A Randomized Controlled Trial of an Enhanced Balance Training Program to Improve Mobility and Reduce Falls in Elderly Patients

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OBJECTIVES: To evaluate the effectiveness of an enhanced balance training program in improving mobility and well-being of elderly people with balance problems.

DESIGN: Prospective, single-blind, randomized, controlled trial.

SETTING: District general hospital.

PARTICIPANTS: One hundred ninety-nine patients aged 60 and older with a Berg Balance Scale (BBS) score of less than 45.

INTERVENTIONS: Six weeks enhanced balance training consisting of a series of repetitive tasks of increasing difficulty specific to functional balance. The control group received physiotherapy conforming to existing practice in elderly patients with mobility problems.

MEASUREMENTS: Ten-meter timed walk test (TWT), BBS, Frenchay Activities Index (FAI), Falls Handicap Inventory (FHI), and European Quality of Life questionnaire (Euroqol) measured at 6, 12, and 24 weeks after intervention.

RESULTS: The mean age ± standard deviation of subjects was 82.7 ± 5.6, and baseline characteristics were comparable between the groups. Both groups showed improvements in TWT (intervention: 22.5–16.5 seconds, $P = .001$; control: 20.5–15.8 seconds, $P = .054$), BBS (intervention: 33.3–42.7, $P = .001$; control: 33.4–42.0, $P < .0001$), FAI (18–21, $P = .02$ in both groups), FHI score (intervention: 31–17, $P = .0001$; control: 33–17, $P = .0001$) and Euroqol score (intervention: 58–65, $P = .04$; control: 60–65, $P = .07$). There were no intergroup differences at any time. More patients reported increased confidence in walking indoors (36% vs 28%; $P = .04$) and outdoors (27% vs 18%; $P = .02$) in the enhanced balance-training group.

CONCLUSION: Exercise programs significantly improve balance and mobility in patients with balance problems, independent of strategy. Enhanced balance training may, in addition, improve confidence and quality of life but needs further investigation. **J Am Geriatr Soc 51:847–852, 2003.**

Key words: elderly people; balance; mobility; falls; quality of life; physiotherapy; outcome research

Falls are a common problem in older people; one or more falls have been reported by one-third of the population aged 75 and older and account for two-thirds of home accidents.[1] Balance-related problems also result in considerable health and social services costs because of loss of confidence, injury, inability to maintain a safe environment, and dependence in basic functional activities.[2,3] It is not surprising that prevention of falls has been identified as a priority in national healthcare programs.[4]

Several studies have shown the effectiveness of rationalization of drug treatment regimens, appropriate management of disease processes, intensive exercise training, and environment reengineering in reducing the number of falls in elderly patients.[5,6] Most successful physical therapy programs have used nonspecific exercise interventions or combined balance therapy with other exercises such as resistance training.[7–10] This "black box" approach to falls rehabilitation makes it difficult to evaluate which individual components in the therapy program are responsible for favorable outcomes. Analysis of pooled data from intervention studies suggests that emphasis on balance training may reduce falls by 25%,[6] but methodological differences between studies and post hoc determination of the nature of interventions actually provided to subjects limit this conclusion.

The method of outcome measurement may also be important. Most studies have used reduction in the number of falls as the primary outcome measure, although in a day-to-day context, other aspects of balance such as improvements in mobility, function, confidence, and quality of life may be more relevant to patients.[3,4] Of these, walking is particularly important; patients' perception of their

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walking ability correlates with balance, and walking speed can discriminate between fallers and nonfallers, especially when static assessments fail to show impairment of balance.[11]

Enhanced balance training exercises are designed to improve confidence, mobility, and functioning in a day-to-day context.[12] Balance training includes equilibrium control exercises that are repetitive and graded in complexity that enhance balance by improving sway control and inhibiting inappropriate motor responses.[9,12] However, whether enhanced balance training has any advantages over balance training undertaken as a part of conventional physiotherapy remains open to question. The objective of this randomized, controlled trial was to evaluate the effectiveness of enhanced balance training in improving mobility and function in elderly people with impaired balance.

METHODS

Design

This study was a single-blind, randomized, controlled trial of 198 subjects aged 60 and older allocated to the intervention group receiving enhanced balance training (EBT) or to the control group receiving conventional physiotherapy (CT). The Bromley Local Research Ethics Committee approved the study.

Patient Selection

Subjects were recruited from attendees at the multidisciplinary falls clinic. A comprehensive medical assessment was undertaken using a standardized protocol, and potential risk factors for falls were addressed. This included assessments for neurological disorders, locomotor diseases, cardiac disease, and vascular disease and evaluation of medication that might contribute to falls. Patients were included if they continued to have balance problems after adequate management of potential risk factors, identified as a Berg Balance Scale (BBS) score of less than 45.[13]

The study excluded amputees, patients unable to walk less than 10 meters, recent stroke ($<$6 months), progressive neurological disorder, unstable medical conditions, or severe cognitive impairment (abbreviated mental test score $<$7)[14] that would preclude their ability to participate in the exercise programs.

