CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

In a 31 year-old woman with relapsing remitting multiple sclerosis (RRMS) and Expanded Disability Status Scale (EDSS) 2.5, is balanced-based torso-weighting an effective treatment compared to traditional strengthening and mobility training for improving walking difficulties?

AUTHOR

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CLINICAL SCENARIO

During a clinical rotation in an outpatient neurological MS center, I saw a 31 year old woman with MS (diagnosed 11 years prior, fully ambulatory, EDSS 2.0-2.5) experiencing an increase in balance deficits, resulting in her recent inability to jog without fear of falling. Her therapist decided to evaluate her for a BalanceWear vest. He fit her with the vest and placed the weights in the optimal location on the vest via the Balancewear Therapy specific evaluation. The therapist wanted her to wear the vest for a few hours every day and more on days that she felt unsteady. After seeing the improvements in her prolonged perturbation testing, Timed Up-and-Go (TUG), and sharpened Romberg with the vest on, I wanted to know what research was available on this intervention regarding its use in multiple sclerosis and its effect on gait. This particular woman expressed a desire to jog again and was hoping this vest could help her do that after seeing how fast she was able to walk in it without losing her balance. I think if this form of intervention, "balanced-based torso-weighting" (BBTW), proves to be an effective tool, it could have the same impact orthotics or AFOs have in correcting deviations by increasing the safety from falls risks and improving the quality of life of its wearers.

It is important to know the evidence behind this intervention because practicing BBTW requires a certification, so clinicians want to know if this therapy positively impacts deficits before spending time and money getting certified in it. Gait is comprised of moments of single and double limb stance, and balance plays a role in the presence or absence of gait deficits. Clinicians would benefit from knowing more about an intervention that could target both balance and gait deficits and potentially allow a patient the ability to focus on task-specific practice of one or the other while wearing the intervention in clinic, or minimize the chance of falls during ambulation when worn outside the clinic.

SUMMARY OF SEARCH

[Best evidence appraised and key findings]

The quality as well as quantity of the evidence relevant to my clinical question is relatively low. After searching three databases, I was able to find only eight articles[1-8] that covered BBTW and met my inclusion/exclusion criteria. Three of those articles articles[1,7,8] focused specifically on MS, BBTW as well as improvements in gait but none addressed my comparison intervention (strengthening or mobility training). The "best evidence" gathered from the two articles selected for critical appraisal is:

- The use of BBTW results in the immediate clinically significant improvement of gait velocity, cadence and percentage of gait cycle in single-limb vs. double-limb support in individuals with MS.
- The increase in percentage of gait cycle in single-limb vs. double-limb support could imply more stability during gait with the use of BBTW.
- The use BBTW results in the immediate improvement of spatiotemporal gait parameters in individuals with MS and in healthy controls.

CLINICAL BOTTOM LINE

The comparison of effectiveness of BBTW is currently limited to unweighted or standard weighted conditions, which does not offer enough evidence to answer my clinical question. The evidence found does support the immediate positive effect BBTW has on gait and mobility.

This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor

The above information should fit onto the first page of your CAT

SEARCH STRATEGY

Terms used to guide the search strategy			
Patient/Client Group	**I**ntervention (or Assessment)	**C**omparison	**O**utcome(s)
Woman Female Relapsing Remitting Multiple Sclerosis (RRMS) MS EDSS 2.5	Balanced-based torso training BBTW BalanceWear Therapy BalanceWear Vest	Strengthening "Mobility training" Rehabilitation Physical therapy Physiotherapy Exercise	Gait Walk* Ambulat* Locomotion "Walking Ability" "Gait Ability"

Final search strategy (history):

Show your final search strategy (full history) from PubMed.

Search	Query	Items found
#1	Search Multiple Sclerosis	75491
#2	Search relapsing remitting multiple sclerosis	9131
#3	Search torso weighting OR weighted vest OR balancewear	165
#4	Search (Strengthening OR "mobility training" OR exercise) AND (physical therapy OR physiotherapy OR rehabilitation)	93337
#5	Search Gait OR Walk* OR Ambulat* OR Locomotion OR "walking ability" OR "gait ability"	514638
#6	Search #1 AND #3	9
#7	Search #2 AND #3	2
#8	Search #3 AND #4	24
#9	Search #1 AND (#3 OR #4) AND #5	476

In the table below, show how many results you got from your search from each database you searched.

Databases and Sites Searched	**Number of results**	**Limits applied, revised number of results (if applicable)**
PubMed	**9**	
Web of Science	**8**	
EMBASE	**2**	

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
Studied women in their early 30's with RRMS and EDSS 2.5
Measured walking ability
Protocol that included balanced-based torso-weighting or BalanceWear Vest intervention
Published in English

Exclusion Criteria
Abstracts, letters to the editor, conference proceedings, dissertations, narrative review articles

RESULTS OF SEARCH

Summary of articles retrieved that met inclusion and exclusion criteria

For each article being considered for inclusion in the CAT, score for methodological quality on an appropriate scale, categorize the level of evidence, indicate whether the relevance of the study PICO to your PICO is high/mod/low, and note the study design (e.g., RCT, systematic review, case study).

