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RESEARCH PAPER

Falls prevention and balance rehabilitation in multiple sclerosis: a bi-centre randomised controlled trial

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ABSTRACT

Purpose: People with Multiple Sclerosis (PwMS) have a high incidence of accidental falls that have a potentially detrimental effect on their daily life participation. The effect of balance specific rehabilitation on clinical balance measures and frequency of falls in PwMS was studied.

Method: A bi-centre randomised rater-blinded controlled trial. Participants in both groups received 20 treatment sessions. Participants in the intervention group received treatment aimed at improving balance and mobility. Participants in the control group received treatments to reduce limitations at activity and body function level.

Primary measures were frequency of fallers (>1 fall in two months) and responders (>3 points improvement) at the Berg Balance Scale (BBS). Data was analysed according to an intention to treat approach.

Results: One hundred and nineteen participants were randomised. Following treatment frequency of fallers was 22% in the intervention group and 23% in the control group, odds ratio (OR) and (confidence limits): 1.05 (0.41 to 2.77). Responders on the BBS were 28% in the intervention group and 33% in the control group, OR = 0.75 (0.30 to 1.91). At follow up ORs for fallers and responders at BBS were 0.98 (0.48 to 2.01) and 0.79 (0.26 to 2.42), respectively.

Conclusions: Twenty sessions 2–3 times/week of balance specific rehabilitation did not reduce fall frequency nor improve balance suggesting the need for more frequent and challenging interventions.

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KEYWORDS
Posture; physiotherapy; Berg Balance Scale

➤ IMPLICATIONS FOR REHABILITATION

- Programs for balance rehabilitation can improve balance but their effects in fall prevention are unclear.
- Twenty treatments sessions 2/3 times per week did not reduced frequency of falls in MS.
- The comparison with similar studies suggests that higher intensity of practice of highly challenging balance activities appears to be critical to maximizing effectiveness.

Accidental falls are common in People with Multiple Sclerosis (PwMS) and have a potentially detrimental effect on their daily life participation.[1,2] In two recent meta-analyses, the proportion of fallers among PwMS was found to vary from 30% to 63% in a timeframe ranging from one to 12 months [3,4] underlining the importance of intervening to prevent falls.

Evidence shows that programmes for balance rehabilitation can prevent many falls among older people living in the community,[5] however, evidence for effective interventions to prevent falls in PwMS is limited.[6] An early pilot RCT study using rehabilitation targeting balance on 44 PwMS found a 22.0% reduction of fallers in the intervention groups.[7] In a second study, a cohort of 111 PwMS was treated with various approaches comprising yoga, one to one and group interventions with only the group intervention showing a 35% reduction of fallers.[8]

Exercise interventions using Wii Nintendo to improve balance have shown controversial results. Two studies on the effect of Wii Nintendo on balance, each with 36 PwMS reported positive results in terms of balance recovery as measured with Berg Balance Scale (BBS) and stabilometric platform.[9,10] These results were in contrast with a multi-centre, randomised controlled trial involving 84 PwMS reporting no improvement on the BBS in the group receiving Wii treatment when compared to a group receiving no intervention.[11] Unfortunately, these studies did not report number of falls as an outcome making it impossible to understand their effectiveness in fall reduction.

In summary, falls are a relevant problem for PwMS but there is limited evidence on the effect of balance rehabilitation in preventing falls. This prompted us to set up a bi-centre randomised controlled trial of a balance intervention aimed at falls prevention. Both centres are involved in RIMS.[1] Our hypothesis was that PwMS specifically treated for balance disorders would improve their stability with respect to a control group and that following intervention rate of fallers would be reduced.

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Clinical trial registration number: NCT02390830

Methods

Participants

Between March 2011 and October 2013, a parallel randomised (Rater) blinded controlled trial was carried out in an outpatient rehabilitation setting in Italy and in Czech Republic. All PwMS meeting the following inclusion criteria were included: ability to walk (also with aid) for 6 m and ability to maintain standing position with open eyes for at least 30 s. Exclusion criteria were: Ability to maintain monopodalic-standing position for 10 s, ability to maintain tandem position for 30 s, cognitive disorders hampering the execution of the exercises/assessment. The study was approved by the local Ethics Committees. All participants gave written informed consent prior to inclusion in the study. In each clinical centre, an independent clinician allocated participants to either the control or intervention group according to a randomisation list made before the beginning of the study. The participants' ratio between the control and the intervention group was 1:2. Evaluation was done by a blinded assessor in each centre and group allocation was kept concealed from them throughout the study. Participants were not aware of group assignment.