Block randomization was undertaken in groups of 30 using computer-generated random numbers. Allocation schedules were prespecified, and consecutive patients were assigned to EBT or CT interventions on the basis of name and hospital number alone. The clerical assistant communicated assignment directly by the therapist delivering the treatment.

Interventions

Mainstream clinical physiotherapists of equal grade and experience, who followed a written protocol in each group, treated patients in the EBT and CT groups. Individual exercises for EBT and CT groups were clearly described in these protocols, which adhered to national guidelines recommended by the Chartered Society of Physiotherapy.[15] A full explanation and practical demonstration of therapy techniques was given to ensure that therapists participating in the trial understood the key differences between the two interventions.

Conventional Therapy

Conventional therapy consisted of flexible patient/goal-oriented therapy conforming to existing practices of treatment for elderly patients with mobility problems. Treatment consisted of assisted walking within parallel bars, assessment for mobility aids, stair practice, general bed mobility skills, and transfers. The activity of sitting to standing was included, because this is a basic functional requirement, but upper limb reaching was not practiced. The emphasis was on improving functional activities, but there was no defined repetition of tasks or progressive grading in complexity. The treatment schedule concentrated on augmenting balance with emphasis on a safe gait pattern. Patients attended for two sessions per week for 4 weeks with 2 final weeks of telephone follow-up by the treating physiotherapist.

Enhanced Therapy

Enhanced therapy program consisted of all the components of CT as described above plus additional balance exercises, which formed the enhanced part of the treatment schedule. Additional activities consisted of repetition of a series of graded tasks specific to functional balance with targets of distance and time to provide feedback. The objective was to narrow the base of support and progressively move the center of gravity outside the base of support. Active movement was encouraged throughout the therapy program. Patients were asked to perform all appropriate exercises and progressed in terms of time and number of repetitions when the treating therapist judged that the patient has adequate endurance to focus on a higher level of training. Examples of these exercises included sit-to-stand practice, standing unsupported with visual feedback from Balance Performance Monitor (BPM), lateral reaching, retrieving an object from the floor, turning through 360° with time feedback, step-ups, tandem standing, and walking practice with timed feedback. The distance of walking or the complexity of tasks was increased as the patient gained increased competence. Patients received two sessions per week for 6 weeks.

Each treatment session lasted for no more than 45 minutes in both groups. Extra time was spent to discuss fall avoidance behaviors and strategies for coping with a long time on the floor in both groups. Subjects in both groups received instruction and practice in getting up from the floor. Although the same therapist could offer both types of therapy, crossover of therapists was kept to a minimum to avoid crossover effects.

Assessment and Data Collection

A therapist who was not involved with randomization or delivering the interventions (JS) completed baseline and outcome assessments at 6, 12, and 24 weeks after commencement of treatment. Outcome was measured using tools validated in the target population and included the BBS for the assessment of balance,[13] number of falls, 10-meter timed walk test (TWT) for assessing mobility and dynamic balance,[16] Frenchay Activities Index (FAI) for assessing wider activities of daily living,[17] Falls Handicap Inventory to measure limitation of social participation,[18] and European Quality of Life (Euroquol) to assess quality of life.[19] Objective measurement of balance was undertaken using the BPM (sway number, sway frequency, mean balance, sway area, and sway pathway length).[20,21] Patient satisfaction was assessed using a questionnaire designed specifically for the study.

Structured observation schedules were used randomly to monitor adherence to treatment protocols in both groups. An independent observer who was neither involved with treatment nor assessment of outcome completed this. Items on the observation schedule were developed in consultation with mainstream physiotherapists and included location, treatment duration, adherence to treatment protocol, interactions with patients, and feedback provided to patients.

Statistical Analysis

A sample size of 80 subjects in each group was required to give the study 80% power at 5% significance level to detect a 20% difference in the 10-meter TWT at 24 weeks between the two groups (primary outcome measure). The study also had 80% power at the 5% significance level to show a six-point difference in BBS and a 20% or more difference on BPM measures, number of falls, Falls Handicap Inventory (FHI), FAI, and Euroquol questionnaire.

Data were analyzed on an intention to treat basis to evaluate the effectiveness of the intervention at all three time-points (6, 12, and 24 weeks). Analysis of variance (ANOVA) with four repeated measures (baseline, 6, 12, and 24 weeks) was used for each of the outcome variables, with the type of treatment received as a between-group variable (FAI was only measured at baseline and at 24 weeks). Multiple comparisons after ANOVA were Bonferroni adjusted.