Author (Year)	Risk of bias (quality score)*	Level of Evidence**	Relevance	Study design
Widener et al. (2009)	**RoBANS: Low Risk**	**3b**	**High**	**Quasi-experimental study**
Vincenzo et al. (2016)	**PEDro 10/11**	**1b**	**Low**	**RCT**
Wallace et al. (2013)	**RoBANS: Moderate Risk**	**3b**	**Low**	**Case Study**
Crittendon et al. (2014)	**RoBANS: Moderate Risk**	**2b**	**Low**	**Non-randomized controlled trial**
Hunt et al. (2014)	**RoBANS: Moderate Risk**	**2b**	**Low**	**Quasi-experimental study**
Gibson-Horn et al. (2014)	**RoBANS: Moderate Risk**	**4**	**Moderate**	**Case Report**
Gorgas et al. (2015)	**RoBANS: Moderate Risk**	**2b**	**High**	**Non-randomized controlled trial**
Widener et al. (2009)	**PEDro 8/11**	**1b**	**High**	**2-phase RCT**

*Indicate tool name and score

**Use Portney & Watkins Table 16.1 (2009); if downgraded, indicate reason why

BEST EVIDENCE

The following 2 studies were identified as the 'best' evidence and selected for critical appraisal. Rationale for selecting these studies were:

- Widener GL, Allen DD, Gibson-Horn C. Randomized clinical trial of balance-based torso weighting for improving upright mobility in people with multiple sclerosis. *Neurorehabil Neural Repair*2009;23(8):784-791. doi:10.1177/1545968309336146.
- Gorgas A-M, Widener GL, Gibson-Horn C, Allen DD. Gait changes with balance-based torso-weighting in people with multiple sclerosis. *Physiother Res Int* 2015;20(1):45-53. doi:10.1002/pri.1595.

I chose these two studies because of the relative quality of the studies and because they both are highly relevant to my clinical question since they address my population (MS), intervention (balance-based torso weighting) and outcome of interest (gait).

SUMMARY OF BEST EVIDENCE

(1) Description and appraisal of Randomized clinical trial of balance-based torso weighting for improving upright mobility in people with multiple sclerosis by Widener GL, Allen DD, Gibson-Horn C, 2009[7]

Aim/Objective of the Study/Systematic Review:
The objective of this study was twofold:

1) to assess whether the balance-based torso-weighting (BBTW) intervention had an immediate impact on postural control and upright mobility in individuals with MS compared with an unweighted control group
2) to compare the BBTW intervention impact on postural control and upright mobility in individuals with MS with the impact of a sham standard weighted vest (SSWV) intervention on the same deficits

Study Design

[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]

Note: For systematic review, use headings 'search strategy', 'selection criteria', 'methods' etc. For qualitative studies, identify data collection/analyses methods.

2-Phase Randomized Clinical Trial:

- Phase I consisted of randomized stratification of participants into the BBTW intervention and the unweighted control group.
- Phase II consisted of the control group from Phase I being randomized into the BBTW intervention and the SSWV intervention. Phase II was held a different day than Phase I and only included control group participants from Phase I to control for potential carry-over effects experienced by participants in the original BBTW intervention group.

Blinding:

All participants were initially categorized as "high functioning" (8-10 second TUG) or "low functioning" (TUG>12 seconds) to allow for stratified randomization. The high functioning group and the low functioning group then drew an opaque group assignment envelope from their designated group pile of envelopes. The contents of the envelope with their designated intervention was not revealed to the participants or the tester. Testers were blinded to the test condition in both phases (Phase I: BBTW vs. Control; Phase II: BBTW vs. SSWV) by having participants wear an oversized black t-shirt to hide whether or not they were wearing a vest, and if the weights on that vest were standardized or not. Participants in Phase I were not blinded to the test condition but participants in Phase II were blinded to the test condition due to being unaware of the difference between test conditions (BBTW vs. SSWV).

Outcome Measures:

For Phase I, outcome measures for the BBTW group were tested at baseline, participants were given a 15 minute rest, tested with BBTW vest, given a 30 minute rest, and then retested with BBTW vest. The control group was tested at baseline, given a 30 minute rest, and then retested.

For Phase II, outcome measures for both groups were tested at baseline without either intervention, both groups were given a 30 minute rest then placed in either the BBTW intervention or SSWV intervention. Both groups were then retested with their respective intervention vests donned. The outcome measures, also known as dependent variables, administered were:

- Timed Up and Go
- Sharpened Romberg
- Timed 360-degree Turns
- 25-foot Walk
- Computerized Platform Posturography

Additional measurements taken only at baseline to ensure comparable groups:

- Strength
- Range of Motion
- Muscle Tone:
    - flexion and extension at the knees
    - dorsiflexion and plantarflexion at the ankles

Data Analyses:

- Performed with nonparametric statistics
- Differences between groups at baseline were determined by
    - *t* tests for mean age and years with MS diagnosis
    - the Mann-Whitney *U* test for differences in the median EDSS score
    - Chi-squared test for all other demographic data
- The Wilcoxen signed ranks test used to test paired differences between baseline and second baseline
- The Mann-Whitney *U* test used to test differences in average change in performance between groups
- 1-tailed tests used to assess paired differences and the group differences between BBTW and control groups in Phase I
- 2-tailed tests used to assess group differences between BBTW and SSWV

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

Samuel Meritt University Research Lab, Oakland, CA

Participants

[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]

Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article.