Intervention

Participants in both groups received 20 treatments sessions lasting 45 min 2/3 times per week by experienced physical therapists trained for the study. Participants in the control group were treated to reduce limitations at body function and activity levels, while treatment for balance disorders was restricted to a maximum of 10 min per session. Participants in the intervention group received at least 25–45 min of balance treatment. The balance treatment was based on recommendations from published sources where the description of the training protocol can be found.[7,12] The treatment protocol was aimed at improving participants' control of posture, and movement of the centre of mass and body segments during static, dynamic and transitional tasks.

Outcome measures

Clinical measures were collected before and at the end treatment. Follow-up measures were collected two months after the end of the study.

Primary outcome measures were number of fallers and number of responders.

Number of fallers: Participants who reported at least one fall at the post assessment or after the follow-up period, and number of frequent fallers: >2 falls in the same period. A fall was defined as "an episode of unintentionally coming to rest on the ground or lower surface that was not the result of dizziness, fainting, sustaining a violent blow, loss of consciousness or other overwhelming external factor".[13] Only four participants reported falls that needed medical attention, thus injurious falls were not reported.

Number of responders: Participants improving more than three points (at post or follow-up minus baseline assessment) on the BBS were defined as responders.[7] The BBS [14] is one of the most frequently used scales to rate balance skills and has a maximum score of 56 (best performance).

The secondary outcome measures were the following:

The Dynamic Gait Index (DGI) [13] is a tool that rates walking function and dynamic balance with a score ranging from 0 to 24 (best score). The Activities-specific Balance Confidence scale (ABC) [16] is a scale in which the subject rates his or her perceived level of balance confidence. Scores range from 0 to 100 (best score). The Timed Up and Go Test (TUG) is a timed test that measures gait and balance. It requires the participants to stand up from a chair, walk 3 m, turn around and be seated.[17]

The validity and reliability of these outcome measures have been established for PwMS.[18,19] To ensure standardisation of the assessments between centres a common instruction booklet was used.

Statistical analysis

Data was analysed according to a preplanned protocol using an intention to treat approach.

The comparisons of number of fallers between groups were done with logistic models.[2] An additional logistic model adjusted for number of fallers at baseline was also calculated. The same procedure was applied for responders on BBS adjusting also for baseline measure.

All secondary outcome measures were estimated using general linear models. The primary analysis only included adjustment for baseline measures. Additional models adjusted for baseline measure, and additional covariates (age, sex and years since the onset of the disease) were calculated. Residuals and influential points were checked. BBS and DGI were transformed (cubed) to improve normality and linearity.

Differences in baseline characteristics between dropouts and treated groups, as well as, differences between centres were tested with logistic regressions and generalised linear models.

On the basis of a previous study,[7] we estimated the sample size (for logistic regression analysis) with a P_1 (the probability of being a faller under H_0) of 0.46 and an odds ratio (OR) between intervention and control group of 0.12.[20] A total of 107 participants were needed (71 in the intervention group and 36 in the control group) to have 98% power at the two-sided 5% significance level.

Results

Overall, 119 participants were recruited (Figure 1). The baseline characteristics of the participants were broadly similar between the two groups (Table 1) although fewer people in the intervention group had a history of more than two falls in the previous two months. No statistically significant differences ($p < 0.01$) were found between centres.

Thirty-three and 36 falls respectively occurred in the study period and during the follow-up. The overall rate of falls was 5.23 per 1000 participant/day at post and 7.14 falls per 1000 participant/day at follow-up.

Primary outcomes

In total, 119 participants were randomised (Figure 1). Fourteen (nine in the intervention group and five in the control group) dropped out during the execution of the study, while 21 (11 in the intervention group and 10 in the control group) dropped out after the end of the intervention. Among these 35 dropouts 10 withdrew from the study because of new co-morbidities. Non-medical reasons for withdrawal were lack of motivation (3), long holiday (2), other/unknown reasons (20).

