Original Article

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Effect of CoDuSe and step square exercises on risk of fall in multiple sclerosis: a randomized controlled trial

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Abstract

Objective: Impaired balance and the difficulty to execute dual tasks are common in patients with multiple sclerosis (MS), which are the main causes of risk of fall. The purpose of the study was to determine the effect of a rehabilitation program composed of CoDuSe balance training and step square exercises (SSE) on the risk of fall in MS. *Methods:* Fifty-two patients with MS were randomly divided into two equal groups; the study group that received CoDuSe balance training and SSE combined with the selected exercise program for four weeks, while the control group received only the selected exercise program. All patients were assessed pre-and post-rehabilitation program with the Biodex Balance System (BBS) using the fall risk index test, Short Physical Performance Battery (SPPB), and Morse Fall Scale (MFS). *Results:* Comparing groups post-treatment revealed significant reductions in MFS and risk of falls scores ($p < 0.05$) and a significant increase in balance, gait, lower limb strength, and total scores of SPPB of the study group compared with the control group. *Conclusions:* The combination of CoDuSe balance training and SSE had a significant effect in reducing the risk of fall and improving balance in patients with MS, thus this treatment program should be considered in MS physical rehabilitation.

Keywords: Multiple Sclerosis, Balance, Exercises, Risk of Fall, Gait

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INTRODUCTION

Multiple sclerosis (MS) is the most neurologic well-known progressive disease in young adults, and due to the demyelination of different distribution throughout the central nervous system (CNS), patients with MS present commonly with disorders of balance, sensation, coordination, and strength, as the imbalance and frequent falls lead to fear of falling that may affect the quality of life [1]. Satisfactory balance depends upon appropriate motor reactions and the integrated input from somatosensory, visual, and vestibular systems, which are frequently impaired in patients with MS. Poor balance control is common in patients with MS, which is known as one of the main causes of risk of fall which is considered the initial manifestation of MS even in patients with minimal clinical assessment problems [2]. The risk of falls in patients with MS increased during daily activities, and also during transferring activities, walking, and turning [3].

Patients with MS have a considerable fall risk, especially during gait [4], because of the slower proactive equilibrium reactions, and the diminished capacity to keep a position when attempting to reach, also due to the central integration impairment, the slowness of somatosensory conduction, fatigue, delayed response, impairment of attention as well as the difficulty of stability maintenance during exposure to any external perturbations [5], also any overload fatigue of the muscles could affect individual postural balance, righting reaction and proprioception [6]. Patients with MS suffered from the reduction of trunk stability as in standing position, the level of trunk sway increased, and the postural sway increased with dual-task [7].

The postural balance is characterized as the capacity to keep an upright posture during static and dynamic functions that need complex integration of both central and peripheral factors like motor output, somatosensation, vision, and vestibular sensation [8]. The falling is an unexpected situation in which an individual comes to the floor while a near fall is a situation in which the patient felt that they were going to fall however didn't really fall [9].

The patients with MS consistently experience reduced ability to move toward the limits of stability, swaying during standing, slowness in both gait, and reactions to postural sway, all these factors are contributed to the risk of falls in MS [10]. The main aim of physical therapy for patients with MS is to facilitate balance during upright posture and movement to enhance dual-task training, the stability of the trunk, and the sensory strategies [9], therefore, both trunk muscles and core stability exercises are important in MS [11].

Hence, the CoDuSe training is considered a valuable rehabilitation training program to enhance equilibrium and balance in MS [12]. The CoDuSe exercise includes core stability exercises, dual tasking, and sensory strategies, as the main objective of CoDuSe exercises is to maintain balance during activities, and dual tasking, also to improve both the trunk stability and the sensory strategies that stimulate both the static and dynamic balance and furthermore can diminish the risk of fall and postural sway during gait [12]. However the ability to maintain equilibrium to avoid any slip needs quick instead of slow reactions or stepping movements, also high accuracy of foot placement for the correct initiation of step or reduce a wrong one to quickly avoid any unexpected perturbation or obstacle, so the treatment program mainly focused on performing coordinated, fast, and precise step patterns [13].

Therefore, the Square stepping exercise (SSE) is viewed as a type of profoundly explicit equilibrium exercise to prevent falls which depends mainly on the strategy of protective execution to maintain balance in different activities and environment**s** and also to enhance intellectual fall risk factors [13]. The SSE contains various directional advance examples of step patterns, which are applied on a thin mat that is classified into squares, and incorporate a progression of different modified and complex steps patterns, hence the SSE could enhance the reaction time with the restorative stepping patterns, as it was planned to improve the standards of reactive and proactive reactions [14].

