Clinical Rehabilitation 2007; **21**: 771–781

Effects of balance exercises on people with multiple sclerosis: a pilot study

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Received 30th September 2006; returned for revisions 26th November 2006; revised manuscript accepted 29th January 2007.

Objective: To evaluate the effects of balance retraining in a sample of people with multiple sclerosis.
Design: Randomized controlled trial.
Setting: Rehabilitation unit.
Subjects: A consecutive sample of 44 subjects was randomized into two experimental groups and one control group. The inclusion criteria were: ability to stand independently more than 30 seconds, ability to walk for 6 m.
Interventions: Group 1 received balance rehabilitation to improve motor and sensory strategies. Group 2 received balance rehabilitation to improve motor strategy. Group 3 received treatments not specifically aimed at improving balance.
Main outcome measure: Berg Balance Scale, Dynamic Gait Index and fall frequency were used to assess balance impairments. Dizziness Handicap Inventory and Activities-specific Balance Confidence were used to assess handicap and the level of balance confidence.
Results: Frequency of falls post treatment was statistically different among groups ($P = 0.0001$); The Berg Balance Scale showed an overall statistically significant difference ($P = 0.0008$) among groups. Change pre–post scores were 6.7, 4.6 and 0.8 points for groups 1, 2 and 3. Dynamic Gait Index showed an overall near statistically significant difference among groups ($P = 0.14$), with change pre–post scores of 3.85, 1.6 and 1.75 points for groups 1, 2 and 3; after the exclusion of drop-outs a statistically significant difference was observed ($P = 0.04$). The self-administered tests (Activities-specific Balance Confidence and Dizziness Handicap Inventory) did not show clinically relevant improvements.
Conclusions: Balance rehabilitation appeared to be a useful tool in reducing the fall rate and improving balance skills in subjects with multiple sclerosis. Exercises in different sensory contexts may have an impact in improving dynamic balance.

Introduction

Abnormalities in balance control are common findings in people with multiple sclerosis[1–3] and can along with other risk factors increase risk of falls.[4] These abnormalities, together with other impairments and disabilities, often prevent people from performing their daily

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10.1177/0269215507077602

living activities. In the past decade much attention has been directed towards the rehabilitation of balance in elderly people. Recently the assessment[5,6] and the treatment[7–10] of balance and gait impairments in multiple sclerosis have gained more interest within the scientific community.

One of the goals of balance rehabilitation is to reduce the number of falls, however the frequency of falls cannot be considered the only outcome for balance rehabilitation. Falls may not be a reliable outcome because people tend to not report falls, or they consider a fall only if they hit the ground. Moreover, a reduction of range of activities may in part reduce the frequency of falls. Thus it is of primary importance to assess balance skills in different relevant tasks (e.g. during standing and walking) and to assess patients' perception of their own balance. Perception of balance may be an important factor in explaining the level of disability because balance perception can have direct consequence on patients' behaviours.

Sensory strategies allow the central nervous system to select and mix the relevant incoming input thus allowing the balance system to adapt its output to a variety of environmental contests and tasks. The rehabilitation of sensory strategies is an integral part of the rehabilitation programme in many published trials.[11–14] Since demyelinization of sensory pathways is a common finding in multiple sclerosis special attention has to be directed to the sensory impairments.

In recent years we have studied the frequencies of falls and the risk factors of falls in multiple sclerosis.[4] We have also evaluated the validity[15] and reliability[16] of the balance scales used to measure rehabilitation outcome in this population. This pilot study was set up to assess the effectiveness of balance rehabilitation and to estimate parameters for the implementation of a larger randomized control trial.

The aim of this study was to evaluate the effects of balance retraining in a population of people with multiple sclerosis with two different ways of improving balance, one focused purely on motor retraining and the other on an integrated sensory motor retraining.

Materials and methods

From 1 January 2004 to 30 December 2005 a consecutive convenience sample of 87 inpatients with multiple sclerosis referred for rehabilitation to the Department of Multiple Sclerosis of Don Gnocchi Foundation were assessed.