Fallers

One hundred and five participants (Figure 1) were assessed at the end of treatment. The observed differences in number of fallers and frequent fallers between the intervention and the control

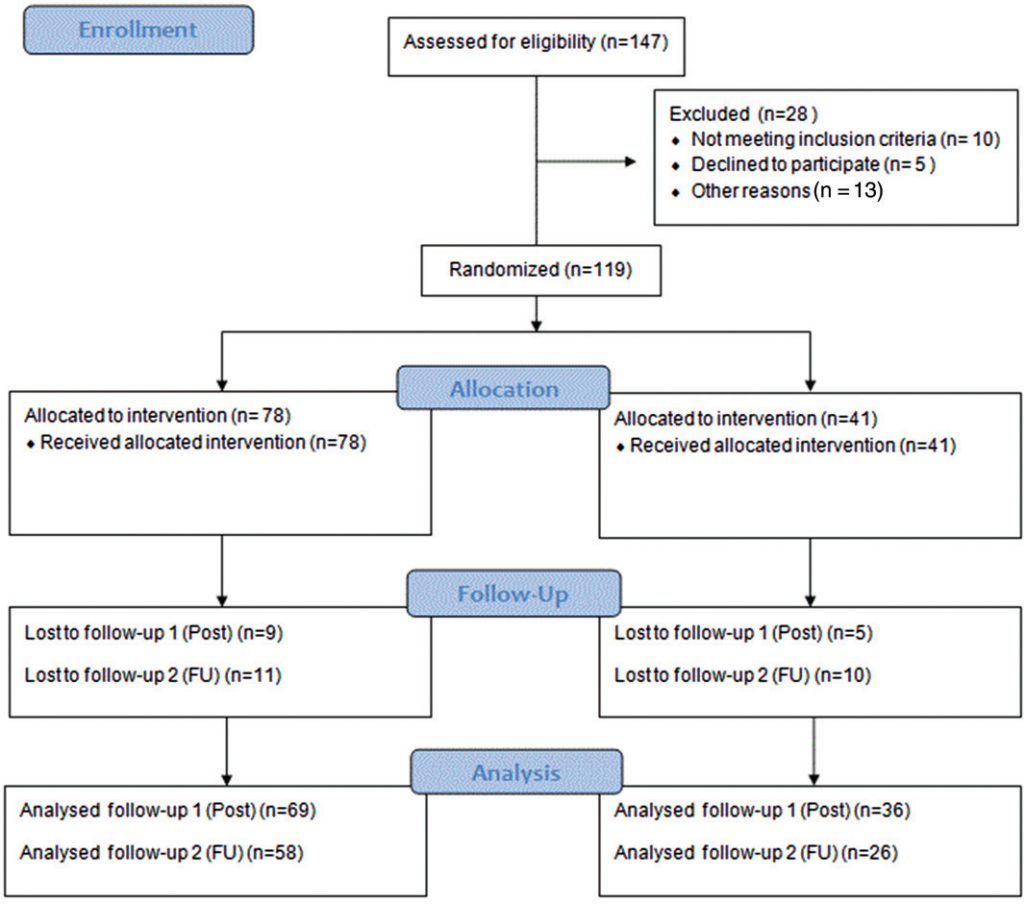

Figure 1. CONSORT flow diagram shows the flow of participants through the trial.

Table 1. Baseline characteristics of participants randomised to intervention group or to control group. Values are numbers (percentages) unless stated otherwise.