Therefore, the main goal of the rehabilitation program in MS with the risk of fall is to improve the interactions between sensory-motor integration and to regain the ability to perform a complex step pattern with adequate reaction, in this way the principal point of the current investigation is to research the impact of CoDuSe exercise training and SSE on the risk of fall in MS.

METHODS

Study Design

Pre and post-experimental study, designed as a randomized, controlled trial. The patients randomly were assigned into two matched groups, every group included 26 patients with MS as the study group received CoDuSe balance training and SSE for four weeks combined with the selected exercise program, while the control group received the selected exercise program for four weeks. This study was conducted between September 2020 to December 2020.

Participants

Fifty-two patients with MS were referred from a neurologist with a diagnosis of Remitting-relapsing Multiple Sclerosis (RRMS), they were randomly selected from the Kasr Al- Ainy Hospital, MS unit, Cairo University, Egypt, Outpatient clinics of Faculty of Physical Therapy, October 6 University hospital and Physical Therapy Center of Modern University of Technology and Information. The inclusion criteria for the patient selection were as follows: the age ranged from 20 to 40 years, the duration of illness not more than 10 years, with no relapses over the past three months, all the patient's physical performance according to The Short Physical Performance Battery (SPPB) was ranged from mild to moderate limitations [15], and the body mass index (BMI) was 25 to 35 kg/m^2. While the exclusion criteria were as follows: patients with any difficulty to communicate or understand the program instructions, any other neurological deficits or orthopedic abnormalities, any secondary musculoskeletal complication, any peripheral vestibulopathy, hepatic, renal, hemopoietic, thyroid and cardiovascular diseases, cognitive dysfunction, visual and hearing deficits, epilepsy or electroencephalogram abnormalities.

Randomization

Before the beginning of the study, all the patients read and signed a consent form, as anonymity and confidentiality were assured, and the study was performed in consistence with significant laws and institutional rules. The patients were allocated randomly into two groups (study and control group) equally, by a computer-based randomization program, by an independent researcher. No dropping out of patients from the study was reported after randomization (Figure 1).

Ethical approval for the study

The Institutional Ethics Committee of the Faculty of Physical Therapy, Cairo University approved the study (No: P.T.REC/012/002865), and clinical trials.gov ID NCT04528121.

Sample size

To avoid type II error, sample size calculation was performed using G*POWER statistical software (version 3.1.9.2; Franz Faul, Universitat Kiel, Germany)[16], and found that the suitable sample size for this study was 26 subjects per group. Calculations were performed as allocation ratio N2/N1 =1 and α=0.05, β=0.2, with effect size = 0.8.

Outcome measures

All patients were assessed pre-and post-rehabilitation program after four weeks with the Biodex Balance System (BBS) using the fall risk index test, Short Physical Performance Battery (SPPB), and Morse Fall Scale (MFS). Data collection was carried out in the Biodex laboratory of MTI university, Faculty of physical therapy. The examiner was blinded if the subject belonged to the study or control groups.