Subjects who met the following inclusion criteria were enrolled in the study: clinically or laboratory definite relapsing–remitting, primary or secondary progressive multiple sclerosis,[17] ability to stand independently in upright position for more than 3 seconds in order to be able to complete the first items of the standing balance test, maximum score of 53 on the Berg Balance Scale in order to not include subjects with high level of balance and to allow some points for improvement, ability to walk for 6 m even with an assistive device.

Subjects who had already received the planned treatment regime were excluded.

A subgroup of 50 subjects met the inclusion–exclusion criteria and were enrolled in the study (Figure 1). Four subjects dropped out because they were discharged from the hospital before the end of the protocol and two subjects dropped out for unknown reasons.

Assessment

After informed consent was obtained, subjects completed a questionnaire providing information about their age, the onset of pathology, and the number of falls one month before the assessment procedure. A fall was defined as any event that led to an unexpected contact with a support surface. Due to the natural course of the pathology we restricted the fall report to one month prior to the evaluation in order to obtain a reliable picture of subjects' characteristics. Subjects were tested wearing their normal shoes and the assessment was carried out in one session. The assessment protocol consisted of one test on static balance and one test on dynamic balance as primary outcome measures and two self-administered scales on balance confidence and level of handicap.

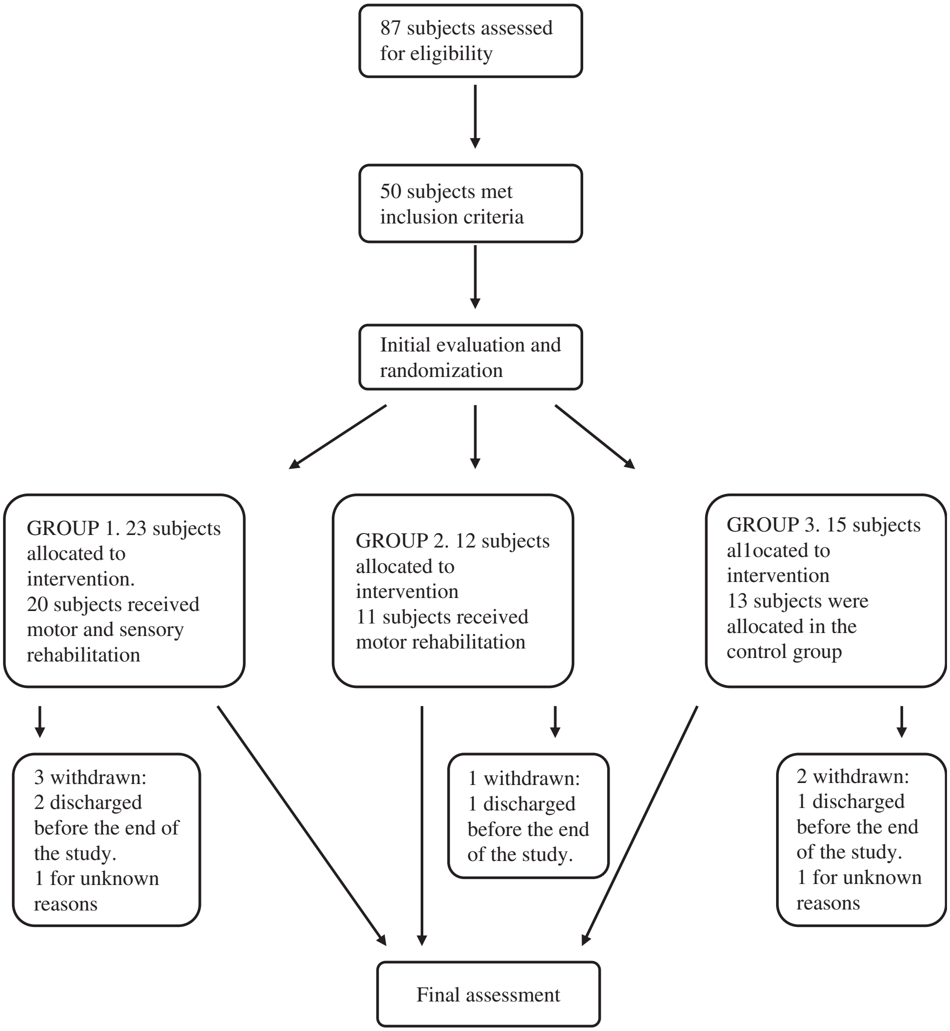

Figure 1 Flow of subjects through the study.

