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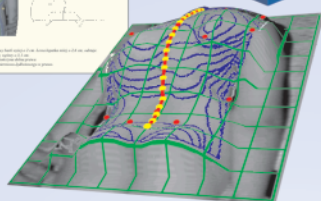
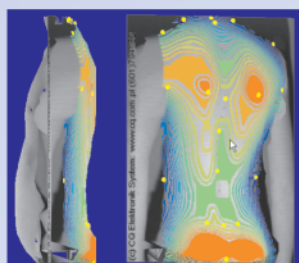
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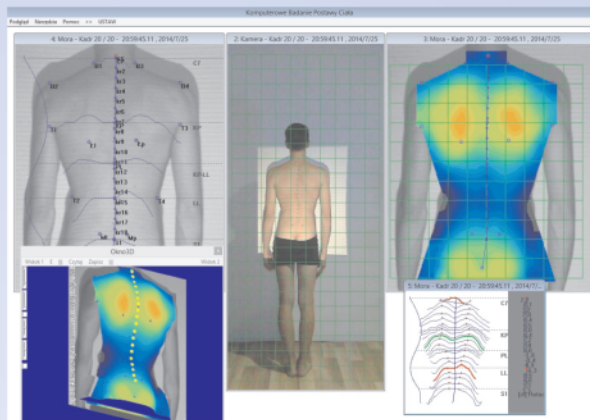
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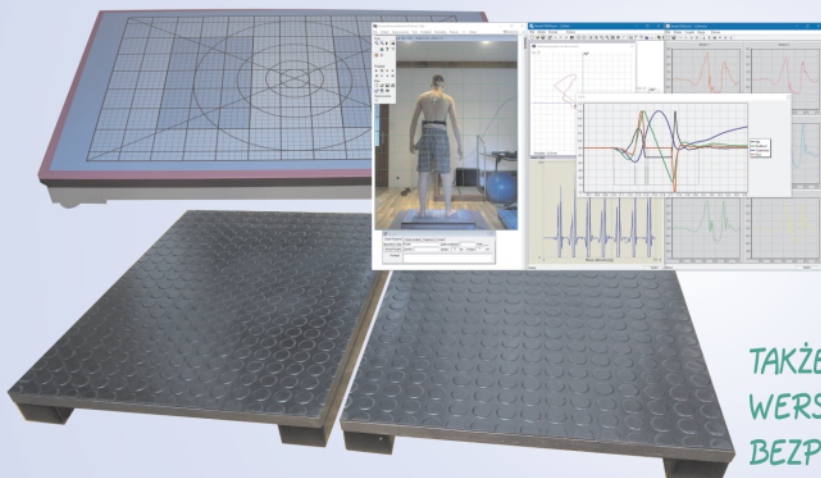


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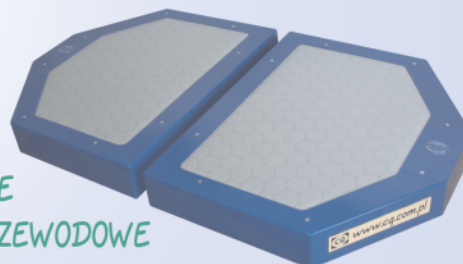


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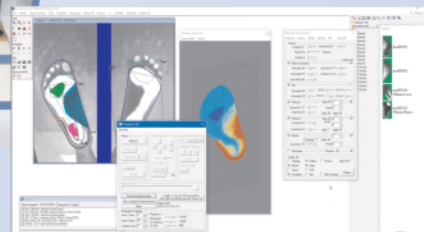
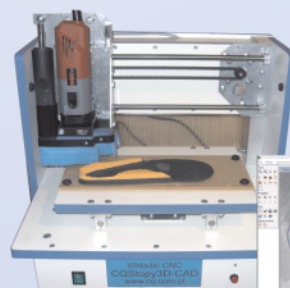
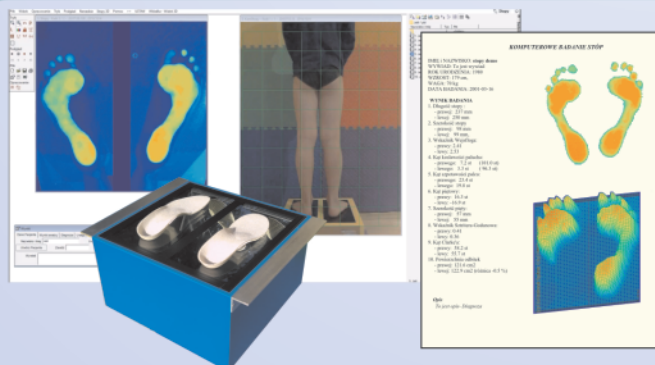