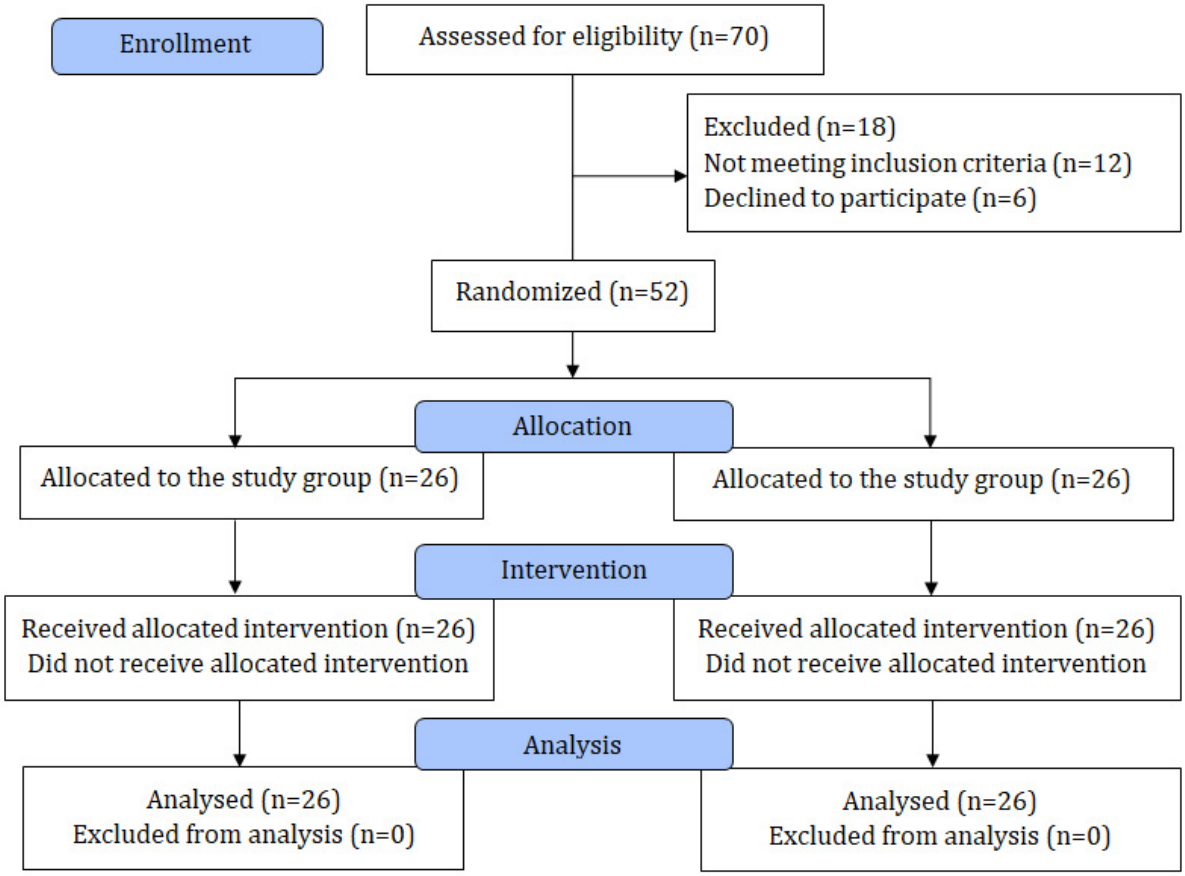

Figure 1. Flow chart showing the experimental design of the study

Biodex Balance System (BBS) For Fall Risk Test

The BBS (Biodex Medical Systems Inc., Brookhaven R&D plaza, 20 Ramsey Road Box702, Shirley, New York 11967-0702), comprises of a rounded foot platform that grants 20° inclining in all directions, that moves in both anteroposterior and mediolateral axes, it also consisted of a supported rail, display screen, and a printer (Figure 2). The device includes the measurement of 12 dynamic levels in addition to static measurements. The fall risk index test allows the mechanoreceptors maximum excitation of the ankle joint, which gives data on different patients' capacities to prevent falls and keep balance [17]. Each patient was asked to stand on the BBS platform with bare feet then the therapist selected the fall risk test, as the stability levels were automatically changed from the most stable level (level 12) to the more dynamic level (level 6) for the test period (20 seconds) with 3 trials and then the device calculates the mean of three trial, the patient foot angle was distinguished by utilizing the alphanumeric matrix on the foot platform (15-20°) and once the patient could stand easily on the platform, the patient was asked to put the hands on the hips and to stand stable as much as possible, at that point the screen gave a three seconds countdown before beginning each test trial. The display screen incorporated the test preliminary time, trial number, and patient score of fall risk (Figure 3). The patient was asked to keep the vertical position with the center of gravity in the platform midpoint by monitoring the screen that was placed 30 cm in front of the patient's face. The time for each measurement was 20 seconds, with a "10 seconds" rest in between. After three measurements, the mean was scored. Overall Stability Index (OSI) measurement was estimated in degrees as zero degrees is the most ideal score and higher scores indicate increased fall risk value.

