue. This is only minor as the authors allowed subjects to rest for as long as needed between treatments and because it is realistic that patients with MS will fatigue throughout the day. The authors controlled for interaction of testing by measuring gait velocity without the BBTW vest first to ensure the subjects were not sensitized by the BBTW. The good internal validity does not compromise our ability to generalize these results. The subject sample is similar to our population of interest because, although there are no men in the study, the incidence of MS is greater among women (Gorgas, et al., 2012). Therefore, we can only extrapolate the results to adult females with MS.

Article: Widener, GL, Allen, DD & Gibson-Horn, C. Randomized clinical trial of balanced-based torso weighting for improving upright mobility in people with multiple sclerosis. *Neurorehabilitation and Neural Repair*. October 2009; 23 (8): 784-791.

Clinical Bottom Line:

Based on the analysis of Widener et al. (October, 2009), BBTW significantly increased gait velocity compared to non-BBTW in adults with MS. Eighteen adults (16 women, 2 men) with MS who were able to walk 30 feet, had difficulty walking and were afraid of falling were included in the study. The design was a within subject comparison. All subjects were measured with the timed 25-foot walk test first without BBTW and then with BBTW. BBTW placements were individualized for each subject. A major threat to internal validity was lack of subject blinding. One minor threat to external validity was multiple treatment

interference. The effect size for this study was small-medium. There was a mean difference of 10.1 cm/sec, which surpasses the clinical significant difference for subjects with MS, claimed by Morris et al. (2002). It is worthwhile to recommend a trial of the BBTW vest for patients with MS when one considers the significant difference of 10.1 cm/sec in gait velocity that meets a clinically significant standard and a small-medium effect size. If our client notices a significant improvement in function, it would justify the cost of purchasing the BBTW vest that may not be covered by insurance. We should be cautious when generalizing these findings to adult males with MS since only two were included in the study (Gorgas et al., 2014).

Article PICO:

Population— Middle-aged and older adult population with MS

Intervention— BBTW with individualized weight placement

Comparison— No BBTW and Standard Weight Placement of approximately 1.5% body weight

Outcomes— Average velocity, sharpened Romberg with eyes open and closed, timed up and go, 360 degree turns and computerized platform posturography.

Blinding: The test administrators were blinded to each test condition. The subjects were not blinded which is considered a major threat. Subjects may have increased their gait velocity while wearing the BBTW vest due to their positive perceptions of the vest's efficacy. The therapists were not blinded, as they had to assess the placement of weights for the BBTW vest, which is not considered a threat.

Controls: Subjects served as their own control as it was a within subject comparison.

Randomization: The experimental BBTW group was created through concealed randomization for phase I. The authors stratified their randomized groups further by high functioning (8-15 sec.) and low functioning (12+ sec.) Timed Up and Go (TUG) scores for subjects at baseline. This was appropriate to insure the change in scores were not based off of general differences in function at study initiation. This process was successful as there was no statistically significant difference between groups at baseline. Phase I BBTW group was not randomized as they served as their own controls.

Study: Nineteen subjects with MS were recruited based on their ability to walk 30 feet, difficulty with walking, and fear of falling. The authors excluded subjects who would not allow their balance to be challenged by the administrators or had TUG scores of less than 8 seconds. Stratified randomization of subjects was based on subject baseline TUG scores. All subjects performed the timed 25-foot walk where the subjects were directed to walk as "quickly and safely as possible." Then, the experimental BBTW group had a weight placement assessment by the researcher that included perturbations in all directions in order to determine

weight placement in the vests. The subjects were then given 30 minutes of rest to ensure they were not fatigued. After the 30 minute rest period, subjects completed a second timed 25-foot walk test with the BBTW vest. In both conditions, with and without weights, subjects wore a large t-shirt over the vest to blind the administrators.

Outcome measures: This study has good validity. The outcome measure most relevant to our clinical question was gait velocity in ft/sec using the timed 25-foot walk test, which has been validated and is reliable (Timed-25-foot walk, 2010). The 25-foot walk test has good face validity for measuring gait velocity. All subjects were administered the same test, which included specific verbal instructions indicating good construct validity. There is no known MCID for this outcome measure for subjects with MS at this time. However, a gait velocity of 3.3 cm/second has been claimed to be clinically significant in this population (Morris et al., 2002). Measurements of gait velocity were taken on the same day, first without BBTW and then with the BBTW after a mandatory resting period. The authors did not include an inter/intra-rater reliability from other studies for the BBTW as they have not been established.