Berg Balance Scale

This scale rates performance from 0 (cannot perform) to 4 (normal performance) on 14 items with a maximum total score of 56.[18,19] The validity and reliability of the scale have been assessed on populations of subjects with multiple sclerosis.[15,16]

Dynamic Gait Index

This scale measures the mobility function and the dynamic balance. The performance is rated on a 4-point scale. The total score ranges from 0 to 24. A score of 19 or less has been shown to be related to self-reported falls in people with vestibular disorders.[20] The psychometric properties of the scale have been assessed in people with vestibular disorders[21] and with multiple sclerosis.[15,16,22]

Dizziness Handicap Inventory

This scale is a multidimensional self-administered scale that quantifies the level of disability and handicap in three subscales. Scores range from 0 to 100, with 0 being the best score. We reversed the score range (making 100 equal to 0 and 0 equal to 100).

The Dizziness Handicap Inventory has demonstrated good internal consistency (0.91) and test–retest reliability (0.97) in a population of dizzy subjects[23] and good validity and reliability for people with multiple sclerosis.[15,16]

Activities-specific Balance Confidence

This is a scale in which the subject rates his or her perceived level of confidence while performing 16 daily living activities.[24] Scores range from 0 to 100, where 100 means high level of confidence in balance skills. The test–retest reliability of the Activities-specific Balance Confidence scale among people who have a lower limb amputation was found to be 0.91. The validity and reliability of the scale have been assessed and found to be good for people with multiple sclerosis.[15,16]

Whenever possible an independent rater not directly involved in the treatment rated both the initial and the final assessment. The rater was not masked with respect to the subject's group assignment. The raters did not have further access to any of the initial scores before the second assessment.

Following initial assessment, the subjects were randomly assigned to three subgroups using computer-generated random numbers. We allocated subjects by matching the order of subjects' entry to the hospital with a randomization list made before the start of the study. The ratio of subjects within each group was 2:1:1 for groups 1, 2 and 3; subjects were blinded with respect to group assignment.

Group 1 received balance rehabilitation aimed at improving motor strategies and sensory strategies. Group 2 received balance rehabilitation just for motor strategies, whereas the sensory strategies retraining was withheld. Group 3 received 'conventional therapy', which means treatment not specifically aimed at balance rehabilitation. No other co-interventions were allowed during the intervention.

Intervention

Following evaluation of balance disorders and group allocation each subject received intensive practice with a multidimensional exercise programme (see Appendix). Because of the high variability of symptoms a tailored rehabilitation programme was developed based on each group's specific protocol.

During the treatment sessions we stressed the function, quality of performance of the tasks retrained and the underlying impairments. The difficulty of the exercises was based on the subject's performance and followed the subject's level of recovery. The difficulty of exercises generally progressed from body stability exercises to gait exercises in a variable environment.

Biofeedback techniques were also used. These included positional, force feedback and verbal cues provided by the therapist. In order to maximize the benefits of the training known principles of motor learning were applied to the treatment protocols.[25–28]

Guidelines for the intervention were developed and discussed with the therapists. The treating therapists had long clinical experience in the protocol development. Each subject, irrespective of group assignment, had a total of between 10 and 12 sessions spread over three weeks, each session lasting 45 minutes.

Data analysis

Descriptive statistics were used to detect the presence of outliers. One subject in group 2 was considered an outlier and thus removed from the analysis. The normality of distributions and the homogeneity of variances were assessed by Shapiro–Wilks and Levene tests. Berg Balance Scale cubed scores were computed to improve the normality of distribution. To exclude misleading results from analysis of variance both parametric and non-parametric tests were computed on post scores. No relevant differences were observed between tests, so parametric tests were reported. Baseline characteristics and change scores among the three groups were compared using one-way ANOVA. Statistical differences between groups were assessed with Newman–Keuls post hoc test. Because of the low percentage of subjects who fell during the rehabilitation trial the differences in percentages of falls among groups were analysed by the *G*-score.[29] The *G*-scores uses logarithmic transformation of frequencies and is more robust than chi-square for low frequencies.