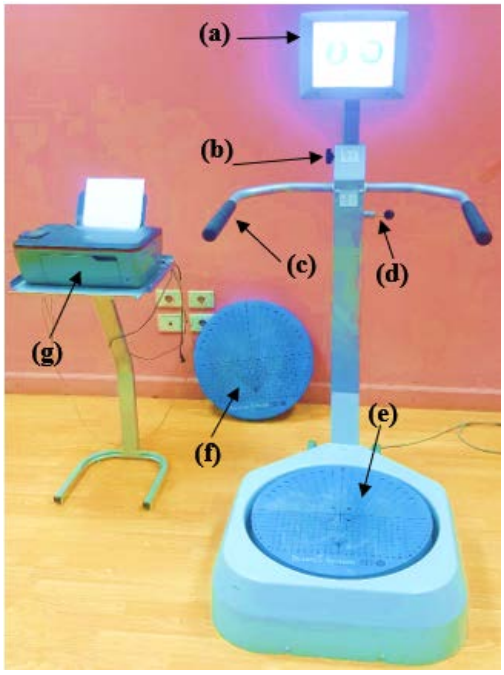

Figure 2. (a) color touch-screen, (b) Display Height Locking Knob, (c) adjustable support handle, (d) Support Handle Release Pin, (e) hard foot platform, (f) foam foot platform, (g) printer

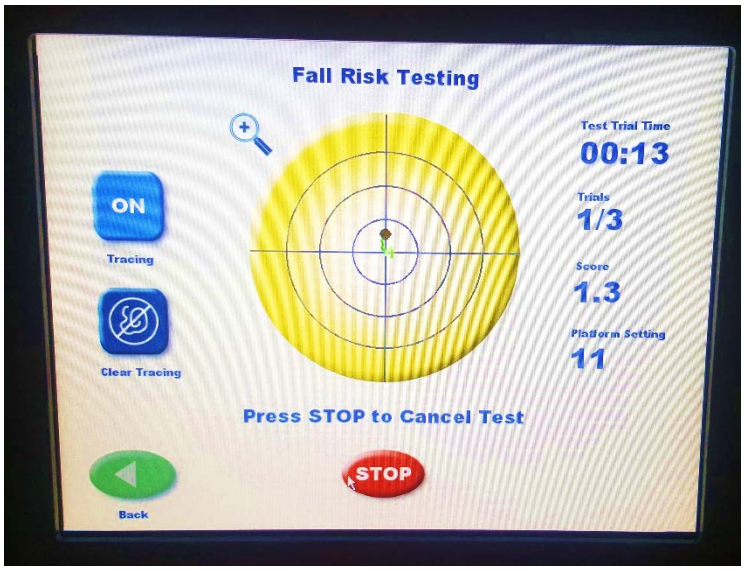

Figure 3. The BBS screen represented a sample of fall risk test including (test trial time, number of trials, score, and platform setting).

The Short Physical Performance Battery (SPPB)

The Short Physical Performance Battery (SPPB) is an objective measurement method for assessing patients balance and physical performance, it included 10 seconds balance tests that involve "semi tandem, full tandem, and side by side", the speed of four-meter walking test, and a lower limb strength test. Decreased SPPB scores showed poor outcomes, as fall risk or mobility loss. The total score and the three subtest scores of "balance, walking speed, and lower extremity strength in form of repeated chair sit-to-stand" were assessed, as every subtest was scored from zero to 4, and summed for a total score that ranged from zero to 12, as the elevated scores indicated a good balance and

function [15]. The four total SPPB score categories are 0~3 Severe limitations, 4~6 Moderate limitations, 7~9 Mild limitations, and 10~12 Minimal limitations" [18].

Morse Fall Scale (MFS)

The Morse Fall Scale (MFS) is an easy method for evaluating the patient's risk of fall [19]. The MFS consisted of six measuring classes as follows: 1) The History of falling; 2) secondary diagnosis; 3) ambulatory aids; 4) intravenous therapy/injection lock; 5) gait /Transferring, and 6) mental status. The MFS total scores represent a four-level of risk of fall as follows: (0) no risk, (less than 25) low risk, (25~44) moderate risk, and (45 or more) high risk [20].

Interventions

The rehabilitation program of the study group consisted of both the CoDuSe and SSE for 4 weeks, in addition to the selected exercise program. The CoDuSe balance exercise including core stability, dual tasking, and sensory strategies, as the first 15 minutes were mainly focused on core stability that facilitates contraction of the core muscles, also during performing the exercises of dual-task and sensory strategies as carrying something while walking or walking on an uneven surface [9]. The patient performed the core stability exercise inform of pelvic bridging, single leg bridging, prone on the elbow, then as a progression a 4-point kneeling then the patient was asked to try to extend one leg in a straight line from a 4-point kneeling position and to take it back to the starting position, and for more progression, the patient was sitting on a ball and extended one knee forward with both arms across patient's chest, under therapist supervision and guidance to avoid loss of balance.

