

EFFECT OF EXERCISES REHABILITATION PROGRAM IN STABLE AND UNSTABLE SURFACES ON TRUNK CONTROL, BALANCE, FATIGUE AND QUALITY OF LIFE IN PATIENTS WITH MULTIPLE SCLEROSIS: A RANDOMIZED CONTROLLED TRIAL WITH 10-WEEK FOLLOW-UP.

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ABSTRACT

Aim: The aim of the present study was to investigate the effect of 10-week exercises rehabilitation program in stable and unstable surfaces on balance, fatigue and quality of life in patients with multiple sclerosis. **Material and method:** Thirty patients were divided into two exercise groups. All patients received supervised exercise training sessions, 3 times per week for 10-week. The patients in both groups performed a combined set of strength, stretch, core stability, balance and walking exercises. However, patients in combined exercise training group in unstable surface practiced on foam surface. After a baseline outcome measurements, including Berg Balance Scale, Timed single leg stance Fatigue Severity Scale and Multiple Sclerosis Quality of Life-54, patients were submitted to a run-in period lasting 10 weeks without any rehabilitative intervention. Three other assessments of outcome measurements were performed before and after intervention and also 10-week after the end of intervention. Data were analyzed by using independent samples t-test, repeated measures analysis of variance, mixed ANOVA repeated measure and Bonferroni's post hoc test at a significance level of $P < 0.05$. **Results:** The results showed that there were significant improvements for all outcome measures in both exercise groups. Exercise group in unstable surface showed significantly larger improvement in balance than exercise group in stable surface. **Discussion:** According to research findings, exercise in both groups resulted in considerable improvements in balance, fatigue and quality of life in patients with multiple sclerosis.

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Introduction

Multiple sclerosis is one of the most common debilitating diseases, affecting millions worldwide [1]. Patients with multiple sclerosis frequently experience symptoms and problems such as pain, fatigue, spasticity, muscle weakness, balance/coordination problems, walking impairment and poor quality of life [2]. The benefits of exercise in patients with multiple sclerosis have been investigated in relation to aerobic training [3], resistance exercise [4], and core stability training [5]. Since multiple sclerosis has caused many clinical problems, studies examining adaptations to exercise training in patients with multiple sclerosis have focused on different outcome measures. A Cochrane systematic review of exercise therapy for patients with multiple sclerosis confirms there is good evidence that exercise can be beneficial for mobility, isometric muscle strength, physical fitness, fatigue and quality of life [6,7]. Although balance, coordination, functional and core stability exercises have an important contribution to function in individuals with multiple sclerosis, a limited number of studies have contained specific exercises for balance and coordination as well as strengthening and stretching exercises [8]. Therefore, we aimed to investigate the efficacy of our exercise program, including all dimensions in accordance with our outcome measures.

Exercise training on unstable surfaces is an important aspect of neuromuscular rehabilitation and conditioning and consequently furnishes improvement in coordination and the neuromuscular recruitment pattern. During physical training, the instability of movement places joints in situations of risk. Thus, the activation of proprioceptive impulses that are integrated in various sensory-motor centers regulates adjustments in the contraction of postural muscles, thereby maintaining general postural balance [9]. Thus, exercises on unstable surfaces generate rapid changes in the length of the ankle ligament due to the stimulation of the joint on multiple planes of movement, thereby generating afferent stimuli and reflexive motor responses in order to produce rapid joint stability [10]. Braun Ferreira et al. [9] suggested that exercises on unstable surfaces generated a significant increase in EMG activity, especially with eyes closed, and are therefore a valuable resource in the sensory-motor rehabilitation of the muscles. According to Oliveira et al. [11] the aim of this type of training is to induce unforeseen perturbation, thereby stimulating the stabilization reflex and the production of agonist-antagonist co-contraction. There is evidence indicating exercise training on unstable surfaces has the potential to induce a positive effect on muscle force and activation, muscle strength, balance, stability and fatigue [12]. Nevertheless, no study has yet investigated the effects of exercise training in unstable surfaces on various components of impairment and functional limitations in patients with multiple sclerosis. Overall, the studies of postural responses indicate that patients with multiple sclerosis have delayed automatic postural responses to postural perturbations, that there is a relationship between these postural response delays and delays in spinal somatosensory conduction [13]. In addition, patients with multiple sclerosis have also been found to have poorer trunk control than healthy people when sitting on an unstable surface [14]. For these reasons, in the present study, foam surface with similar advantages to other unstable surfaces were put to use. Therefore, the aim of this randomized controlled pilot study was to investigate the comparative effects of a 10-week exercise rehabilitation program in stable and unstable surfaces on balance, fatigue and quality of life in patients with multiple sclerosis.