All group comparisons were based on an intention-to-treat analysis.

Because some subjects' Berg Balance Scale and Dynamic Gait Index test scores were close to the maximum possible score a ceiling effect might have occurred. To control this problem, efficiency of therapeutic treatment was calculated as:

$$\text{Efficiency} = \frac{\text{post} - \text{pre}}{\text{max} - \text{pre}} \times 100$$

where pre was the subject's score at baseline, post was the subject's score after the rehabilitation protocol and max was the maximum score for each test. Using transformation of data allowed us to compare the efficiency of the therapy with respect to the maximum score possible (max score 56 on the Berg Balance Scale) and thus to assess the expected percentage amount of improvement for each patient irrespective of the number of points to recover.

On the basis of our experience, and with respect to the population treated, the kind of treatment and the number of sessions, we set a clinically significant improvement as an increment of 4 points for Berg Balance Scale and 3 points for Dynamic Gait Index.

The level of statistical significance test was set at $P < 0.05$, and we defined a near statistically significant level as a *P*-level ranging from $P < 0.06$ to $P < 1.5$.

Results

The whole group consisted of 13 men and 31 women, mean age 46.0 years, standard deviation (SD) 10.2 years. The mean onset of pathology was 13.8 years (8.1 years SD) before the beginning of the study (Table 1). Fifteen subjects used a walking aid in their daily activities.

The demographic characteristics of the sample were similar to those reported in other studies.[4,15]

Table 1 Sample characteristics

	Group 1	Group 2	Group 3
Age (years)			
Mean	44.8	47.7	46.5
SD	11.2	8.7	10.7
Min	26.6	34.8	25.6
Max	66.8	61.2	62.8
Onset[a] (years)			
Mean	13.2	15.0	13.3
SD	10.1	4.4	8.7
Min	2.4	7.4	4.4
Max	37.7	19.4	27.3
Assistive device (%)	35.0	36.4	30.8
Male (%)	15	36.4	46.2

Group 1: Treated group: sensory and motor strategies; Group 2: Treated group: motor strategies only; Group 3: Control group.
[a]Years from the beginning of the pathology.

The three groups were matched for all variables. No statistically significant differences were found in the sample characteristics (Table 1) or in baseline measures among the three groups (Table 2).

The relative frequencies of subjects who had one or more falls pre treatment were (percentage and (number of falls)) 42 (8), 45 (5) and 45 (6)% for groups 1, 2 and 3, respectively; the differences among groups were not statistically significant (χ^2: $P = 0.98$). Post-treatment relative frequencies of subjects who had one or more falls were 5 (1), 10 (1) and 25 (3)% for groups 1, 2 and 3, respectively; the differences among groups were statistically different (χ^2: $P = 0.0001$).

Berg Balance Scale showed a difference between pre and post scores of 6.7, 4.6 and 0.8 points for groups 1, 2 and 3, respectively (see Tables 2 and 3 for means and change scores). The analysis of variance showed an overall statistically significant effect for group ($P = 0.0008$). Post-hoc analysis reported statistically significant differences between groups 1 and 3 ($P = 0.01$) and between groups 2 and 3 ($P = 0.03$); no statistically significant differences were found between groups 1 and 2. One subject in group 1 and one in group 2 reached the maximum score of the scale. No differences were observed with the exclusion of drop-outs.