The participants for this research study were a sample of convenience, recruited through newsletter ads distributed by a local chapter of the National Multiple Sclerosis Society. One hundred individuals with MS responded to the ad, which resulted in 44 individuals enrolled based on preliminary information. Due to 3 no shows on the day of the study and 3 individuals whose TUG scores of less than 8 seconds excluded them from participating, 38 subjects were randomized into Phase I of the study.

To be included in the study these 38 subjects exhibited the following characteristics: ability to ambulate 30 feet, difficulty with ambulation, and fear of falling. Those that were excluded from the study were either unwilling to have their balanced challenged by a researcher or had TUG scores less than 8 seconds which was the cut off the researchers decided for those that only had minor difficulty walking. In Phase I, 1 individual from each group dropped out (Control: due to unrelated emotional breakdown; BBTW: due to inability to follow directions). In Phase II, the TUG <8 second cut off score resulted in 1 individual being excluded from the SSWV group and 2 individuals being excluded from the BBTW group.

Key demographic information was collected at baseline for all participants and were comparable in all groups. Below is a combination of this data from Table 1 and 2 from Widener et al. outlining these characteristics:

	Phase I			Phase II		
	Control (n=18)	BBTW (n=18)	P value	SSWV (n=9)	BBTW (n=6)	P value
Age in years, mean (SD)	53.2 (9.7)	55.7 (7.5)	.40	53.2 (10.9)	53.3 (8.8)	.99
MS Disease Type	Secondary Progressive: 2 Primary Progressive: 2 Relapsing Remitting: 10 Unknown: 4	Secondary Progressive: 4 Primary Progressive: 4 Relapsing Remitting: 10 Unknown: 0	–	Secondary Progressive: 1 Primary Progressive: 1 Relapsing Remitting: 5 Unknown: 3	Secondary Progressive: 1 Primary Progressive: 1 Relapsing Remitting: 5 Unknown: 1	–
Years with diagnosis, mean (SD)	13.3 (11.7)	13.2 (10.1)	.96	12.0 (7.5)	15.0 (16.0)	.61
EDSS, median (range)	5.0 (2-5)	4.5 (2-5)	.41	4.5 (2-5)	5.0 (3-5)	.41
Number (%) claiming falls in past 6 months	16 (88.9)	14 (77.8)	.66	6 (60)	8 (100)	.09
Number (%) claiming MS-related fatigue	12 (66.7)	16 (88.9)	.23	6 (60)	6 (75)	.64

Number (%) female	12 (66.7)	16 (88.9)	.23	7 (70)	5 (62.5)	1.00

Intervention Investigated

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

Control

Both control and experimental data were collected in the same laboratory space with a designated researcher (GLW) administering all tests and a designated research (CGH) administering SSWV intervention weight placement. Dependent variables outlined in Outcome Measures section.

Phase I control group participants had the dependent variables tested at baseline. The participants were given a 30 minute rest, and then the dependent variables were retested.

Phase II SSWV participants had the dependent variables tested at baseline without the SSWV intervention donned. Participants were given a 30 minute rest, then the dependent variables were retested with the SSWV intervention donned.

The SSWV intervention consisted of CGH attaching small weights, totalling 1.5% of the participant's body weight, to the torso of a vest designed with Velcro. The weights were evenly split, with half of the weight placed on either side of the waist. The vest was donned only when testing dependent variables.

Experimental

Both control and experimental data were collected in the same laboratory space with a designated researcher (GLW) administering all tests and a designated research (CGH) administering balance assessment for BBTW intervention weight placement. Dependent variables outlined in Outcome Measures section.

The balance assessment completed to designate weight placement for the BBTW intervention followed a procedure developed by researcher Gibson-Horn (CGH) and was done by her as well. This procedure consists of:

- Romberg testing with eyes open and eyes closed
  - Specifically noting relative amount and direction of sway
- Perturbations in the anterior, posterior, and lateral (right and left) directions to the shoulders and pelvis
  - Specifically noting response latency as well as amount and direction of balance loss
    - Balance loss= compensation with trunk, stepping response, or manual contact needed to maintain centre of mass over base of support
- Rotational forces applied to shoulder and pelvis
  - Specifically noting if there was any asymmetry in resistance

Based on the findings from the assessment described above, small weights were placed to the torso of a vest designed with Velcro allowing weight placement to the front, back and sides of the torso between the shoulders and waist. The weights were placed on the vest counter the direction of balance loss and resistance asymmetry exhibited in the balance assessment. Balance was reassessed after first application of weights and weights were adjusted until stability improved with reassessment. This procedure lasted 10 to 30 minutes depending on the number of balance errors found during the balance assessment, and consisted of reassessment of balance and readjustments of weights until final weight placement product (BBTW vest) was complete.