Study losses: Data from one of the subjects was lost due to the subject's inability to follow directions. There was no intention to treat performed and there does not appear to be any missing data. All subjects were analyzed in the groups they were originally randomized in.

Summary of internal validity: Internal validity is good based on one major threat. Subjects were not blinded to treatment condition, which could have caused a placebo effect making them feel more confident to walk faster. There was no randomization within the BBTW group. All subjects were measured at baseline and with the BBTW vest. They did not require randomization for this reason and is why lack of randomization was not considered to be a threat.

Evidence:

There was a minimal mean change increase in gait velocity of 0.6 seconds when subjects walked with the BBTW than without ($p < .001$). The condition without BBTW was completed first. After converting the data from the 25 foot walk test into cm/sec, the overall increase in gait velocity was 10.1 cm/sec. The mean gait velocity difference between conditions was clinically significant for subjects with MS as claimed by Morris et al. to be greater than 3.3 cm/sec (2002). The subjects in this study improved by 0.6 of a second. The outcome of interest was the timed 25-foot walk test. Statistically and clinically significant differences were found in average gait velocity between the BBTW vest and baseline without the vest. The effect size was found to be small to medium (0.3). A confidence interval for effect was not calculated because it was a within group study.

Sixteen women and two men with MS participated in each treatment condition. Gait velocity measurements were taken using the timed 25-foot walk test. Weighting for the BBTW was individualized for each subject. The average gait velocity of subjects with MS without BBTW was 7 seconds and with BBTW

was 6.4 seconds. Converted data and effect size (0.30) were calculated by Sarah Tomscha and Christina Dodini-Marquez. See Table 2 below.

Table 2. Within Group Gait Velocity Comparison, with and without BBTW Vest.

	Average 25 foot walk test without BBTW	Average 25 foot walk test with BBTW	Overall Velocity Change	P-Value
Subjects with MS	7.0 (s) SD: 2	6.4 SD: 1.6	0.6	P <0.001
Converted Data	108.9 (cm/s)	119.0 (cm/s)	10.1 (cm/s)	

Applicability of study results:

Benefits vs. Costs:

The subjects on average showed a statistically significant increase in velocity within the same treatment day after applying the BBTW ($p < 0.001$). An effect size of 0.30 indicates the relationship between gait-velocity and BBTW in subjects with MS has a small to medium effect. Therefore, we can say there is a relationship between the use of the BBTW vest and gait velocity in people with MS. This is comparable to a difference in tenths of a second to seconds in a 25 foot walk test. With improved gait speed, subjects could improve in community ambulation, which includes activities such as crossing crosswalks efficiently and keeping up with peers for social interaction. Vest fitting requires minimal therapist and patient time commitment. Currently, no adverse events due to treatment have been reported. The cost of the BBTW vest is \$795.00 for a non-rigid model (the same version used in the study), which currently is not covered by insurance. (Frequently asked, 2013).

Feasibility of treatment:

The timed 25-foot walk test is a test with published standardized procedures and would be easily reproduced in a clinical setting (Timed 25-foot, 2010). The individualized placement of weights and testing for effectiveness could easily be accomplished in a physical therapy initial evaluation of a patient. It is feasible that insurance companies would cover the cost of PT treatment, which could include both fitting, trial and training with a BBTW vest. Since this study was completed over the course of a single day, it is difficult to say whether adherence is practical as well as how often the BBTW vest would need to be worn to achieve benefits. However, if patients notice gait speed benefits while wearing a weighted vest, it is potentially realistic they would have good adherence.

Summary of external validity: The good internal validity does not compromise our ability to generalize the results to patients with MS. External validity was considered to be good, given only one minor threat. All testing occurred on the same day, which may have fatigued subjects. Subjects were given 30 minutes to

recover between trials, which may not have been a sufficient amount of time to recover from their fatigue. It is possible to consider this a major threat but because it is realistic for patients with MS to fatigue throughout the day, we believe this is a minor threat. The findings from this study can be generalized to female individuals with MS as the majority of study subjects were females all presenting with MS. Generalization to men with MS is somewhat limited as there were only two male study subjects.

Article: Widener, GL, Allen, DD & Gibson-Horn, C. Balance-based torso-weighting may enhance balance in persons with multiple sclerosis: Preliminary evidence. *Arch Phys Med Rehabil.* April, 2009; 90: 602-609.