Dynamic Gait Index showed a difference between pre and post scores of 3.85, 1.06 and

Table 2 Results of the four primary outcome measures at baseline and post treatment for the three groups

	Group 1		Group 2		Group 3	
	Pre	Post	Pre	Post	Pre	Post
A) Berg Balance Scale and Dynamic Gait Index tests						
Berg Balance Scale						
Mean	43.90	50.55*	44.30	48.90^	41.31	42.15
SD	7.22	4.16	5.37	5.58	9.64	9.29
Min	25.00	43.00	35.00	37.00	22.00	24.00
Max	53.00	56.00	51.00	56.00	53.00	55.00
Dynamic Gait Index						
Mean	13.95	17.80†	13.44	14.50	10.92	12.67
SD	3.84	4.18	4.84	5.40	6.71	6.96
Min	8.00	10.00	5.00	7.00	1.00	0.00
Max	20.00	24.00	22.00	23.00	21.00	23.00
B) Activities-specific Balance Confidence and Modified Dizziness Handicap Inventory tests						
Activities-specific Balance Confidence						
Mean	38.50	40.82	39.05	51.60	43.89	44.79
SD	20.42	21.79	14.35	14.83	21.77	18.52
Min	8.13	8.13	16.88	29.38	10.00	19.38
Max	80.00	83.13	61.87	71.87	70.63	70.63
Modified Dizziness Handicap Inventory						
Mean	42.88	47.75	53.71	56.00	47.67	45.50
SD	22.80	17.31	12.98	16.08	20.76	26.45
Min	8.00	12.00	34.00	30.00	10.00	6.00
Max	88.00	82.00	74.00	74.00	84.00	86.00

Group 1: Treated group: sensory and motor strategies; Group 2: Treated group: motor strategies only; Group 3: Control group.
*Statistically significant difference between group 1 and 3.
^Statistically significant difference between group 2 and 3.
†Statistically significant difference between group 1 and 3 with the exclusion of drop-outs.

1.75 points for groups 1, 2 and 3, respectively (see Tables 2 and 3 for means and change scores). The analysis of variance showed a near overall statistical significant effect for group ($P = 0.14$). The results of ANOVA reached a statistically significant effect with the exclusion of drop-outs ($P = 0.04$). In this case the means post treatment among groups were 18.25 (4.37 SD), 15.22 (5.19 SD) and 13.54 (6.56 SD) for groups 1, 2 and 3. Change scores were 4.65 (95% CI 2.68, 6.56), 1.77 (95% CI −0.45, 4.01) and 1.90 (95% CI −0.57, 4.39) points for groups 1, 2 and 3, respectively. Post-hoc analysis for this condition reported statistically significant differences between groups 1 and 3 ($P = 0.04$) and a near statistically significant difference between groups 1 and 2 ($P = 0.08$).

With respect to Berg Balance Scale the mean values of efficiency in the three groups were (mean (SD)): 55.1% (32.6%), 40.2% (45.0%) and 5.0% (52.3%) respectively for groups 1, 2 and 3. This means that subjects of group 1 (drop-outs included) recovered on average 55.1% of the points available for Berg Balance Scale. The ANOVA showed an overall statistically significant difference among groups ($P = 0.008$). Post-hoc analysis showed statistically significant differences between groups 1 and 3 ($P = 0.01$) and between groups 2 and 3 ($P = 0.04$).

With respect to Dynamic Gait Index the mean values of efficiency in the three groups were 42.1% (32.5%), 11.0% (36.2%) and 12.5% (40.3%) respectively for groups 1, 2 and 3. The ANOVA showed an overall statistically significant difference among groups ($P = 0.03$). Post-hoc analysis showed statistically significant differences between groups 1 and 3 ($P = 0.04$)

Table 3 Change scores pre–post treatment of the four primary outcome measures

	Groups		
	1	2	3
Berg Balance Scale			
Change[a]	6.65	4.60	0.85
95% −	3.59	0.81	−1.29
95% +	9.71	8.39	2.98
Dynamic Gait Index			
Change[a]	3.85	1.06	1.75
95% −	2.10	−0.91	−0.52
95% +	5.60	3.03	4.02
Activities-specific Balance Confidence			
Change[a]	2.32	12.55	0.90
95% −	−9.45	−.95	−8.06
95% +	14.09	26.05	9.87
Modified Dizziness Handicap Inventory			
Change[a]	4.87	2.29	−2.17
95% −	−3.57	−3.77	−10.29
95% +	13.31	8.35	5.95

Group 1: Treated group: sensory and motor strategies; Group 2: Treated group: motor strategies only; Group 3: Control group.
[a]Change scores, 95%: interval coefficient of change scores.

and almost statistical significance between groups 1 and 2 ($P=0.08$).