Phase I BBTW group participants had the dependent variables tested at baseline. Participants participated in BBTW weight placement procedure. Participants were given a 15 minute rest then dependent variables were tested with the BBTW vest donned. Participants were given a 30 minute rest, then dependent variables were retested with the BBTW vest donned. The vest was donned only when testing dependent variables.

Phase II BBTW group participants were tested at baseline without the BBTW vest donned. Participants participated in BBTW weight placement procedure. Participants were given a 30 minute rest, then dependent variables were retested with BBTW vests donned. The vest was donned only when testing dependent variables.

Outcome Measures

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

Both control and experimental data were collected in the same laboratory space with a designated researcher (GLW) administering all tests. Outcome measures administered:

- Timed Up and Go

- "Low Functioning": TUG score > 12 seconds
- "High Functioning": TUG score 8-12 seconds

- Sharpened Romberg
  - Time summed across 4 trials, maximum 30 second hold recorded
- Timed 360-degree Turns
  - Performed as directed by the turning item in the Berg Balance Scale (BBS)
  - Time summed across turns to the left and to the right
- 25-foot Walk
  - Timed, measured in seconds
- Computerized Platform Posturography
  - Average body sway in cm/second during 10 seconds of standing with eyes open and eyes closed using a Basic Balance Master

Additional measurements taken only at baseline:

- Strength
  - Manual Muscle Testing, 0/5 to 5/5
- Range of Motion
  - Goniometric values, comparing to established norms
- Muscle Tone:
  - flexion and extension at the knees
  - dorsiflexion and plantarflexion at the ankles
  - Type of test used not reported

Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. Use a table to summarize results if possible.]

Phase I Findings:

- TUG ICC 0.98; 25-Foot Walk ICC 0.96; Sharpened Romberg ICC 0.73; 360-degree Turn ICC 0.96; CPP ICC 0.80
- BBTW showed significant improvement over baseline in the following:
  - TUG ($P < .001$)
  - 25-foot walk ($P < .001$)
    - average 8.5% improvement from baseline in BBTW group
  - Sharpened Romberg ($P < .02$)
  - 360-degree Turn ($P < .004$)
- Control group showed no significant difference between baseline 1 and baseline 2 measurements

	Control (n=18)		Experimental (n=18)	
	Baseline 1 Mean (SD)	Baseline 2 Mean (SD)	Baseline 1 Mean (SD)	BBTW1 Mean (SD)
TUG (seconds)	12.4 (3.6)	12.1 (3.6)	11.0 (2.7)	10.4[a] (2.4)
25-foot walk (seconds)	7.4 (2.2)	7.4 (2.2)	7.0 (2.0)	6.4[a,b] (1.6)
Sharpened Romberg (seconds held)	14.4 (21.2)	13.8 (18.8)	26.7 (26.6)	33.2[a] (28.0)
360-degree turn (seconds)	10.1 (4.3)	9.5 (4.1)	7.8 (2.8)	6.8[a] (2.4)
CPP (cm/second)	0.8 (0.4)	0.7 (0.3)	0.5 (0.2)	0.5 (0.2)

Phase II Findings:

- ICCs ranged from 0.86 to 0.97 for the 5 dependent variables tested
- BBTW group showed significant improvement over baseline in the TUG ($P=0.1$)

- Statistical difference between improvement in BBTW group (9%) vs. SSWV group (1.5%)
- SSWV group showed significant improvement over baseline in the 25-foot walk (P=.004)

	SSWV (n=9)		BBTW (n=6)	
	Baseline 3 Mean (SD)	SSWV Mean (SD)	Baseline 3 Mean (SD)	BBTW2 Mean (SD)
TUG (seconds)	13.0 (3.8)	12.8 (4.0)	13.6 (3.4)	12.4[a,b] (3.0)
25-foot walk (seconds)	7.8 (1.8)	7.2[a] (1.8)	7.9 (2.3)	7.7 (2.0)
Sharpened Romberg (seconds held)	15.7 (26.2)	16.6 (26.8)	17.6 (26.3)	18.4 (21.3)
360-degree turn (seconds)	9.5 (4.0)	9.2 (4.4)	11.4 (5.4)	10.6 (5.7)
CPP (cm/second)	0.7 (0.3)	0.6 (0.2)	0.8 (0.3)	0.8 (0.4)

a=Testing in weighted condition showed a significant improvement over baseline.

b=Testing in BBTW condition showed significantly different improvement over SSWV condition in that phase of testing.

Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

The authors concluded that their null hypotheses (quoted below) could be rejected and that while weighting the torso produced immediate effects in upright mobility for all groups, the specific BBTW weighting method did show advantaged results over the standard weighting condition. The BBTW groups in both Phase I and Phase II showed changes compared to their own baseline, the control group and the SSWV group in all measures of mobility; which allows the authors to conclude that individuals with MS who are ambulatory with walking difficulties may benefit from the BBTW intervention.