Clinical Bottom Line:

This study included 13 women and 2 men with a diagnosis of MS and an average age of 44.5 years. The authors found no statistical difference when comparing the timed 25-foot walk test at baseline (6.7 seconds), in a non-weighted vest condition (6.5 seconds) and in a BBTW vest condition (6.7 seconds), $p=0.49$. The order of the BBTW vest and non-weighted vest conditions was randomized. The comparison of interest to answer our clinical question was the within subject comparison between baseline and the post intervention BBTW vest condition. Subjects did not show a statistical difference between baseline and post BBTW vest condition. However, it is interesting to note that there was also no difference between the BBTW vest condition and the non-weighted vest condition. This could mean that the BBTW is no different than a non-weighted vest. This being said, we believe it is equally likely that there may have been a carry over effect from the BBTW vest to the non-weighted vest condition because the subjects were randomized in the order in which they received the testing condition. A power analysis was conducted as none was reported by the authors. For a medium effect size, 17 subjects would need to be included in the study. This study only included 15 subjects and therefore the authors may not have found a significant difference when in reality one did exist. Internal validity was considered to be good based solely on the lack of subject blinding. External validity was considered to be good based on two minor threats: multiple treatment interference and the discrepancy in testing protocol. Based on this study, evidence is not sufficient to warrant BBTW vests as an intervention to increase gait velocity in patients presenting with MS.

Article PICO:

Population— Adults with MS

Intervention— BBTW with individualized weight placement (up to 1.5% of the subject's body weight)

Comparison— No BBTW vest

Outcomes— Sharpened Romberg, eyes open and Sharpened Romberg, eyes closed, computerized dynamic platform posturography, Timed Up & Go and 25-foot timed walk

Blinding: The therapists were not blinded to the treatment because they administered the placement of the weights. The assessors were blinded to the test condition in all dependent variables. This was done by having each subject wear an oversized black t-shirt over their vest. Although the subjects were not informed as to which condition they were completing, subjects reported being able to feel the added weight making it difficult to say they were completely blinded to the treatment conditions of BBTW or the non-weighted vest. For this reason we believe it to be a minor threat because subjects may have altered their gait velocity on the second test.

Controls: Subjects served as their own control.

Randomization: The two conditions of wearing a BBTW vest and wearing a non-weighted vest were performed in a random order. Randomization was concealed to the assessor.

Study: This study was quasi-experimental because the subjects served as their own control. Inclusion criteria included diagnosis of MS, could walk at least 35 feet with or without a cane or walker, could stand at least 10 seconds without support, and could speak English. Subjects were excluded if they had problems that would limit their ability to tolerate testing and treatments such as: complete blindness, current back pain, osteoporosis, or steroid treatment for longer than one year. For the first four subjects in the study, testing was completed in one day. The next 12 subjects received the initial screen and baseline data collection on the first day. The BBTW and non-weighted testing occurred on a second day that was within roughly a week of the first assessment. This change in methodology was due to fatigue experienced by one subject who completed all the testing in one day. Subjects were given 1 trial prior to each condition for the 25-foot walk and were instructed to walk comfortably as quickly as they could. An average of 3 trials of the 25-foot walk test for each condition was taken for all subjects. For the non-weighted condition, subjects wore the vest with no additional weight. For the BBTW condition the subjects had 0.25 pound and 0.5 pound weights placed in the vest pockets for a maximum total of 2.5 pounds or approximately 1.5% of their body weight on average. Subjects were assessed for a direction of balance dysfunction through anterior, posterior and lateral perturbations, as well as manually resisted trunk rotation. After individualized weight placement to counteract the identified direction of instability, each subject was assessed for greater stability and improved qualitative changes in movement. This was done to confirm appropriate weight placement. Measurements for the 25-foot walk test were taken for baseline, non-weighted, and BBTW conditions.

Outcome measures: The outcome measure of greatest interest in answering our clinical question is the 25-foot walk test. Measures were taken at baseline and

again in the non-weighted and BBTW conditions. The 25-foot walk test has good face validity for measuring gait velocity. Specific verbal instructions were used when administering the 25 foot walk test to all subjects, indicating good construct validity. All subjects were administered with the same test, which included specific verbal instructions indicating good construct validity. No known MCID for this outcome measure specific to subjects with MS was identified. However, a gait velocity of 3.3 cm/sec has been claimed to be clinically significant in this population (Morris et al., 2002). The authors did not include an inter/intra-rater reliability because this has not yet been established for gait velocity with BBTW. Nor did it appear that the authors established inter/intra-rater reliability for this specific study as none was reported.