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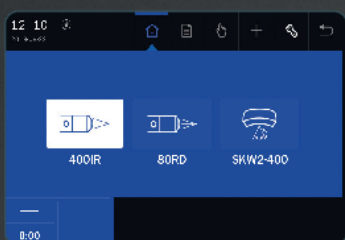
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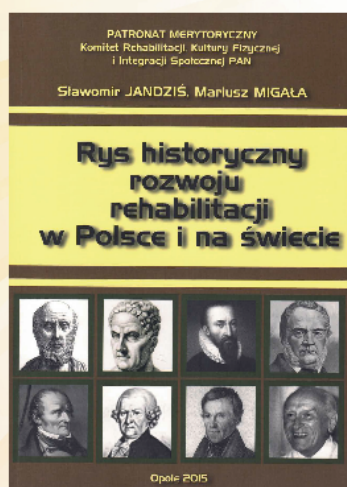
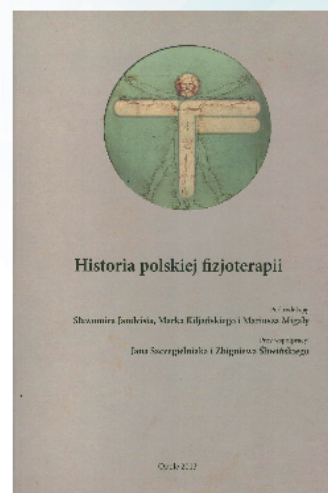
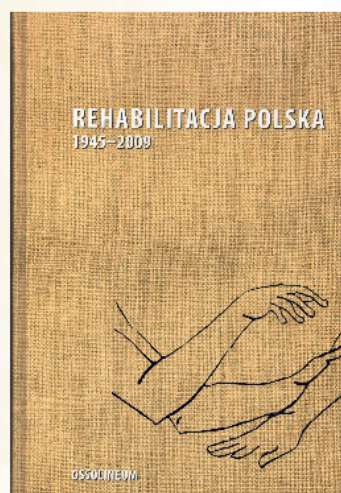
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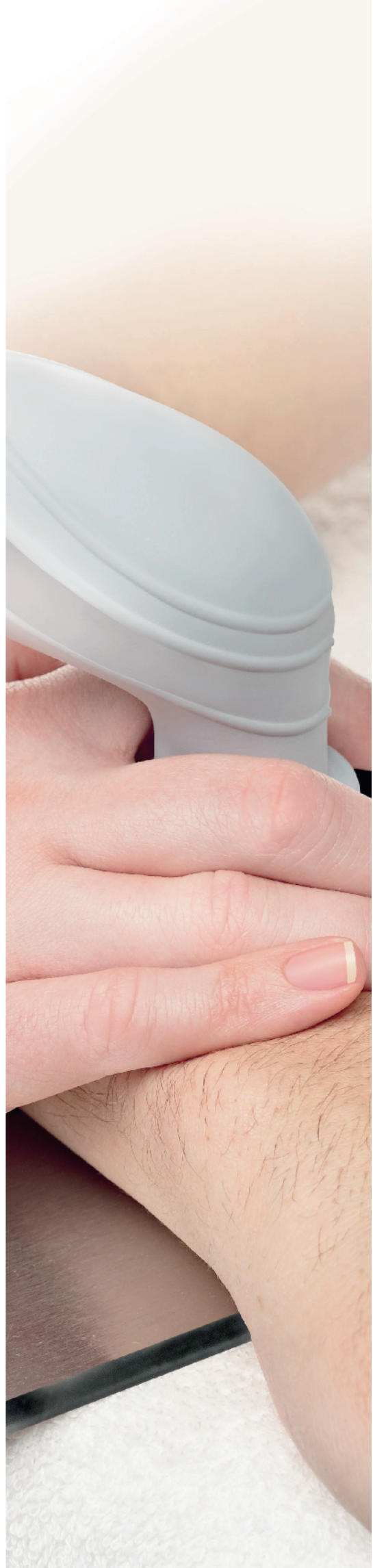
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Influence of Vestibular Rehabilitation on Balance and Dual-Task Cost of Walking in Patients with Multiple Sclerosis: A Randomized Controlled Trial