"The null hypotheses were that no postural control or upright mobility measures would show a difference with weighting, and that no differences in postural control or upright mobility would be noted between people with weight placed according the BBTW method compared to those with no weight or to those with standard weight placement (SWP)." (page 785[7])

Critical Appraisal

Validity

[Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.]

Internal Validity Strengths:

- Using one researcher to administer all outcome measures and one researcher to administer the BBTW weight placement system
- Blinding tester to the test condition by having participants don a black t-shirt
- Accounting for carry-over effects in selection of Control Group participants for Phase II
- Allowing participants rest between testing to account for fatigue in this patient population

Internal Validity Weaknesses:

- Not being able to blind participants to the intervention in Phase I
- The BBTW group in Phase I may have had higher functioning than the control group when comparing TUG scores, even though stratified randomization occurred
- BBTW vest weight was 0.5 kg on average, while the SSWV weight was 1 kg on average which could have impacted symptoms of fatigue in the SSWV group

Overall quality of the evidence of this study is moderate. The quality of design and internal validity is relatively high, but the small sample size, the association between the researchers and the BBTW system and the limited scope of the study (immediate effects only) retract from the quality. As the creator of the BalanceWear Theory and the BalanceWear Vest that utilizes the BBTW system described in this article and as the one most likely to profit from its success, Gibbons-Horn's association and participation in the study could result in bias. Gibbons-Horn also has part ownership in Motion Therapeutics which manufactures and sells BBTW garments.

In terms of external validity it is difficult to determine how applicable these results are to the general population due to the small, convenience sample consisting of mostly women. In terms of the intervention tool, there is no evidence supporting intra-rater or inter-rater reliability and validity for the BBTW system. A therapist would have to be certified in the BBTW method and own the BBTW vest/weights to be able to apply the intervention in practice as well. Other than the use of computerized platform posturography, all other measures could easily be administered in clinic. Due to the length of the BBTW assessment (30 minutes), the use of this as an intervention in clinic is dependent on total treatment time and if the patient is limited by fatigue.

Interpretation of Results

[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]

Based on the immediate improvements of BBTW and torso weighting in general on mobility measures, without addition of active intervention or adjunct therapeutic intervention, I would view these results as compelling and worthy of further research. While these results cannot be equated to or compared to general physiotherapy interventions (immediate effects vs. cumulative effects), I would be interested to see if the immediate results of the BBTW vest could assist patients more effectively complete traditional interventions in clinic. While the results of the BBTW protocol in this study are promising, evidence is needed on carry-over effect for this protocol to be considered beneficial for clinical use vs. personal use. Ultimately, these results do not provide enough evidence for the use of BBTW in clinic as sole intervention or adjunct intervention. The results do show that BBTW has immediate positive effects on mobility measures and gait velocity.

Applicability of Study Results

[Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.]

It is difficult to consider the practicality and feasibility of the intervention because a therapist would need to be certified in the BBTW system and have the BBTW vest/weights to administer this intervention. Assuming that a therapist is already certified and has the BBTW vest/weights, I would say the improvement seen in mobility measures with this technique would be extremely relevant to my clinical question and scenario. The improvements noted in the TUG and the 25-foot walk show increased gait speed is a primary outcome for this intervention, which is the outcome the patient in my clinical scenario wants. While the study showed improvements in mobility measures while the vest was donned, there is no evidence of carry-over effects when the vest is not donned. Based on the results of this article, the patient would see improvements with the vest donned but that would require the patient to purchase the intervention. There is no evidence supporting a "dosing duration" if the intervention is purchased for personal use. More evidence on "dosing duration" and carry-over effects (if used only in clinic) is needed to justify certification in BBTW and purchasing of BBTW equipment.

(2) Description and appraisal of Gait changes with balance-based torso-weighting in people with multiple sclerosis by Gorgas A-M, Widener GL, Gibson-Horn C, Allen DD, 2015[8]

Aim/Objective of the Study/Systematic Review:

The purpose of this study was to assess the immediate impact balance-based torso-weighting (BBTW) has on spatiotemporal gait parameters in individuals with MS and matched healthy controls.

Study Design

[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]

Note: For systematic review, use headings 'search strategy', 'selection criteria', 'methods' etc. For qualitative studies, identify data collection/analyses methods.

Non-Randomized Controlled Experiment: 20 individuals with MS were matched with 20 healthy controls and were asked to walk as quickly and safely as possible over a 26-foot (7.9 m) GAITRite system walkway for 3 trials under two conditions, unweighted and weighted using BBTW. The healthy controls also were instructed to walk at the same velocity as their matching participant with MS.

Data Collection and Statistics:

- Power analysis to determine the number of individuals needed to show significant differences in gait velocity indicated a sample size of 17 participants were needed in each group (individuals with MS and healthy control).
- GAITRite Analysis System collected gait parameters, using foot pressure to calculate spatiotemporal gait variables.
    - This system has documented evidence of reliability and validity
- Paired *t*-tests were used to assess differences between groups

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

University Lab Setting

Participants

[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]

Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article.