Material and Methods

Sample Subjects

This study was a prospective, randomized controlled pilot trial with a repeated measures design and blinded assessments. The method of randomization was a balanced randomization process in which 30 patients were matched based on age and EDSS and randomly assigned to two subgroups in equal sample proportions using a table of random numbers. The groups consisted of the exercise training in unstable surface (group 1) and exercise training in stable surface (group 2). Patients were included in the study if they had clinically or laboratory confirmed relapsing–remitting, an Expanded Disability Status Scale between 2 and 4, ability to stand without any support and ability to walk 500m independently. Exclusion criteria encompassed a severe relapse one month before the study; involvement in any physical therapy program before beginning the study; cardiovascular and respiratory diseases; diabetes; psychiatric disorders or severe cognitive impairment; severe blurred vision and vestibular disease [2,15].

Tests and measurements

Patients with multiple sclerosis first underwent outcome assessments pretest1 (week -10) followed by run-in 10-week period without any intervention or specific training to control the effect of drug and disease progression. Three other assessments of outcome were performed before (week 0) and at the end of the intervention (week +10) and also 10-week after the end of intervention (week +20). Then, Berg Balance Scale [2], Timed single leg stance [5], Fatigue Severity Scale and Multiple Sclerosis Quality of Life-54 [2,15] were used to assess balance, fatigue and quality of life, respectively.

Training program

The training protocol was conducted 3 times per week for 10 weeks in both groups. All sessions began with 5 minutes of warm-up using a treadmill and then the 35 to 50 minutes training protocol and ended with 5 minutes of cool-down including muscle stretching.

The exercise training program was based on the exercise provided in Tarakci et al. [15] and Negahban et al. [2]. In brief, the exercise protocol was a combined set of strength, stretch, core stabilization, balance and walking exercises including straight leg raising, forward lunge, muscles stretching, double/single leg standing and tandem standing. Also, walking activities including forward/backward/side walking, walking through obstacles and tandem walking were exercised by each patient. The patients in the exercise training group in stable surface performed exercises on rigid surface. However, patients in exercise training group in unstable surface performed the same training program on foam (100*200* 10,6 cm to 100 kg/m³, Tuv Inter Cert, GER) surface. The height of foam was gradually increased from 6cm in week 1 up to 10 cm in week 10. The exercise was intended to be moderately intense, and a Borg's scale of rating of perceived exertion (RPE) was targeted for level 13 by all participants over the 10-week period. This exercise was done in 3 sets (Maximum) with 2 to 3 minute rest. The training took place under the direct supervision of the exercise specialist with support of research assistants in an accessible gymnasium at the Multiple Sclerosis Center.

Statistical analysis

Data were analyzed using SPSS software version 22.0 for windows. The level of statistical significance was set at $P < 0.05$. Demographic data of both groups were compared, using an independent samples t-test. Based on the within-subject factor of time (i.e. 4 pre–post times) and the between-subject factor of group (i.e. two study groups), the researchers conducted a 2×4 (2 groups by 4 pre–post times) mixed model of the analysis of variance (ANOVA) to determine the main effects and

interactions of group and time factors for each outcome measurements. Within-group differences for 4 pre–post times (week -10, week 0, week +10, and week +20) were analyzed using a repeated measures analysis of variance. Post hoc analyses were conducted using the Bonferroni correction for multiple comparisons. Between-group differences were analyzed using an independent samples t- test.

Results:

The two groups of this study did not differ in terms of demographics (Table 1).

Table 1. Demographic characteristics

	Exercise group in stable surface (n=15)	Exercise group in unstable surface (n=15)	p
Age	29.20±3.12	29.33±3.97	0.91
Height	166.14±5.91	165.53±8.24	0.81
Weight	52.89±6.35	55.36±6.95	0.31
History	9.40±1.50	9.73±1.38	0.53
EDSS	3.33±0.48	3.53±0.63	0.34

The results of between-group differences in all outcome measurements showed, there was no significant difference between both groups in pretest1 (week -10) and pretest2 (week 0).