Wpływ rehabilitacji przedsionkowej na równowagę i koszt podwójnego zadania podczas chodzenia u pacjentów ze stwardnieniem rozsianym: Randomizowane badanie kontrolowane

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Abstract

Background. Balance dysfunction and high dual-task costs are eminent features in multiple sclerosis (MS). Vestibular rehabilitation therapy (VRT) proved to promote functional outcomes; yet, its influence on dynamic balance and dual-task cost of walking (DTCW) in MS needs further research.

Objective. To investigate the effect of adding VRT to aerobic training on dynamic balance and DTCW in people with MS.

Design. Single blinded, parallel randomized controlled trial.

Settings. Out-Patient Clinic at Faculty of Physical Therapy and Kasr Al-Ainy Multiple Sclerosis Unit, Cairo University, Egypt.

Participants. 40 patients with remitting-relapsing multiple sclerosis.

Intervention. Patients were randomized to a control ($n = 20$) and intervention ($n = 20$) groups. Over four successive weeks, all patients received stationary bicycle aerobic training. Intervention group received an additional VRT program.

Outcomes measures. Berg Balance Scale (BBS), walking speed tested by the 10 meters timed walk test (10 m-TWT), (DTCW), and overall stability index (SI).

Results. Intervention group showed a remarkable improvement in BBS ($p = 0.02$), SI at levels four ($p = 0.002$) and seven ($p = 0.03$), and DTCW ($p = 0.03$) compared with control group. Walking speed did not show significant changes post-treatment within or between groups comparison ($P > 0.05$).

Conclusion. Adding VRT to aerobic training has a positive effect on dynamic balance and dual-task cost of walking in MS.

Key words:

Multiple sclerosis, vestibular rehabilitation, dynamic balance, dual task cost of walking

Streszczenie

Informacje wprowadzające. Dysfunkcja równowagi i wysokie koszty podwójnego zadania to istotne cechy stwardnienia rozsianego (SM). Terapia rehabilitacji przedsionkowej (VRT) okazała się sprzyjać wynikom funkcjonalnym; jednak jej wpływ na równowagę dynamiczną i koszt podwójnego zadania podczas chodzenia (DTCW) w SM wymaga dalszych badań.

Cel. Zbadanie wpływu dodania VRT do treningu aerobowego na równowagę dynamiczną i DTCW u osób ze stwardnieniem rozsianym. **Projekt.** Pojedyncza ślepa, równoległa randomizowana próba kontrolowana. **Miejsce.** Ambulatoryjna klinika na Wydziale Fizjoterapii i Oddziale Stwardnienia Rozsianego Kasr Al-Ainy, Uniwersytet w Kairze, Egipt. **Uczestnicy.** 40 pacjentów z remisyjno-nawracającą postacią stwardnienia rozsianego. **Leczenie.** Pacjenci zostali losowo przydzieleni do grupy kontrolnej ($n = 20$) i grupy interwencyjnej ($n = 20$). Przez cztery kolejne tygodnie wszyscy pacjenci byli poddawani treningowi aerobowemu na rowerze stacjonarnym. W grupie interwencyjnej dodatkowo wprowadzono program VRT. **Pomiary wyników.** Berg Balance Scale (BBS), prędkość chodu badana w teście chodu na czas 10 metrów (10 m-TWT), (DTCW) i ogólny wskaźnik stabilności (SI).