While for the dual-task training from sitting position the patient was asked to move items as a small ball from one side to another, then as a progression the patient was asked to stand from sitting position while carrying a small ball with a gradually decrease base of support (BOS) then as a more progression the patient was asked to walk while carrying an object in an uneven surface as a foam board, also, the patient performed the sensory strategies tasks like standing on balance board, then gradually progressed as catching a ball during standing on a balance board, then the patient asked to try to take few steps on the irregular surface as walking over small obstacles [9], the exercise parameters were as follow, every exercise was performed 3 to 5 times, with two minutes rest after every exercise to prevent fatigue.

The Square-Stepping Exercise (SSE)

The *SSE* is a simple foot placement pattern that comprised of forward, backward, lateral, and diagonal steps using gridded floor squares [21], their size were (90 × 90 cm) which partitioned into (30 × 30 cm) nine equal squares, that were made from the extra non-slip mat. Before starting, the therapist performed the pattern in front of the patient to describe it in detail, then the patient performed the same step pattern on the floor squares. Pattern recognition and memorization could usually be accomplished after 4-5 repetitions, as when the patient effectively completed the pattern, a different pattern was described by the therapist, as the session consisted of three to five different progressive more complicated step patterns. The difficulty level increased gradually session by session upon four standards: the complexity of the pattern, length, execution in dual multi-tasking conditions [13], and execution speed. Also, there was 1-minute rest after each pattern.

The study group and the control group both received the selected exercise program which included progressive static and dynamic balance exercises, that was presented by the ability to hold trunk against minimal then moderate push in unexpected directions from sitting then standing positions, and as a progression, the patient was standing with a narrow BOS, then the complexity of task increased by walking in a different direction forward, backward and laterally, the patient also was asked to perform turning, bending, and stepping on and off steps, and to walk with reduced BOS. Additionally, the program included lower extremity strength exercise in form of short arc knee straightening: as the patient was supine with a large towel roll below the knee, and was asked to tight the thigh muscles and lift the heel off, and maintain the leg as straight as possible for 5 seconds, then from sitting position the patient asked to perform functional ankle, knee, and hip strengthening activities as the therapist asked the patient to perform repeated heel and toe raises, flexion and

extension exercises for hip and knee, with a repetition of 5 to 10 times for every exercise, followed by 60 seconds rest between every exercise to prevent fatigue [22].

Statistical analysis

An unpaired t-test was conducted for the comparison of subject characteristics between groups. A chi-squared test was conducted for the comparison of sex distribution between groups. The normal distribution of data was checked using the Shapiro-Wilk test. Levene's test for homogeneity of variances was conducted to test the homogeneity between groups. Morse scale and OSI were compared between groups by unpaired t-test and between pre-and post-treatment in each group by paired t-test. SPPB scores were compared between groups by Mann–Whitney U test and between pre- and post-treatment in each group by Wilcoxon Signed Ranks. The level of significance for all statistical tests was set at $p < 0.05$. All statistical analysis was conducted through the statistical package for social studies (SPSS) version 22 for windows (IBM SPSS, Chicago, IL, USA).

RESULTS

Patient characteristics

Table 1 contains the patient characteristics of the study and control groups. There was no significant difference between both groups in age, weight, height, BMI, duration of illness, and sex distribution ($p > 0.05$).

Effect of treatment on MFS, OSI, and SPPB scores

Within-group comparison

There was a significant decrease in MFS and OSI post-treatment in the study and control groups compared with that pre-treatment ($p=0.001$) (Table 2). While there was a significant increase in balance, gait, lower limb strength, and total scores of SPPB post-treatment in the study and control groups compared with that pre-treatment ($p=0.001$) (Table 3).

Between groups comparison

Between groups, pre-treatment comparison revealed no significant difference in all measures ($p > 0.05$), while the post-treatment comparison between both groups revealed a significant decrease in both MFS and OSI of the study group compared with that of the control ($p =0.001$) (Table 2). While there was a significant increase in balance, gait, lower limb strength, and total scores of SPPB of the study group compared with that of the control group post-treatment ($p< 0.05$) (Table 3).

Table 1. General characteristics of patients.