Individuals with MS:

The participants for this research study with MS were a sample of convenience, recruited through online postings and a regional newsletter ads distributed by a local chapter of the National Multiple Sclerosis Society.

Eligibility Criteria:

- MS diagnosis
- Speaks and reads English
- Ambulate at least 25 feet, with or without a cane
- Difficulties with balance or mobility
- Tolerate up to 3 hours of multiple short-distance walking trials
- Exacerbation-free for at least the past 2 months
- Not currently experiencing pain that could be worsened with external perturbations

Healthy Controls:

The healthy controls were a sample of convenience, recruited through personal contacts and Craiglist.com. Each healthy control was recruited to match an individual with MS already accepted to the study by sex, age (within 7 years), height (within 5 inches), and weight (within 20 lbs.). No healthy controls with known neurological pathology, musculoskeletal conditions or pain that could be worsened with external perturbations were included.

Key Demographics of Participants:

Variable	Participants with MS (n=20)	Healthy Controls (n=20)	p-value
Age in years, mean (SD), range	49.4 (13.4), 24-68	48.3 (11.1), 29-69	0.394
Years since diagnosis, mean (SD)	12.8 (8.2)	-	-
EDSS score equivalent, mean (SD), range	4.1 (1.6), 2-6	-	-
Number of falls in last 12 months, mean (SD), range	2.0 (3.4), 0-15	0.2 (0.4), 0-1	0.005

Height, mean (SD), cm	166.2 (6.0)	166.1 (6.5)	0.475
Weight, mean (SD), kg	73.2 (15.7)	73.3 (13.1)	0.487
Percentage of body weight BBTW, mean (SD), range	1.0 (0.4), 0.5-1.6%	0.7 (0.2), 0.4-1.2%	0.003
Type of MS: number of people	Primary Progressive: 1 Secondary Progressive: 4 Relapsing Remitting: 11 Unknown: 4	-	-

Intervention Investigated

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

Control

The 20 healthy controls were asked to walk as quickly and safely as possible over a 26-foot (7.9 m) GAITRite system walkway for 3 trials under two conditions (unweighted and BBTW weighted). Prior to beginning testing, an unweighted BBTW vest was donned and shoes were removed. All testing was conducted barefoot.

Condition 1: Unweighted

Participants were told to "walk as fast as you safely can" along a 26-foot (7.9 m) GAITRite system walkway for 3 trials.

Condition 2: Weighted

Participants were then assessed using the BBTW protocol (described below) and fitted with a BBTW vest. After a required rest break, participants were told to "walk as fast as you safely can" along a 26-foot (7.9 m) GAITRite system walkway for 3 trials with the BBTW vest donned.

Additional "Matched Velocity" Trial

The healthy controls, with BBTW vest donned, were instructed to walk at the same velocity (within 5%) as their matching participant with MS. This allowed researchers to compare spatiotemporal parameters between groups by controlling for the effect of gait velocity on those parameters.

BBTW Protocol

The BBTW protocol followed a procedure developed by researcher Gibson-Horn (CGH) and was done by her as well. This procedure is completed with the participant standing feet together and eyes open:

- Perturbations in the anterior, posterior, and lateral (right and left) directions to the shoulders and pelvis
  - Specifically noting response latency as well as amount and direction of balance loss or sway
    - Balance loss= compensation with trunk, stepping response, or manual contact needed to maintain centre of mass over base of support
- Rotational forces (right and left) applied to shoulders and pelvis while patient is instructed to resist
  - Specifically noting if there was any asymmetry in resistance

Based on the findings from the assessment described above, small weights of either 0.25 or 0.5lb (0.11 and .23 kg) were placed to the torso of a vest designed with Velcro allowing weight placement to the front, back and sides of the torso between the shoulders and waist. The weights were placed on the vest counter the direction of balance loss and resistance asymmetry exhibited in the balance assessment. Balance was reassessed after first application of weights and weights were adjusted until stability improved with reassessment. This procedure lasted 10 to 30 minutes depending on the number of balance errors found

during the balance assessment, and consisted of reassessment of balance and readjustments of weights until final weight placement product (BBTW vest) was complete.

Experimental

The 20 individuals with MS were asked to walk as quickly and safely as possible over a 26-foot (7.9 m) GAITRite system walkway for 3 trials under two conditions (unweighted and BBTW weighted). Prior to beginning testing, an unweighted BBTW vest was donned and shoes were removed. All testing was conducted barefoot.

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Outcome Measures

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

The GAITRite Analysis System collected gait parameters by measuring foot pressure over a 26-foot (7.9m) walkway to calculate spatiotemporal gait variables. This system has documented evidence of reliability and validity.

The following gait parameters were assessed by researchers:

- Average velocity
- Cadence
- Step length
- Between-foot support base
- Percentage of the gait cycle spent in single-limb and double-limb support

Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. Use a table to summarize results if possible.]