Wyniki. Grupa interwencyjna wykazała znaczną poprawę w zakresie BBS ($p = 0,02$), SI na poziomach czwartym ($p = 0,002$) i siódmym ($p = 0,03$) oraz DTCW ($p = 0,03$) w porównaniu z grupą kontrolną. Szybkość chodzenia nie zmieniła się znacząco po leczeniu w grupach ani między grupami ($P > 0,05$). **Wniosek.** Wprowadzenie VRT do treningu aerobowego ma pozytywny wpływ na równowagę dynamiczną i koszt podwójnego zadania podczas chodzenia w SM.

Słowa kluczowe:

Stwardnienie rozsiane, rehabilitacja przedsionkowa, równowaga dynamiczna, koszt podwójnego zadania podczas chodzenia

Introduction

Multiple sclerosis (MS) is one of the most common disabling neurological disorders amongst young adults. Balance dysfunction is a frequent early problem in people with MS [1] affecting about 50-80% of them [2]. Impaired balance and mobility is a significant barrier to daily life activities and contributes to reduced quality of life [3] and increased risk of falling in people with MS [4]. Slowed somatosensory conduction with disturbed feedback mechanism and impaired central integration are reported as the primary causes of balance disorder in MS [5, 6].

The cognitive-motor interaction; termed the dual-task cost or dual-task interference is one of the main contextual variables affecting the postural control of daily balance tasks, walking performance, and increase risk of falling in people with MS [7, 8]. The impaired central processing mechanisms in MS requires higher mental attention with increased activation of the prefrontal cortex while doing an upright postural and complex tasks [9, 10]. Accordingly, dual-task paradigms can be considered as sensitive methods in assessing balance control with different attentional demands in daily postural tasks, predicting risk of falling and detecting recovery of stability in people with MS [8].

Vestibular rehabilitation therapy (VRT) is the most common approach used to promote gaze and postural control as well as walking stability in MS [11, 12]. Generally, VRT works through habituation of symptoms, adaptation and /or substitution for various deficits causing balance disorders [13]. To date, there are limited studies investigating the benefits of vestibular training on dynamic balance and functional outcomes in people with MS [14, 15]. Further, there is a lack of studies assessing the influence of VRT on dual-task cost of walking as a measure of dynamic balance in more attention requiring situation as

walking in MS patients. Hence, the current work aimed to investigate the additional effect of VRT on dynamic balance measures and dual task cost of walking in people with MS.

Materials and Methods

Study design

A prospective, parallel randomized, single-blind, pre-post-test, controlled trial was conducted following the Guidelines of Declaration of Helsinki on the conduct of human research. The study was approved from the institutional review board at Faculty of Physical Therapy, Cairo University (No: P.T. REC/012/00685), and registered at the Pan African Clinical Trial Registry database www.pactr.org (PACTR201611001853408).

Participants

A convenient sample of 50 patients with remitting-relapsing multiple sclerosis (RRMS), were screened for study eligibility, 40 patients were included in the study (Fig.1). Patients were recruited from Kasr Al-Ainy Multiple Sclerosis Unit (KAMSU) as well as Outpatient Clinic at the Faculty of Physical Therapy, Cairo University, Egypt. To be included in the study, individuals should be, clinically defined RRMS, 20 to 40 years old, and having no relapses three months before commencing the study, scored between 2.5 and 5.5 on the Expanded Disability Severity Score (EDSS), able to walk 100 meter, and having balance dysfunction (a score < 52 on the Berg balance scale). Patients were excluded if they had other neurological or orthopedic abnormalities interfering with their postural control, secondary musculoskeletal complication, peripheral vestibulopathy, cognitive dysfunction, or hearing deficits. Pregnant ladies and patients who are already receiving a planned physiotherapy program were also excluded. Subjects criteria were based on previously published studies [16, 17].