Variable	Study group X ± SD	Control group X ± SD	p
Age (years)	36.88 ± 4.01	37.51 ± 2.97	0.51
Weight (kg)	83.18 ± 10	81.66 ± 9.31	0.56
Height (cm)	168.51 ± 6.76	167.03 ± 4.38	0.34
BMI (kg/m^2)	29.24 ± 2.75	29.28 ± 3.31	0.96
Duration of illness (years)	6.37 ± 1.77	6.66 ± 1.92	0.55
Gender			
Females	9 (34.6%)	11 (42.3%)	0.56
Males	17 (65.4%)	15 (57.7%)	

X – mean; SD - standard deviation; p- statistical significance

Table 2. Comparison of Morse Fall Scale and OSI between the study and control groups.

Test	Variable	Study group X±SD	Control group X±SD	MD (95% CI)	Statistical significance
MFS	Pre treatment	51.66 ± 14.14	48.7 ± 15.41	2.96 (-5.11: 11.04)	t=0.73; p=0.54
	Post treatment	21.66 ± 7.72	29.62 ± 6.92	-7.96 (-11.96: -3.95) d = 1.08	t=-3.99; p=0.001*
	MD (95% CI)	30 (26.61: 33.38) d = 3.48	19.08 (14.82: 23.32) d = 1.79	—	
	Statistical significance	t=18.23; p=0.001*	t=21.7; p=0.001*		
OSI	Pre treatment	3.05 ± 0.23	3.14 ± 0.33	-0.09 (-0.25:0.06)	t=-1.22; p=0.22
	Post treatment	1.49 ± 0.25	2.06 ± 0.27	-0.57 (-0.71: -0.42) d = 2.19	t=-7.92; p=0.001*
	MD (95% CI)	1.56 (1.43: 1.67) d = 5.19	1.08 (0.91: 1.24) d = 2.66	—	
	Statistical significance	t=19.07; p=0.001*	t=1.04; p=0.001*		

X – mean; SD - standard deviation; MD - mean difference; CI - confidence interval; d - cohen effect size; MFS - Morse Fall Scale; OSI - Overall Stability Index; p- statistical significance; *p<0.05.

Table 3. Comparison of SPPB scores between the study and control groups.

Variable	SPPB	Study group M (IQR)	Control group M (IQR)	Statistical significance
Balance (points)	Pre treatment	2 (2-2)	2 (3-1)	U=353.5; p=0.83
	Post treatment	4 (4-3)	3 (4-2)	U=233.5; p=0.01*
	Statistical significance	z=4.69; p=0.001*	z=4.91; p=0.001*	—
Gait speed (points)	Pre treatment	2 (2-1)	2 (2-1)	U=340.5; p=0.65
	Post treatment	3 (4-3)	3 (3-2)	U=201; p=0.002*
	Statistical significance	Z=4.69; p=0.001*	Z=4.26; p=0.001*	—
Lower extremity strength (points)	Pre treatment	2 (3-1)	2 (2-1)	U=305.5; p=0.26
	Post treatment	3 (4-3)	3 (3-2)	U=147; p=0.001*
	Statistical significance	Z=4.71; p=0.001*	Z=4.47; p=0.001*	—
Total	Pre treatment	6 (7-5)	5 (7-4)	U=322.5; p=0.45
	Post treatment	10 (11-9)	8 (9-7)	U=122.5; p=0.001
	Statistical significance	Z=4.58; p=0.001*	Z=4.63; p=0.001*	—

M - median; IQR - inter-quartile range. U - Mann-Whitney test value; Z - Wilcoxon signed ranks test value; p - statistical significance; *p<0.05.

DISCUSSION

The balance is a complex process including the reception and integration of sensory inputs and the movement planning and execution, which considered the most common problems in patients with MS, hence, the current study found that there was a significant improvement in both balance and a reduction in fall risks in the study group that received the CoDuSe balance training and SSE combined with the selected exercise program in comparison with the control group.

Reducing the risk of fall in the rehabilitation of MS patients is usually designed to reduce the environmental risk factors, improve both muscle power and joint flexibility, or increase the base of support, hence the current study adds more knowledge on the combined roles of feedback cues as somatosensory and proprioceptive stimulation during standing and walking on the irregular surface over small obstacles, together with improving core stability functions and increase patients ability to progress from position to another position during performing different dual tasks as moving from sit

to stand while carrying a small ball with a reduced BOS which in turn increase patient concentration and cognitive functions, therefore, promote risk awareness, planning, concentration and attention functions

Additionally, the intervention in the study group included the SSE that was designed to reduce falls by enhancing the task performance in different movements and multiple directions hence it appears logical to assume that the functional ability of the lower extremities improved more during SSE than with regular exercises or walking, also the time need for improvement in the study group was less than the control group as the patients in the study group showed more functional improvement after two weeks than the control group, all these factors promote more improvement in the study group than the control group that depends mainly on muscle power and balance exercise only.