The self-administered tests (Activities-specific Balance Confidence and Dizziness Handicap Inventory) did not show clinically relevant improvements. Activities-specific Balance Confidence showed a difference between pre and post scores of 2.32, 12.55 and 0.90 points respectively for groups 1, 2 and 3 (see Tables 2 and 3 for means and change scores). The analysis of variance did not show an overall statistically significant effect for group ($P=0.79$). No differences were observed with the exclusion of drop-outs.

The Dizziness Handicap Inventory showed a difference between pre and post scores of 4.87, 2.29 and −2.17 points for groups 1, 2 and 3, respectively (see Tables 2 and 3 for means and change scores). The analysis of variance did not show an overall statistically significant effect for group ($P=0.43$). No differences were observed with the exclusion of drop-outs.

Discussion

The aim of this study was to evaluate the effects of balance retraining in a population of subjects with multiple sclerosis as well as, to evaluate the impact of retraining of sensory strategies on static and dynamic balance.

A relevant effect of balance retraining was the reduction of the number of falls. Pretreatment falls were similar in the three groups of subjects; conversely, following treatment the number of subjects who had a fall was reduced in the two experimental groups.

The clinical test of static balance (Berg Balance Scale) showed a clinically relevant improvement. The results obtained in this study were similar to those obtained by Lord *et al.*[9] Although Lord and colleagues did not specifically address static balance disorders they showed a comparable improvement in the Berg Balance Scale score but with higher variability between scores. Differences between our study and the study by Lord *et al.* consisted in subject samples with different levels of balance impairments and number of rehabilitation sessions.

The clinical test of dynamic balance (Dynamic Gait Index) showed a clinically relevant improvement. Improvements in gait and mobility performance were also reported by Solari *et al.*[10] and Lord *et al.*[9] in a slightly different population of subjects with multiple sclerosis following rehabilitation.

Self-administered scales did not show clinically or statistically significant improvements.

The difference between performance and self-administered tests raises interesting questions about the discrepancy between those two dimensions of balance. One way of explaining this difference could be the lack of effectiveness of the present rehabilitation protocol in promoting balance in more complex real-life activities. A second possibility could be the nature of the self-administered tests and the actual environmental constrains. On the Activities-specific Balance Confidence test, for example, there are items asking if the subject feels confident performing activities such as stepping onto or off an escalator or walking in a crowded shopping centre. Since our sample consisted of inpatients they were unable to experience the effects of treatment received in all the daily living situations listed in the Activities-specific Balance Confidence test and thus relied on a prior evaluation that did not take into account the potential benefits of treatment.

With respect to static balance (Berg Balance Scale) the inclusion of sensory strategies in the rehabilitation protocol did not affect the performance. The same was true for the prevention of falls: no relevant difference in number of fallers was observed within the two groups of treated subjects. Conversely, with respect to dynamic balance just the group treated with sensory strategies showed a statistically difference compared to the control group; moreover, the differences in change scores between the group treated with sensory strategies (group 1) and the group who sustained the same treatment without the use of sensory strategies (group 2) were almost significant. This may imply a higher importance of rehabilitation of sensory strategies for dynamic balance with respect to static balance. Balance in general is more challenged during dynamic activities than during stance, especially for people with multiple sclerosis who, besides trouble with sensory strategies, often have muscle weaknesses and problems with coordination. During dynamic activities sensory conflict may occur more frequently since input signals are complex and thus efficient integration of information is even more important. Thus, the improvement of sensory strategies seems necessary to allow a more effective use of motor strategies.

Finally, the large standard deviation of change scores observed within the treated groups showed that improvements greatly varied across patients. This imposed a closer evaluation of the scores of each subject to verify the presence of specific causes that could have led to poor or good improvements. At first glance the subjects' test scores did not reveal any specific patterns. However, there was a moderate consensus among treating therapists on general predictive variables. Subjects who have never received a rehabilitative programme, who have one sensory impairment (for example just vestibular deficit) and did not show marked cerebellar signs appeared to have better outcomes. Another important characteristic that appeared to discriminate between subjects with different levels of recovery was the level of motivation to the treatment. Other less important predictive signs were strength of axial muscles (especially hip abductors and extensors) and fatigability.