The independent effect of the intervention on 10-meter TWT, BBS, and number of falls was assessed using regression analyses with stepwise deletion. Covariables for this analysis included age, sex, baseline BBS, baseline number of falls, and medical diagnoses. Results were presented as odds ratios (ORs) with 95% confidence intervals (CIs) at each time point.

RESULTS

Three hundred seventy-eight patients were screened, of whom 133 were excluded because of a BBS score of 45 or greater (n = 74), residual medical problems (n = 47), or cognitive impairment (n = 12). Eight patients died before randomization, and 39 refused consent (Figure 1). Of the 96 patients randomized to the EBT group, 14 dropped out by 6 weeks, 19 by 12 weeks, and 27 by 24 weeks. Of the 102 patients randomized to the CT group, 18 had dropped out by 6 weeks, 23 by 12 weeks, and 38 by 24 weeks. Reasons for dropout included new or worsening health problems (n = 29), moving away from the area (n = 6), and patient choice (n = 12). Reasons for discontinuation were not known in 12 patients. There were no significant age or sex differences between subjects who persisted and those who withdrew early. Repeated measures analysis did not show a significant difference in dropout rates between the two groups at any time (P = .09).

The mean age of 198 patients included in the study was 82, and 80% were women. There were no differences in BBS, BPM scores, 10-meter TWT, and other baseline parameters between the two groups (Table 1). The observation schedule of activities undertaken during one treatment session in a random selection of patients showed that the protocol of therapy was being adhered to in all 48 patients observed receiving EBT and 55 patients observed receiving CT. The differences between the treatments are summarized in Table 2 and were consistent with conceptual expectations when developing the therapy regimens as described in Methods.

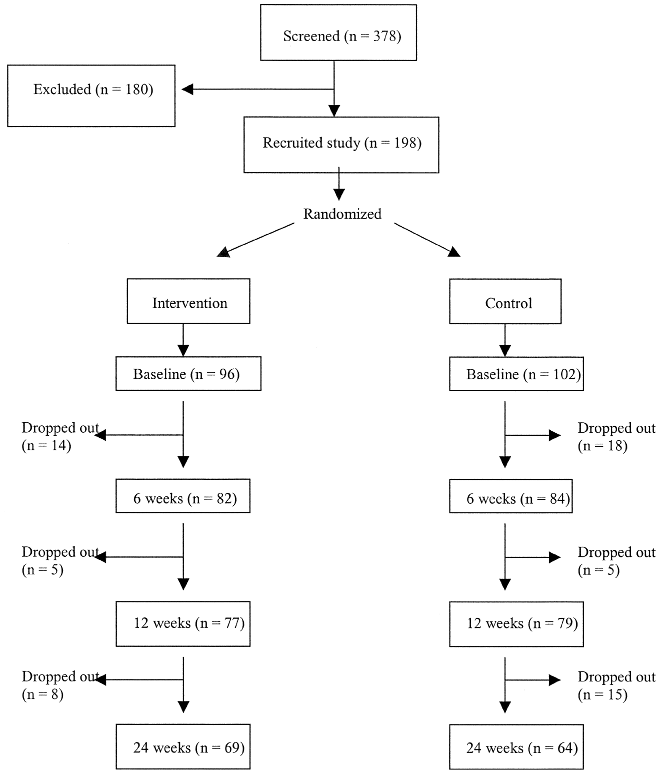

Figure 1. Trial profile for the study.

There was significant improvement in the BBS, number of falls, and FHI score in the CT group soon after completing treatment (6 weeks). This improvement was sustained over the 24-week observation period despite patients receiving no further therapy input (Table 1). Although the speed on the 10-meter TWT improved after therapy, this improvement was not statistically significant. None of the measures on the BPM showed a significant change. Patients receiving EBT also showed improvements in balance and falls after treatment (6 weeks), which were sustained at 24 weeks (Table 1). In contrast to patients receiving CT, walking speed on 10-meter TWT and quality-of-life scores were significantly improved in this group of patients at all time points.