Regarding the study group of the current study, the results were consistent with Forsberg et al [5] who studied the impact of a balance exercise training focused on CoDuSe exercise in patients with MS and their effect on postural sway, balance, and walking, after a program of seven-week, twice-weekly sessions, the results revealed that there was an improvement on balance as the CoDuSe exercise program focused on the core stability training during the exercises in sitting, standing, and walking.

Impaired equilibrium and trunk control with the difficulty to perform dual tasks are common in patients with MS, accordingly, CoDuSe exercises help in reducing fall recurrence, these results were supported by Carling, et al [9] who evaluated the effects of CoDuSe training on balance and walking in MS patients, this study found that the CoDuSe exercise improved balance and decreased limitations of gait, as the treatment decreased the number near falls and falls. One of the main causes of patient improvement in the study group is that dual-tasking and SSE also could help in improving cognitive functions which could help patients with neurological disorders to be more focused during performing activities thus reducing the risk of fall [23].

The CoDuSe exercise, based mainly on core stability in combination with dual-task and sensorimotor training, hence the CoDuSe exercise training in MS can facilitate sensory compensation, decrease the risk of falls and improve both the dynamic and static balance [9]. Also, Amrita and Rekha [12] reported that the CoDuSe training is more effective than the exergaming exercise to improve equilibrium and balance and reduce falls as well as near falls scores in MS patients. The exercises in various sensory settings including proprioceptive-visual training, appear to be applicable to enhance balance in MS patients [24].

The risk of fall prevention exercise programs that depend on the ability to perform movements with various complexity, amplitude, speed, and additional cognitive load is important for the avoidance of falls, thus the stepping square exercise (SSE) training that includes the same aspects had a significant result in falls reduction,[13,25] as it improves balance and prevents fear of fall [14]. The SSE stimulates the activation of lower extremities agonist and antagonist's muscles, thus leads to improve the fitness of lower limb, functional ability and preventing fall among older adults [26], so the SSE training for fall-prone patients who always suffer from neuromuscular, or sensory, and cardiopulmonary deficiencies could be improved by the increase in movement speed that rises the demands in these systems which leads to an increase in physiologic reserve, after the repeated exercise program [27].

Furthermore, stepping exercises improves functional outcome as it facilitates the actions that should be done in real life to prevent fall, additionally, the various high-intensity stepping exercises enhances walking speed and other kinematics of walking in neurological patients [28]. Sebastião et al [26] stated that the SSE program for MS was safe and feasible, therefore the SSE training had an obvious improvement effect in fall risk prevention, balance, gait, and cognition in MS. The findings of a previous study by Okubo et al, [28] revealed that both voluntary and reactive stepping training reduced older adults' falls by nearly fifty percent, due to the improvements in reaction and response time, gait, and equilibrium performance. The program of fall prevention stepping training should incorporate multidirectional steps and furthermore focus on the adaptation of step length to be effective [29]. Pereira et al [21] also revealed a significant improvement effect of SSE on depressive symptoms, mobility, and functional balance in older people.

Harshika et al [22] compared the effect of SSE versus balance exercises training on fear of falling and balance in the elderly, and the results revealed that after four weeks of intervention, both

the SSE and the balance training were effective in improving balance, as the SSE group showed a significant reduction of risk of fall scores and improvement on balance, compared to the selected exercise program group. On the other hand, a previous study by Cho et al [30] confirmed that the training program of lower extremity strength correlated directly to the risk for falls and balance.

The current study's limitation was the incapability to follow up the long-term outcomes of CoDuSe balance training on quality of life in MS because of deficiency of follow up after the rehabilitation period, so for future studies, it would be helpful to assess the long-term outcomes, it is also recommended for future studies to investigate the effect of SSE and balance training on different gait parameters and functional performance, and other neurological disorders.

In conclusion, the findings of this study concluded that CoDuSe balance training and step square exercises are considered an important issue in MS rehabilitation program as both exercises reduced the risk of fall and improved balance, accordingly it should be incorporated in the rehabilitation program for the balance training in neurological cases especially patients with MS.

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