Study losses: The 25-foot walk data of three subjects was eliminated. The data from two of the 18 subjects was eliminated because they did not show up to the second visit. One subject completed all but the last two data collection opportunities due to fatigue (which included the 25-foot walk test). Thus, there was a three subject loss from the original 18.

Summary of internal validity: The internal validity is good based on one minor threat. Although subjects were not formally told what condition was being tested, many reported ability to perceive the increased weight in the BBTW vest condition. We consider this lack of subject blinding to be a minor threat because there was no placebo effect shown. Despite the subjects' knowledge of the treatment condition, there was no significant difference in gait velocity at baseline, in the non-weighted vest condition or in the BBTW vest condition. The authors did not report a power analysis. We conducted a power analysis for an alpha level of 0.05 (type 1 error) and a beta level of 0.6 (type 2 error) and a medium effect size. To meet this criteria 17 subjects would need to have been included in the study. The authors were only able to report on 15 subjects due to subject losses. According to our calculations this subject number suggests that for only 76% of the time would a difference be realized, even if a difference did actually exist. For this reason, we are unable to say if a difference between the treatment conditions actually exists. Randomization was not considered to be a threat. Subjects were randomized in the order in which the condition of non-weighted vest or the BBTW vest was administered in the 25-foot walk test.

Evidence: The outcome measure of the 25-foot walk test was most relevant in answering our clinical question. There was no difference found between baseline, non-weighted vest and the BBTW vest conditions ($p= 0.49$), as reported by the authors. This indicates there is no placebo effect of the vest or the number of subjects was not enough to detect a statistically significant difference between groups. We conducted a power analysis that indicated a sample size of 17 was required to reveal a significant difference in gait velocity. This study only included 15 subjects tested under three different conditions and therefore, even if a difference did exist, we would be unable to see it.

Thirteen women and three men with Multiple Sclerosis participated in each treatment condition. No significant difference was found between treatment

conditions or baseline for the 25-foot walk test (p=0.49). Weighting for the BBTW was individualized for each subject. The 25-foot walk test for the non-weighted vest condition and the BBTW vest conditions were taken approximately one week after the baseline measurement was taken. Calculations were done by the authors of the study. See Table 3 below.

Table 3 Within Group Mean Gait Velocity in 3 conditions in patients with MS.

	Baseline (ft/s) ± (SD)	Non-weighted (ft/s) ± (SD)	Body-Based Torso-Weight (ft/s) ± (SD)	Probability of Alpha Error
Subjects with MS	6.7 ± 1.6	6.5 ± 1.9	6.7 ± 2.3	P=0.49

Applicability of study results:

Benefits vs. Costs:

No statistical difference was found between baseline and BBTW vest conditions. The cost of the BBTW is \$795.00 for a non-rigid model (the same version used in the study), which currently is not covered by insurance (Frequently asked, 2013). Based on this research, we cannot recommend a BBTW vest for patients diagnosed with MS because of lack of evidence. Currently there have been no adverse effects reported with the treatment.

Feasibility of treatment: The timed 25-foot walk test is a test with published standardized procedures and would be easily reproduced in a clinical setting. Weight placement for the BBTW vest was individualized for each subject. This was completed by a physical therapist. The placement of weights and testing for effectiveness could easily be accomplished in an initial patient evaluation. It is feasible that insurance companies would cover the cost of PT treatment, which could include fitting, trial and training for a BBTW vest. Since this study was completed over the course of a single day, it is difficult to say whether adherence is practical as well as how often the BBTW would need to be worn to achieve benefits. It is realistic to expect patients would adhere to wearing the BBTW vest if they perceived increases in gait speed from the use of the device.

Summary of external validity:

The good internal validity does not compromise our ability to generalize the results to patients with MS. External validity was considered to be good based on only two minor threats: multiple treatment interference and the discrepancy in testing protocol. Four subjects completed the 25-foot walk test for all three conditions on the same day with one subject reporting fatigue. The researchers changed testing protocol by administering the 25-foot walk test for the BBTW vest condition and the non-weighted vest condition one week after the baseline measurement. The subject sample was adults with MS, which is similar to the patient population of interest. The findings from this study can be generalized to female individuals with MS as the majority of study subjects were females all presenting with MS. Generalization to men with MS is somewhat limited as there were only two men in the study.