As shown in Table 2, there was no significant interaction of groups by time for some outcome measurements including fatigue and the physical and mental health composite scores of the Multiple Sclerosis Quality of Life-54. The main effect of time was significant for both the physical (PHCS) and mental health (MHCS) composite scores of the Multiple Sclerosis Quality of Life-54 and fatigue, meaning that irrespective of group main effect, patients had a higher quality of life and a reduction fatigue posttest (week +10) relative to the pretest2 (week 0).

	Main Effect				Interaction	
	Time		Group		Group*Time	
	F	p	F	p	F	p
Berg balance scale	48.45	<0.0001	1.98	0.17	4.11	0.021
single leg stance	47.66	<0.0001	13.43	0.001	4.26	0.019
Fatigue scale	335.03	<0.0001	0.04	0.94	0.15	0.857
MSQOL-54 (PHCS)	1533.09	<0.0001	1.88	0.18	1.007	0.372
MSQOL-54 (MHCS)	446.13	<0.0001	0.04	0.95	1.60	0.21

Alternatively, there was a significant interaction of groups by time for other outcome measurements including Berg Balance Scale and timed single leg stance Therefore, the simple main effects of time within each experimental group were analyzed (Table 3). Results from the repeated measures ANOVA test provides evidence of a significant time

Table 3. Pairwise Comparisons

effect for all outcome measurements.

Bonferroni corrected pair-wise comparisons indicate a significant improvement between pre-test (week 0) and post-test (week +10) for Berg Balance Scale, timed single leg stance, fatigue and Multiple Sclerosis Quality of Life-54 in both groups

	Exercise group in stable surface			Exercise group in unstable surface		
		Mean Difference	p		Mean Difference	p
Berg balance scale	Pre1-pre2	0.49	1.00	Pre1-pre2	0.55	1.00
	Pre1-post	4.60	0.004	Pre1-post	7.51	<0.0001
	Pre2-post	4.11	0.010	Pre2-post	8.06	<0.0001
Timed single leg stance	Pre1-pre2	0.14	1.00	Pre1-pre2	0.31	1.00
	Pre1-post	3.40	<0.001	Pre1-post	6.27	<0.0001
	Pre2-post	3.54	<0.005	Pre2-post	6.59	<0.0001
Fatigue severity scale	Pre1-pre2	0.14	1.00	Pre1-pre2	0.07	1.00
	Pre1-post	2.45	<0.0001	Pre1-post	2.33	<0.0001
	Pre2-post	2.30	<0.0001	Pre2-post	2.26	<0.0001
MSQOL- 54 (PHCS)	Pre1-pre2	0.26	1.00	Pre1-pre2	1.10	0.091
	Pre1-post	14.83	<0.0001	Pre1-post	14.67	<0.0001
	Pre2-post	15.09	<0.0001	Pre2-post	15.77	<0.0001
MSQOL- 54(MHCS)	Pre1-pre2	0.42	1.00	Pre1-pre2	1.59	0.015
	Pre1-post	14.03	<0.0001	Pre1-post	12.16	<0.0001
	Pre2-post	14.45	<0.0001	Pre2-post	13.75	<0.0001

The results of between-group differences in change scores showed significant difference between two groups in Berg Balance Scale and timed single leg stance. Patients in the exercise training group in unstable surface showed significantly larger change scores in the Berg Balance Scale (0/006) and timed single leg stance (<0.0001) than the exercise training group in stable surface.

Also, the results of pairwise comparisons showed that the benefits of improvement were maintained at follow up testing; i.e. 10-week after completion of the intervention. The results of between-group differences in change scores showed no significant difference between two groups for Berg Balance Scale and timed single leg stance, after intervention and also 10-week after the end of intervention.

Discussion:

The results of this study showed that balance, fatigue and quality of life all enhanced in favour of the exercise training in stable and unstable surfaces in patients with multiple sclerosis. The results of between-group comparisons showed that exercise training in unstable surface resulted in larger improvement in balance than exercise training in stable surface. However, no significant differences were observed between improvements quality of life and fatigue reduction in two groups.