For individuals with MS:

- Mean velocity significantly improved between unweighted condition and BBTW weighted condition trials
- Mean cadence and percentage of gait cycle in single-limb and double-limb support significantly improved between unweighted condition and BBTW weighted condition trials
- Step length and step width did not change enough to be statistically significant

For healthy controls:

- Statistically significant improvement for all gait variables were noted between unweighted and BBTW weighted condition
- In BBTW weighted condition at fastest speeds, time spent in single-limb and double-limb support and step length did not change significantly
- In BBTW weighted condition matching MS participant, between-group differences were not significant in average velocity, cadence and single-limb and double-limb support

Below is Table 2 from Gorgas et al.[8]:

Gait parameters obtained with GAITRite system

Group, Speed	Variable	Without weights Mean (SD, Range)	With Weights Mean (SD, Range)	P-value within group	P-value MS to HS matched	P-value MS to HS fast
MS fast	Velocity (cm/s)	160.8 (41.1,76–232)	167.7 (39.5, 82–234)	.002		
	Cadence (steps/min)	141.0 (21.6, 92–173)	145.1 (20.8, 99–180)	.007		
	Single Support (%GC)	40.2 (2.1, 35–44)	40.7 (2.2, 34–44)	.014		
	Double Support (%GC)	19.2 (4.3, 11–30)	18.3 (4.2, 12–30)	.004		
	Step Length (cm)	67.6 (10.5, 48–85)	68.7 (9.4, 49–85)	.059		
	Support Base, Step Width (cm)	11.6 (3.8, 2 –20)	11.1 (3.2, 7–20)	.150		
HS matched	Velocity (cm/s)	159.4 (40.0, 80–227)	166.7 (40.1, 83–233)	.002	.449	
	Cadence (steps/min)	132.6 (25.1, 81–193)	136.7 (25.5, 83–200)	.005	.055	
	Single Support (%GC)	40.3 (1.5, 36–43)	40.9 (1.4, 37–43)	.001	.330	
	Double Support (%GC)	19.0 (3.1, 15–27)	18.1 (3.1, 14–26)	.001	.398	
	Step Length (cm)	71.3 (7.3, 59–85)	72.6 (7.3, 60–85)	.009	.028	
	Support Base, Step Width (cm)	10.0 (2.7, 3–15)	9.2 (2.4, 3–13)	.001	.006	
HS fast	Velocity (cm/s)	213.5 (35.4, 158–292)	219.2 (34.7, 166–277)	.012		.000
	Cadence (steps/min)	165.7 (23.6, 127–207)	169.8 (25.8, 138–224)	.015		.000
	Single Support (%GC)	42.3 (1.7, 40–47)	42.6 (1.7, 41–47)	.120		.000
	Double Support (%GC)	14.3 (3.9, 4–18)	13.8 (3.5, 6–17)	.134		.000
	Step Length (cm)	77.3 (6.4, 65–88)	77.7 (5.6, 68–85)	.321		.000
	Support Base, Step Width (cm)	10.3 (2.0, 6–14)	9.3 (2.5, 3–13)	.014		.008

MS = Participants with Multiple Sclerosis; HS = Healthy Controls; SD = standard deviation; cm = centimeters; cm/s = centimeters/second; min = minute; %GC = percent gait cycle

Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

The authors concluded that the BBTW protocol improved gait velocity and other spatiotemporal gait parameters in individuals with MS and in healthy controls.

Critical Appraisal

Validity

[Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.]

Internal Validity Strengths:

- Using one researcher to administer the BBTW protocol
- Using the GAITRite Analysis System to collect gait parameters
- Collecting data in one day and averaging data over multiple trials
- Requiring participants to rest between trials to account for fatigue
- Testing unweighted condition first to account for carry-over effects

Internal Validity Weaknesses:

- Not being able to blind participants to the intervention resulting in potential placebo effect
- Lack of randomization and no comparison to another intervention
- Unable to account for daily variance in MS symptoms/or function in individuals with MS

Overall quality of the evidence of this study is moderate. The internal validity is relatively high, but the study design, the small sample size, and the association between the researchers and the BBTW system retract from the quality. As the creator of the BalanceWear Theory and the BalanceWear Vest that utilizes the BBTW system described in this article and as the one most likely to profit from its success, Gibbons-Horn's association and participation in the study could result in bias. Gibbons-Horn also has part ownership in Motion Therapeutics which manufactures and sells BBTW garments. Asking the participants to walk at their fastest pace contributed to fatigue symptoms and may have affected results (though increased average velocity was still noted in all participants).

In terms of external validity it is difficult to determine how applicable these results are to the general population due to the small, convenience sample consisting of mostly women. A strength of this study is that concurrent therapies or medications taken by participants were not stopped, so the improvements were seen in addition to these other factors. In terms of the intervention tool, there is no evidence supporting intra-rater or inter-rater reliability and validity for the BBTW system. A therapist would have to be certified in the BBTW method and own the BBTW vest/weights to be able to apply the intervention in practice as well. Due to the length of the BBTW assessment (30 minutes), the use of this as an intervention in clinic is dependent on total treatment time and if the patient is limited by fatigue.