Synthesis/Discussion

Overall methodological quality of the three studies was fair with respective PEDro scores of 3, 5 and 6. There are factors that lowered these scores that we do not think greatly detract from the overall quality. The authors chose within subject comparisons, therefore PEDro scores did not include between group comparisons. Lack of blinding of therapists applying weights in the vests and of the subjects themselves in all three studies collectively lowered PEDro scores. It is our opinion neither of these factors impacted the quality of the studies.

The population eligibility criteria included factors relevant to our population of interest: adults diagnosed with MS. These studies limited the population to those who were able to walk at least 25 feet. Clinically, the spectrum of patients diagnosed with MS includes those who will not be able to complete a 25 meter walk. However, being able to walk 25-meters is appropriate inclusion criterion because the standard test of gait velocity in patients with MS is the 25-meter walk test.

The overall process for individualized weighting of the BBTW was similar across all three studies. In Widener, et al. (October, 2009) the therapists used the Romberg test with eyes open and closed and direction of sway to determine placement of weights on the BBTW vest. In Widener, et al. (April, 2009) weight placement was also assessed based on direction of sway and instability. In Gorgas, et al., perturbations were used to determine weight placement. Weight placement was verified for each study after observation of qualitative improvement in the subject's gait or balance.

Rest periods between test trials were used by Gorgas, et al. and Widener (October, 2009) to control for subject fatigue. A rest period was not indicated in Widener, et al (April, 2009). In Gorgas, et al. the subjects were allowed to rest as long as needed following the individualized weighting for the BBTW vest. In Widener, et al. (October, 2009) the subjects had a required 30 min rest period following individualized weight placement of the BBTW vest. In Widener, et al. (April, 2009), most of the subjects were tested within a week of their baseline measure for the standard weighted vest and BBTW vest. Widener, et al. (April 2009) did not state there was a rest period between the treatment conditions on the second testing day. This could have resulted in subject fatigue and may have been a reason no difference was found between baseline and BBTW vest conditions in that study.

In all three studies, subjects were not adequately blinded to their treatment. It is difficult to blind subjects to this particular intervention by the very nature of the intervention. However, ineffective blinding is a major concern as there could have been a placebo effect causing subjects to increase their gait speed. This brings to question whether the BBTW vest actually works or if the improvements seen in gait velocity are due to placebo effect.

A sufficient power analysis of subject numbers was established in Gorgas, et al. and Widener, et al. (October, 2009). In both of these studies a significant difference was found between baseline and BBTW conditions ($p < 0.05$) The sample size was not large enough to detect a difference based on the power analysis in Widener, et al. (April, 2009), and a significant difference was not found between the

BBTW vest condition and the non-weighted condition ($p= 0.49$). Therefore the results of Widener, et al. (April, 2009) are inconclusive.

Based on the research analysis we have done, we believe that the BBTW may have an impact on gait velocity on patients with MS. A trial of the equipment takes minimal time. Although BBTW vest purchase is not currently covered by insurance, the cost may be justified if the vest changes gait velocity. Fatigue has a dramatic impact on the lives of patients diagnosed with MS. With slight increases in gait velocity, patients may show increased accessibility to their community, improved activities or daily living, improved ability to maintain a job and improved social interactions.

Future researchers should attempt to tease out which qualities in patients make them good candidates for the BBTW vest as well as their adherence to the device. Further investigation should also look at dosage and frequency parameters for the use of the BBTW vest. Increased research on quality of gait and rating of perceived exertion could indicate walking efficiency, which is of primary importance in this population.

Guccione, et al. propose there are four categories of gait speed in the aging population: fun, function, frail and failure (2012). All of the subjects in the studies we analyzed were in the fun category (>150 cm/sec) or function category (80-150 cm/sec) at baseline testing of gait velocity. The subjects did not have a large enough mean difference to demonstrate a change in functional categories with use of the BBTW vest. Robinett & Vondran state that a gait velocity of 74-105 cm/sec is necessary to cross a crosswalk (1988). Subjects across all three studies met this gait velocity at baseline so we are unable to state that the BBTW vest would improve this aspect of community ambulation. Future researchers should recruit subjects with lower levels of baseline function in order to investigate the influence of the BBTW vest on gait velocity in this population.

Quality of future studies would be improved through more effective subject blinding to individualized weight placement in comparison to standardized weight placement. All future researchers should conduct a power analysis prior to initiation of the study and ensure there are enough subjects enrolled in the study to meet these requirements.

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