Characteristics	(Intervention group) $N = 78$	(Control group) $N = 41$
Female	54 (69)	29 (71)
Mean (SD) Age	48.9 (11.1)	46.7 (11.4)
Mean (SD) Year since the onset	14.0 (8.6)	12.9 (10.4)
Mean (SD) Falls per 1000 subjects day	14 (62)	21 (61)
Fallers with at least one fall	18 (27)	10 (24)
Frequent fallers with > than 2 falls	3 (4)	5 (12)
Mean (SD) Static balance, BBS[a]	46.6 (9.0)	45.9 (10.8)
Mean (SD) Dynamic balance, DGI[a]	16.4 (5.4)	17.0 (6.0)
Mean (SD) Gait and balance, TUG [s][b]	13.2 (9.7)	14.0 (9.9)
Mean (SD) Balance confidence, ABC[a]	53.5 (21.5)	57.2 (23.6)
Walking aid (none)	56 (72)	36 (88)
(Unilateral)	17 (22)	2 (5)
(Bilateral)	5 (6)	3 (7)

[a]Higher score indicates greater level performance.
[b]Higher score indicates lower level performance.

groups were not statistically significant (Table 2). No statistically significant differences were found for fallers after adjusting for fall rates in the two months before the study, OR (±95% CL) was 1.04 (0.37 to 2.90).

At follow up, 84 participants were assessed. A statistically significant difference was observed in number of fallers between the two groups (Table 2), this difference disappeared after adjusting for faller rates in the two months before the beginning of the study, OR was 0.98 (0.40 to 2.42). Furthermore, the difference in number of frequent fallers between the intervention and the control group was not statistically significant. An adjusted model for number of frequent fallers at post and follow-up was ill conditioned and was not calculated.

Responders according to BBS

Post intervention number of responders (%) was 19 (28%) in the intervention group and 12 (33%) in the control group with no statistically significant difference between groups and OR of 0.75 (0.30 to 1.91). Similarly, no statistically significant differences were found adjusting for baseline measures with an OR of 0.73 (0.26 to 2.08).

At follow-up, number of responders was 12 (21%) in the intervention group and seven (25%) in the control group with no statistically significant difference between groups and OR of 0.79 (0.26 to 2.42). No differences were found adjusting for baseline measure, with an OR of 0.82 (0.24 to 2.78).

Secondary outcomes

No significant differences were found between the intervention and the control group in measures of static (BBS) and dynamic (DGI) balance, gait (TUG) or balance confidence (ABC) post intervention (Table 3). Results were similar after adjusting for baseline measures and other covariates. At follow up, both groups showed slight nonsignificant decline in balance performance compared to

Table 2. Effects on fallers at the end of treatments and at two months of follow up according to treatment. Values are numbers (percentages) of participants.

	Post intervention				Follow up			
	(Intervention group) $N = 78$	(Control group) $N = 41$	OR	−95CL to +95CL	(Intervention group) $N = 58$	(Control group) $N = 26$	OR	−95CL to +95CL
Fallers with at least one fall	16 (23)	8 (22)	1.05	0.41 to 2.77	18 (31)	1 (4)	11.3	1.41 to 89.58
Frequent Fallers with more than 2 falls	0 (0)	1(3)	0.95	0.01 to 10.99	4 (7)	0 (0)	0.96	0.14 to 6.28

OR: odds ratio; CL: confidence limits.

Table 3. Effects on balance and secondary outcome measures at the end of the treatments and at two months of follow up according to treatment. Values are means and standard error of means adjusted for baseline measure.

	Post intervention			Follow up		
	(Intervention group) $N = 78$ Mean (St.Err)	(Control group) $N = 41$ Mean (St.Err)	Difference (−95%CI to +95%CI)	(Intervention group) $N = 58$ Mean (St.Err)	(Control group) $N = 26$ Mean (St.Err)	Difference (−95%CI to +95%CI)
Static balance, BBS[a]	49.2 (0.6)	48.9 (0.8)	−0.4 (−2.4 to 1.6)	47.8 (0.6)	47.8 (0.9)	0.0 (−2.2 to 2.2)
Dynamic balance, DGI[a]	17.6 (0.4)	18.1 (0.6)	0.6 (−0.9 to 2.0)	16.9 (0.5)	17.0 (0.8)	0.1 (−1.8 to 2.1)
Gait and balance, TUG[b]	12.4 (0.65)	12.5 (0.65)	0.1 (−1.5 to 1.7)	13.7 (1.2)	11.6 (1.8)	−2.0 (−6.3 to 2.2)
Balance confidence, ABC[a]	59.1 (1.6)	62.9 (2.1)	3.8 (−1.6 to 9.2)	55.2 (3.4)	66.2 (5.3)	10.8 (−2.5 to 19.1)

(St.Err): standard error of means; CI: confidence interval of mean.
[a]Higher score indicates greater level performance.
[b]Higher score indicates lower level performance.

post intervention and again there were no differences between groups.