One of the limitations of this pragmatic trial was the lack of masking procedures; this might limit the reliability of results. To reduce this drawback the same rater, not involved in the treatment, usually rated the subjects. The rater was well aware of the potential distortion caused by the use of a not masked rater. A partial estimation of the distortion caused by repeated measures of the same test by the rater involved in this study has already been evaluated[16] and variability of measurements were found to be well under the levels of change scores observed in the present study.

Ceiling effect may have reduced the amount of improvement since four subjects in the treatment groups reached the top score on Berg Balance Scale; other more difficult tests should be used in future studies to monitor balance improvement in this sample of subjects.

A stabilometric platform assessment might also be useful for a closer evaluation of the effectiveness of sensory strategy rehabilitation.

The low number of sessions in our study might be an important issue because there are some evidences of a positive correlation between the outcome of balance rehabilitation and number of treatment sessions.[30] A larger study with a more numerous group of patients, more treatment sessions and a follow-up assessment are needed to increase confidence in the results.

In conclusion, balance rehabilitation appears to be a useful tool in reducing the fall rate and improving balance in subjects with multiple sclerosis. The assessment and rehabilitation protocols used in this study were the same as those currently adopted in our institute. This increases the confidence that the improvements observed may be generalizable to other similar clinical settings. The retraining of sensory strategies may be an essential component in improving balance and in particular dynamic balance. Specificity of intervention may be important. Intervention specifically aimed towards improving balance or tasks related with balance[9] give better results with respect to intervention on strength of lower limbs or aerobic exercises.[7] Further studies have to be carried out to assess the retention of results and

Clinical messages

- Balance rehabilitation may have a positive effect on subjects with multiple sclerosis.
- Exercises carried out in different perceptual conditions appeared to be important in improving dynamic balance.
- Balance rehabilitation should be included in a multidimensional approach aimed at reducing the subject's level of handicap.

the generalization of skills acquired to activities of daily life.

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Appendix – Rehabilitation strategies

Group 1

Group 1 received balance rehabilitation to improve motor and sensory strategies.

Motor strategies

Patients were retrained with standing and dynamic tasks. We paid attention to postural alignment, especially to the attitude of axial segments. More attention was directed toward the patient's ability to detect the position and movements of the centre of mass and to control them. During the execution of exercises attention was directed towards the improvement of ankle strategy. The ability to explore limits of stability with a voluntary shift of the centre of mass and the quantification of its movements were improved also with biofeedback technique and modelling technique.[31] Finally, axial[32] and postural anticipatory strategies were improved using reaching tasks and the manipulation of object with different sizes and weights.

During gait activities two main aspects were addressed: abnormal movement of the centre of mass, especially in the frontal plane, were treated with biofeedback technique. The exercises generally progressed from static tasks toward exercises carried out during gait activities. The same progression was adopted to improve the stability of trunk and head, a positional feedback of axial segments was provided to the patients.

The generalization of results were obtained introducing late in the treatment dual tasks exercises and exercises with the use of the ball to provide an open tasks.

Sensory strategies

With respect to sensory strategies the aim of provided exercises were to promote sensory compensation and habituation.[33] More specifically exercises were used to improve the use of the most impaired sensory system. That usually meant improving vestibular and somatosensory information by a reduction of visual input. For this purpose the exercises for motor strategies were performed in different perceptual contexts. The exercises were done in eyes-closed condition, with the use of foam pads under the feet and with the use of modified lenses. Finally, tasks for improving balance during head, eyes and head and eyes movements were added. Different combinations of sensory conditions were chosen with respect to the individual subject's sensory impairments.

Group 2

Group 2 received task-oriented balance rehabilitation to improve motor strategy and not specifically sensory strategy. This was pursued by improving motor strategies, as described above for group 1, avoiding eyes closed exercises, exercises on foam mat, the use of modified lenses.[34]

Group 3

Group 3 received 'conventional therapy', that is, various therapeutical approaches not directly aimed at improving balance impairments.