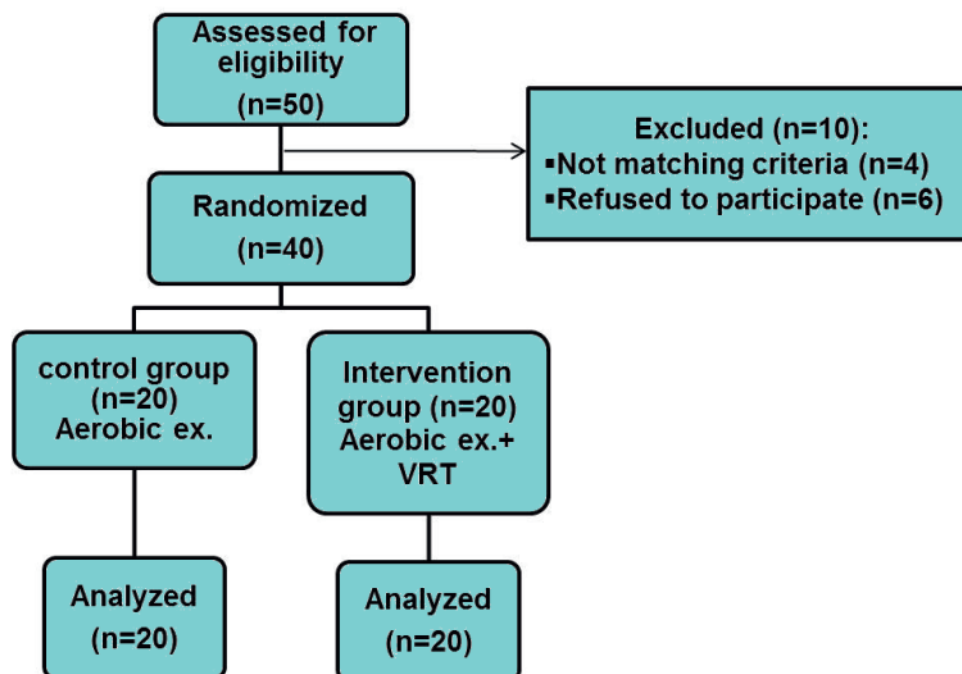


Figure 1: Participants flow chart throughout the study

Randomization

Informed consent was obtained from each participant after explaining the purpose and benefits of the study. Participants were informed about the confidentiality of obtained information and their right to refuse or withdraw at any time. Patients were randomly assigned into two groups; control group ($n = 20$) and intervention group ($n = 20$) by a blinded and an independent research assistant who opened sealed envelopes that contained a computer generated randomization card.

Interventions

The intervention period lasts for a total of four successive weeks for both groups. All patients were treated for 55 minutes at a frequency of three times per week; regularly every other day (12 therapeutic sessions) as follows:

The control group was treated by two (15 minutes sessions) of aerobic exercise in the form of submaximal stationary endurance bicycle training with intensity of 65% to 75% of the age predicted maximum heart rate (MHR). The first session started by five minutes of warming up followed by 15 minutes of continuous training (with the intensity mentioned above) and finally five minutes for cooling down. After 5 minutes rest, the second session was repeated with the same procedure of the first one. The level of intensity and duration of cycling were based on the recommended capacity for people with MS and previous literature [18, 9].

The intervention group was treated by one (15 minutes session) of aerobic exercises; prescribed as in the control group and a designed VRT in addition. The VRT consists of eye movement exercises and upright postural control training. Each exercise was applied for 1-2 minutes with a total of 30 minutes for the whole VRT program [19,9]. The VRT is reported to induce significant changes when applied for four weeks [20]. All patients were treated by one physiotherapist who is experienced in the field of neurological rehabilitation for 10 years.