Dropouts

The participants who dropped out before follow-up did not show statistically significant differences from the rest of the sample except for number of frequent fallers. The number of people having more than two falls was higher among those who dropped out: 7 (20%) versus 1 (0.01%), OR 20 (2.3 to 173.3).

Discussion

This targeted balance intervention programme had no effect on rate of fallers in multiple sclerosis. Furthermore, after completion of the intervention, there were no statistically significant differences between the intervention group and the control group in balance and mobility outcomes.

Results from this study highlight that PwMS are at high risk of falls as evidenced by the frequency of fallers (24–27%) in both groups at baseline. The participants had evident balance and mobility disorders, with a mean BBS score of around 45 points and a DGI score of 17.

After intervention, the overall frequency of fallers was not diminished in either group although both groups had an improved static and dynamic balance with a concomitant slight increase of balance confidence. Balance improvements were similar in the two groups which makes it difficult to understand which components of the respective interventions were effective. The balance improvements seen in this study correspond to improvements observed in a review by Howe and colleagues [21] of studies involving elderly subjects reporting an increase from 2 to 5 points on the BBS post balance intervention.

Regarding effect of rehabilitation on reducing number of fallers, our results are in contrast with those of two previously published studies on falls prevention. Coote et al. [8] found that group physiotherapy intervention involving balance and strengthening exercises using functional positions resulted in a lower number of fallers following intervention. Similarly, Cattaneo et al. [7] found that an intervention involving balance exercises in different sensory contexts led to a reduced frequency of fallers compared to a control group that did not receive a specific balance rehabilitation.

One of the reasons for lack of effect in the present study may be that the intervention was not intensive and multimodal enough to prevent falls. The International MS Fall Prevention Research Network (IMSFRPN) has recently identified the key outcomes for a fall prevention intervention in MS emphasizing the multifactorial nature of falls in PwMS and the need for multimodal interventions to reduce them.[25] Besides balance and strength training, behavioural approaches may be needed in order to alter knowledge, skills, and attitudes about falls.[23]

Second, there is no agreement on the number of treatment sessions needed to achieve a substantial improvement of balance with a concomitant reduction in number of fallers.[24] The treatment procedures provided in this study were similar to those provided elsewhere [7] to a hospital-based population where a reduction in frequency of fallers was found. However, in that study, five sessions per week were provided compared to only two to three weekly sessions in the present study. It is possible that a greater frequency of treatments may partially explain the observed differences in outcome with similar rehabilitation procedures.

Finally, most of the participants with more than two falls in the two months preceding the study dropped out during the study. This could have influenced the outcome since they might have been expected to benefit most from the intervention. Yet another explanation for lack of effect may be the methodology of the study since multi-centre trials tend to show fewer treatment effects compared with single-centre trials [25] that ensure a more homogenous study sample and treatment delivery.

The strength of our study includes: first its large sample size, which resulted in fairly narrow confidence intervals. Second, there were no strong deviations from the random allocation which levelled out differences at baseline, further all participants randomised for the study started the intervention. A limitation of this study is the rate of dropouts. A second limitation is that we did not control for activities performed outside the protocol. It is possible that some falls prevention activities were occurring in both groups. Finally, the current study only used clinical scales to assess balance, adding sensitive instrumental outcome measures of

balance such as posturography might have identified sub-clinical or minor changes in balance performance.

In conclusion, this specific balance protocol with only two to three sessions per week was not effective in reducing falls in PwMS who live in the community. Since falls and mobility impairments remain a serious problem among PwMS, alternative strategies to prevent falls and reduce balance deficits need to be developed. A more intensive treatment, a multivariate intervention and a selection of PwMS likely to improve their balance might result in better outcomes.

Notes

1. http://eurims.org
2. Statistica software.

Disclosure statement

The authors report no conflict of interest related to the manuscript that could inappropriately influence their work.

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