Interpretation of Results

[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]

The use of the BBTW protocol resulted in the immediate improvement of spatiotemporal gait parameters in both individuals with MS and healthy controls. The average velocity increased by almost 7 cm/seconds from the unweighted to the BBTW protocol weighted condition, which is clinically significant based on previous research (MCID: 3.3 cm/second)[9]. There also was an increase in the percent of the gait cycle spent in single-limb support vs. double-limb support which could imply more stability during gait with the BBTW intervention donned. I think that the results of this study show that BBTW has immediate positive effects on gait, in individuals with MS and individuals who do not have MS. Further research is needed to show long-term effects of this intervention on the wearer ("dosing duration"), whether effects are cumulative and if this intervention can be used to enhance outcomes when worn during traditional therapeutic interventions.

Applicability of Study Results

[Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.]

As noted in the previous study, it is difficult to consider the practicality and feasibility of the intervention because a therapist would need to be certified in the BBTW system and have the BBTW vest/weights to administer this intervention. Assuming that a therapist is already certified and has the BBTW vest/weights, I would say the improvement seen in gait with this technique would be extremely relevant to my clinical question and scenario. The improvements in gait speed as well as increase in single-limb support time compared to double-limb support time, which is imperative to the patient in my clinical scenario who wants to be able to jog again. While the study showed improvements in mobility measures while the vest was donned, there is no evidence of carry-over effects when the vest is not donned. Based on the results of this article, the patient would see gait improvements with the vest donned but as noted before that would require the patient to purchase the intervention. There is no evidence supporting a "dosing duration" if the intervention is purchased for personal use or of the long-term wear effects. More evidence on "dosing duration" and carry-over effects (if used only in clinic) is needed to justify certification in BBTW and purchasing of BBTW equipment.

SYNTHESIS AND CLINICAL IMPLICATIONS

[Synthesize the results, quality/validity, and applicability of the two studies reviewed for the CAT. Future implications for research should be addressed briefly. Limit: 1 page.]

The evidence resulting from the studies conducted by Widener et al.[7] and Gorgas et al.[8] support immediate positive effects of BBTW on gait and upright mobility in individuals with MS. The results from Widener et al.[7] confirm that the immediate effectiveness of BBTW compared to an unweighted control is significant for the following mobility parameters: TUG, 25-foot walk, sharpened Romberg, and 360-degree turn; and confirms the immediate significant improvement with BBTW compared to a standard weighted vest for the TUG. The results from Gorgas et al.[8] supports the use of BBTW for immediate clinically significant improvement of gait velocity, cadence and percentage of gait cycle in single-limb vs. double-limb support in individuals with MS. This study also found that BBTW results in an increase in percentage of gait cycle in single-limb vs. double-limb support, which could imply more stability during gait with the use of BBTW. This study also found that healthy controls also experienced an immediate improvement in spatiotemporal gait parameters when donning the BBTW vest.

The quality of both studies are limited by study design and the inability to blind the participants to the intervention of the results were limited. Concurrent therapies or medications taken by participants were not stopped in either study, so the improvements seen were in addition to these other factors. The validity of both studies are hurt by the small sample size of convenience tested, that consist of mostly women which prevents applicability to the general MS population. Another factor affecting validity of this intervention is that a therapist would have to be certified in the BBTW method and own the BBTW vest/weights to be able to apply the intervention in practice. Even if the therapist was certified in the technique, there is no evidence supporting the intra-rater or inter-rater reliability and validity of the BBTW system. Due to the length of the BBTW assessment (10-30 minutes, on average 20 minutes[7]), the use of this intervention in clinic is dependent on total treatment time allowed per patient and if the patient is limited by fatigue. The largest potential source of bias which affects the quality and validity of these two studies is that one of the authors (Cynthia Gibbons-Horn) is the creator of the BalanceWear Theory and the BalanceWear Vest that utilizes the BBTW system described both articles. Seeing as Gibbons-Horn also has part ownership in Motion Therapeutics which manufactures and sells BBTW garments, she is likely to profit from its success.

The applicability of these two studies is limited due to the lack of evidence on long-term effects, carry-over effects, and dosing of the intervention on individuals with MS. The comparison of BBTW effectiveness to other interventions is currently limited to unweighted or standard weighted conditions, which does not offer enough evidence to answer my clinical question. There also is no evidence to justify the effectiveness of the use of BBTW concurrently with traditional therapeutic interventions. The studies reviewed for this CAT provided enough evidence to justify the use of BBTW to immediately improve gait and mobility in individuals with MS.

Future research is needed to show long-term effects of this intervention on the wearer and whether there is an optimal "dosing duration". Research needs to be carried out to see if this intervention has carry-over effect on individuals who don the BBTW vest, for how long they need to don the vest for these effects to take place, and how long these carry-over effects take place after the vest is doffed. Additional areas of research on BBTW should assess if the immediate effects of the intervention can have a cumulative or enhanced effect on outcomes when worn during traditional therapeutic interventions.

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