Outcome Measures

All patients were evaluated before and after the completion of treatment program by the following measures:

1. Walking speed; the 10 meters timed walk test (10 m-TWT)

Walking speed, is the most common finding described in the studies with dual-task condition [21,22]. The 10 m-TWT test is a valid and reliable tool for patients with neurologic impairment and found to have a good test-retest and inter-rater reliability in people with MS [23]. Participants were instructed to walk bare feet along a 14 meters walkway at their preferred speed, as a recommended in the vestibular outcome measure [24]. Walking speed was only calculated for the 10 meters distance between the starting and finish lines.

2. Dual task cost of walking (DTCW)

DTCW is expressed as the percentage change of walking speed between the single and dual-task walks [25]. The single task was represented by the 10 m-TWT. For dual-task trials, the patients were instructed to accomplish 10 m-TWT while executing an arithmetic task, by counting aloud backwards from 100,

subtracting by 3. This task was selected because it is commonly recommended in many studies examining the DTCW. Participants walked three times under each condition (single and dual task walking) to achieve the main score of trials. For the dual task, an examiner walked alongside the patients to provide the needed help in case of losing their balance [21,22]. The dual task cost is calculated through the following equation: $DTC = (single-task - dual-task) / single-task \times 100$ [8]

3. Berg-Balance Scale (BBS)

The scale consists of 14 items used to evaluate balance and performance in various daily living tasks. It rates the subject performance of each item from 0 (cannot perform) to 4 (normal performance) with a maximum total score of 56 [26]. It is a valid instrument used for quantitatively describing the function and evaluating the effectiveness of interventions in clinical practice and research. Its validity and reliability have been evaluated on people with MS [27].

4. Stability Index (SI)

Biodex Balance System (BSS) (Biodex Corp. Shirley, Ny, USA) is a system which uses a circular platform that is free to move in the antero-posterior and medio-lateral axes simultaneously. It allows up to 20° of foot platform tilt so the patient is challenged to maintain his/her center of gravity over his base of support by keeping the platform leveled. The Biodex Balance System offers several levels of difficulty from L1 (most difficult) to L8 (least difficult), which determines the rate of deflection of the platform. Reliability of the BSS has repeatedly been proven [28]. The testing was conducted in dynamic conditions, with eyes open through two levels of stability; seven (moderately stable) and four (unstable). Test duration was settled by the system on 20 seconds. Each test was repeated three times with rest intervals. The overall stability index (SI) was measured considering the mean of (COP) displacement during the three test trials. Higher values of stability indices indicate greater difficulty in maintaining balance [29].

Statistical analysis

Descriptive and t-test were conducted for comparison of subject characteristics between both groups. Normal distribution of data was tested using the Shapiro-Wilk test for all variables. Levene's test for homogeneity of variances used to test homogeneity between groups. Mixed MANOVA was performed to compare within and between groups effects on 10 m-TWT, BBS and SI. Dual task cost of walking was compared between groups by Mann-Whitney U test and within each group by Wilcoxon Signed Ranks. Level of significance for all statistical tests was set at p value < 0.05 . Statistical package for social studies (SPSS) version 25 for windows (IBM SPSS, Chicago, IL, USA) was used for statistical analysis.

Results

Subjects characteristics

There was no significant difference between both groups in the mean age, weight, height, duration of illness and EDSS score ($p < 0.05$), see table 1.

Table 1. Demographic data of both groups

	Intervention group (n = 20) Mean ± SD	Control group (n = 20) Mean ± SD	p-value
Age [years]	34.57 ± 9.58	34.06 ± 8.63	0.86
Weight [kg]	76.94 ± 16.61	77.13 ± 12.4	0.97
Height [cm]	164.5 ± 8.23	165.66 ± 7.74	0.65
Duration of illness [years]	5.34 ± 3.55	5.66 ± 3.3	0.77
EDSS	2.51 ± 0.83	3.03 ± 1.27	0.11
Sex:	n	n	
Male	6	8	
Female	14	12	