Following a 10-week study, patients in both groups showed significant improvements in Berg Balance Scale and timed single leg stance scores. Similar to our findings, Freeman et al. [5] found a significant improvement with fewer group exercise sessions (10 weeks, twice weekly) in Berg Balance Scale and timed single leg stance scores. Also, Tarakci et al. [15] showed significant improvements in Berg Balance Scale after the 12-week group exercise training. On the other hand, Learmonth et al. [8] reported improved physical activity levels and perceived balance confidence, but they did not observe improvements in Berg Balance Scale after 12-weeks group exercise in with multiple sclerosis.

Also, the results of present study showed that exercise training on unstable surface resulted in larger improvement in balance than exercise training on stable surface. There are several possible reasons that might explain these results. Research on focus of attention has consistently demonstrated that an external focus (i.e., foam) enhances motor performance and learning relative to an internal focus (i.e., on body movements) [16]. Wulf et al. [16] showed that the performance and learning advantages through instructions or feedback inducing an external focus extend across different types of tasks, skill levels, and age groups. Benefits are seen in movement effectiveness (e.g., accuracy, consistency, balance) as well as efficiency (e.g., muscular activity, force production, cardiovascular responses). Therefore, external focus (foam) could result in the larger improvement of balance in exercise training group on unstable surface as compared to the exercise training group on stable surface [16,17]. Furthermore, Behm et al. [18] showed that the activation of the trunk stabilizers was significantly greater with the unstable surfaces. Unstable exercises on trunk muscle activation seem to concur that the introduction of instability into the activity increases the extent of muscle activation. Trunk or core stabilization is essential for maintaining static or dynamic balance especially when attempting to exert forces upon external objects (foam) [12]. Therefore, unstable exercises with positive effects in activation of the trunk stabilizers could result in the larger improvement of balance in exercise training group on unstable surface as compared to the exercise training group on stable surface [12,18].

Our results showed that exercise training on stable and unstable surfaces is effective on fatigue reduction in patients with multiple sclerosis. Parallel to our findings, the effects of various exercise programs on improving fatigue have been published before, using different fatigue scales [7,19]. Increased fatigue in patients with multiple sclerosis is likely to consist of both motor-related and mood-related dimensions [7,19]. Hebert et al. [20] studied that symptomatic fatigue is significantly related to balance, and is a significant predictor of balance as a function of central sensory integration in patients with multiple sclerosis. They support the theory that for those patients with multiple sclerosis who struggle to maintain steady balance during tasks that stimulate the central sensory integration process, complaints of significant levels of fatigue are probable [20]. Stretching exercises which improve endurance, and might reduce fatigue [19,20]. We applied some stretching exercises that might reduce fatigue in patients with multiple sclerosis.

The results of present study showed that exercise training on stable and unstable surfaces was associated with significant improvement in quality of life in people with multiple sclerosis. While improvements were found significant after exercise sessions in some studies, there are other researches that have not supported this finding [21]. Our findings are similar to studies that found significant improvement in quality of life after exercise training. The improvements in quality of life suggest that a better perception of balance can have a positive impact on patient behavior. It has been previously reported that balance disorders with fear of falling represent an important problem affecting quality of life, even in early and mild stages of multiple sclerosis [22].

However, no significant differences were observed between improvements quality of life and fatigue reduction in both groups. Therefore, it could be argued that in cases where the aim is to improve fatigue and quality of life in patients with multiple sclerosis, exercise training on unstable surface do not have any specific advantages over exercise training on stable surface.

This study has several strengths in terms of the interpretation of the findings. First, one of the important issues in randomized controlled trials is whether the positive training effects are retained several months after the end of training. We included a follow-up period after the end of intervention to assess the long-term effects of the combined exercise training program and found that the combined training effects in stable and unstable surfaces were maintained at 10-week follow-up. Second, due to the ethical considerations, there was no true control group with no exercise program, thus we included a run-in period lasting 10-week without any rehabilitative intervention to control the effect of drug and disease progression.

Conclusion:

According to research findings, exercise in stable and unstable surfaces resulted in considerable improvements in balance, fatigue and quality of life in patients with multiple sclerosis, with no worsening of their clinical status.

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Declaration of conflicting of interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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