Values were expressed as (means ± standard deviation) (means ± SD), except for sex which is expressed as nominal counts, EDSS: Expanded Disability Severity Scale, kg: kilogram, cm: centimeters. P: probability

Results of treatment effect on 10 m-TWT speed, BBS and stability index

Mixed MANOVA revealed a significant interaction effect of treatment and time (Wilks' Lambda = 0.69, F (4,38) = 4.24, p = 0.006) and main effect of time (Wilks' Lambda = 0.19, F (4,38) = 40.62, p = 0.001), while there was no significant main effect after treatment (Wilks' Lambda = 0.84, F (4,38) = 1.72, p = 0.16). Table 2 showed descriptive statistics of 10 m-TWT speed, BBS and SI; and the comparisons within and between groups before and after treatment.

Within and between group comparison

As represented in table (2), both groups showed a significant difference (p < 0.05) in the results of BBS, SI at level four and seven post-treatment when compared with pre-treatment. The walking speed (10 m-TWT) did not show significant changes in either group

up after treatment (p > 0.05). Before treatment, there was no significant difference between both groups in all measures (p > 0.05). After treatment, the intervention group showed a remarkable improvement in the measures of BBS (p = 0.02), SI at level 4 (p = 0.002), and SI at level 7 (p = 0.03) when compared with the control group.

Results of the effect of treatment on dual task cost of walking DTCW

Within and between groups comparison

As seen in Table 3, within group pre-post treatment comparison showed a significant decrease in the DTCW in each group; the intervention (p = 0.001) and control (p = 0.002) groups. Furthermore, there was a remarkable significant difference of the DTCW between the groups after treatment in favor to the intervention one (p = 0.03).

Table 2. Results of the 10 m-TWT speed, BBS and SI at pre & post-treatment in both groups

	Between Groups						Within group Before vs After	
	Before treatment		p-value	After treatment		p-value	Intervention group p-value	Control group p-value
	Intervention group Mean ± SD	Control group Mean ± SD		Intervention group Mean ± SD	Control group Mean ± SD			
10mTWT	0.58 ± 0.17	0.57 ± 0.1	0.8	0.61 ± 0.21	0.58 ± 0.12	0.56	0.07	0.74
BBS	50.6 ± 4.01	48.26 ± 5	0.1	52.71 ± 3.2	49.93 ± 4.83	0.02*	0.001*	0.002*
SI- 7	3.62 ± 0.84	3.86 ± 0.94	0.4	2.82 ± 0.76	3.34 ± 0.77	0.03*	0.001*	0.001*
SI- 4	4.36 ± 0.91	4.55 ± 0.72	0.48	3.15 ± 0.87	4.09 ± 0.86	0.002*	0.001*	0.008*

SD: Standard deviation; p-value: level of significance; * Significant

Table 3. The dual task cost of walking pre and post-treatment of intervention and control groups

	Intervention group Median	Control group Median	U- value	p-value
Before treatment	19.87	18.5	183.5	0.49
After treatment	8.03	11.05	128	0.03*
Z- value	3.94	3.17		
p-value	0.001*	0.002*		

U- value: Mann-Whitney test value; Z-value: Wilcoxon signed ranks test value; p-value: level of significance; *Significant

Discussion

This study was designed to investigate the additional effect of VRT on dynamic balance measures as well as on dual task cost of walking in people with MS. Results revealed that adding the VRT to aerobic exercises can remarkably improve dynamic balance measures (BBS & SI) and reduce the DTCW in comparison to using conventional aerobic training only.

According to the published review; VRT is mostly examined through its effect on gaze, postural stabilization, vertigo and dizziness in people with MS [30]. Up to our knowledge, limited randomized controlled trials (RCT) have been conducted to evaluate the effect of the VRT on dynamic balance and dual task cost in MS. Recent RCTs come in agreement with our results as they reported significant improvements in the score of sensory organization test [11, 12], and in BBS scores [31]; following participation in a vestibular based rehabilitation protocol. The resulted progress of SI in the current work is consistent with the result of Abou Shady et al. [32] in which people with MS showed a remarkable improvement in their SI at a moderately stable level (6) after participating in a VRT program.

Vestibular system activity is enhanced in antigravity positions and shows the greatest activation during standing and walking [33]. Vestibular rehabilitation is reported to provide task-specific stimuli essential for promoting neural reorganization and central sensory integration [34], that subsequently improve the upright postural control in people with MS [9]. Connection of vestibular system to reticular formation, through the vestibulospinal and ipsilateral reticulospinal pathways, produces selective activation of axial muscles and promotes cortical arousal and general body awareness [33]. Optimal alignment of trunk, hip, ankle, and foot which are essential elements for sufficient ankle and hip strategies [33,35], together with a proper somatosensory input and dynamic adaptation to variable base of support; are all addressed during practicing the VRT program. This working design allows patients to integrate somatosensory with vestibular inputs and becoming less reliant on visual input [36]. In addition, VRT program could modulate the gamma and alpha motor neurons firing which increases excitability of lower extremity antigravity muscles and activates the feedback mechanism [37, 38]. Furthermore, the ocular motor and gaze stabilization training involved in the VRT program plays a key role in improving neuromuscular reorganization [39], and the vestibulo-ocular reflex adaptation mechanism [40]; that could enhance postural control in people with MS [9, 12].

Investigating the effect of VRT on dual tasking as an outcome measure for balance is poorly studied in the literature review. However, The remarkable reduction of DTCW in the intervention compared to control group in this study, could be correlated with the reported role of VRT program in enhancing neural processing in different brain areas as; the cerebellum, basal ganglia, thalamus, hippocampus and inferior parietal cortex [41]. Some of those brain regions along with the middle frontal lobe, superior temporal and posterior cingulate gyri are verified to be involved in the vestibular neural processing activated by different vestibular

stimulation approaches [42, 43]. A significant vestibular connectivity primarily with frontal cortex (responsible for attention) was found mainly during saccade eye movements [44], which may explain the influence of VRT on reducing attentional demands of balance during dual-task walking demonstrated in this study. Hall and Heusel-Gillig [44], revealed similar results of significant improvement in balance measures; as balance-related confidence, dual-task ability, walking speed, fall risk, and sensory integration after a standard balance training program in older adults. Miller et al. [45], reported that, aerobic exercise training is an efficient easy tool for enhancing cognition and functional status in MS. Aerobic training is also reported to improve the dual-task walking in older adults [46].

The insignificant change of the walking speed (10 m-TWT) in either group post-treatment in current study, is consistent with results of Hebert et al. [9], who reported insignificant effect of either VRT or aerobic exercises on walking distance measured by a similar test; the 6-minute walk test. Arntzen et al. [17], also reported non-significant difference in preferred walking speed (10m-TWT) after a core stability and balance training program in MS. However, Hall and Heusel-Gillig [44], revealed an improvement in walking speed and other measures of balance as balance-related confidence and fall risk, after a standard balance training program in older adults.

A possible explanation for the insignificant change in walking speed in the current work could be that walking impairment in MS is multifactorial; as the lack of postural control, sensory impairment, muscle weakness, incoordination, lack of flexibility, spasticity, and fear of falling, that was not all addressed in the present study [47]. Moreover, locomotion is controlled by different motor control mechanisms and promoting walking performance requires numerous elements to be covered to induce neuroplastic changes. Hence, an approach such as the task-specific gait training might be a suitable therapeutic approach in enhancing in gait performance compared to aerobic, resistance or universal physiotherapy exercises alone [48].

Conclusion

It could be concluded that: adding the VRT to aerobic training can positively improve not only the dynamic balance control in people with MS, but also reduces the cost of adding a cognitive task to a highly demanding balance task as the ambulation. The finding of our study could highlight the role of VRT in enhancing the central sensorimotor processing which is recommended for further studies. Larger sample sizes that include participants with greater level of disability and different levels of cognitive impairments should be undertaken to confirm the present results.

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