There were no significant intergroup differences in any of the outcome measures between patients receiving CT or EBT for balance problems soon after completion of treatment at 6 weeks or in the long term at 24 weeks. This was confirmed on multiple regression analysis, which showed no significant differences between the two treatment strategies for the BBS (OR = 0.6, 95% CI = 0.4–3.6) or for 10-meter timed walking test (OR = 0.7, (95% CI = 0.1–3.5) at any time after adjustment for confounding variables. Age was the only variable that had an inde-

Table 1. Baseline Assessment and Outcome at 6, 12, and 24 Weeks in Patients in the Enhanced Balance Therapy and the Conventional Therapy Groups

	Conventional Therapy					Enhanced Balance Therapy				
	Baseline (n = 102)	6 Weeks (n = 84)	12 Weeks (n = 79)	24 Weeks (n = 64)		Baseline (n = 96)	6 Weeks (n = 82)	12 Weeks (n = 77)	24 Weeks (n = 69)	
Parameter	Mean ± Standard Deviation				*P*-value	Mean ± Standard Deviation				*P*-value
Berg Balance Score	33.4 ± 8.7	39.8 ± 9.8	40.9 ± 9.7	42.0 (9.5)	.0001	33.3 ± 8.7	41.2 ± 9.3	43.1 ± 8.5	42.7 ± 8.2	.0001
10 m timed walk test in sec.	20.5 ± 22.0	17.3 ± 12.6	16.1 ± 6.3	15.8 ± 7.2	.054	22.5 ± 18.7	16.3 ± 6.3	16.4 ± 7.4	16.5 ± 8.9	.001
Falls in the last month	4.7 ± 8.3	0.4 ± 0.9	0.4 ± 0.8	0.6 ± 1.0	.0001	5.0 ± 4.5	0.5 ± 1.0	0.3 ± 0.9	0.6 ± 2.2	.0001
Falls Handicap Inventory score	32.9 ± 17.4	23.6 ± 14.4	19.5 ± 14.3	17.1 ± 13.6	.0001	30.9 ± 15.6	20.2 ± 15.6	16.8 ± 15.1	17.0 ± 17.1	.0001
Frenchay Activities index	18.1 ± 8.7	—	—	21.1 ± 7.8	.03	18.2 ± 7.4	—	—	21.0 ± 7.3	.02
Euroqol visual analogue scale score	59.4 ± 17.2	64.9 ± 17.3	65.7 ± 16.9	64.5 ± 17.4	.07	57.8 ± 19.7	65.1 ± 19.6	65.1 ± 17.7	64.4 ± 19.9	.04
BPM sway number	6.3 ± 4.5	6.3 ± 6.8	5.7 ± 5.0	5.8 ± 3.8	.44	6.8 ± 10.8	5.4 ± 3.3	5.9 ± 3.9	5.5 ± 3.7	.31
BPM sway frequency, Hz	1.4 ± 0.4	1.4 ± 0.3	1.4 ± 0.4	1.3 ± 0.4	.77	1.5 ± 0.4	1.5 ± 1.1	2.2 ± 6.6	1.4 ± 0.4	.10
BPM mean balance, %	56.0 ± 4.9	56.5 ± 5.1	55.8 ± 5.4	62.0 ± 6.9	.31	56.3 ± 7.5	61.2 ± 9.4	56.1 ± 5.8	54.4 ± 7.9	.14
BPM sway area, mm^2	1,687 ± 2,029	1,566 ± 2,243	1,394 ± 2,083	1,718 ± 4,628	.66	1,703 ± 3,309	1,378 ± 1,494	1,438 ± 1,845	1,420 ± 2,220	.53
BPM sway path length, mm	763 ± 407	686 ± 384	810 ± 947	686 ± 369	.22	761 ± 416	736 ± 405	722 ± 415	733 ± 347	.22

Euroqol = European Quality of Life questionnaire; BPM = Balance Performance Monitor.

Table 2. Frequency of Different Exercises Undertaken in the Two Groups During Random Observation Sessions in the Enhanced Balance Therapy (EBT) and Conventional Therapy (CT) Groups

	Frequency in EBT (n = 48)	Frequency in CT (n = 55)	
Exercise	n (%)		*P*-value
Sit to stand	47 (98)	52 (95)	.18
Bed mobility	14 (29)	47 (85)	.0001
Transfer practice	18 (38)	51 (93)	.0001
Walking practice	46 (96)	52 (95)	.193
Turning 360°	43 (90)	43 (78)	.04
Stair practice	30 (63)	33 (60)	.31
Step-ups	45 (94)	25 (45)	.0001
Tandem stand	45 (94)	0	—
One-leg stand	45 (94)	0	—
Balance board	42 (88)	0	—
Balance performance monitor	44 (92)	0	—
Discussion of strategies to cope with consequences of falls	25 (52)	15 (27)	.0002

pendent effect on the BBS (OR = 0.4, 95% CI = 0.1–0.6) and number of falls (OR = 0.08, 95% CI = 0.03–0.1) at 24 weeks.

The questionnaire on patient satisfaction at 24 weeks was returned by 44 (54%) of the 82 subjects in the EBT group and 65 (77%) of the 84 subjects in the CT group (Table 3). A significantly greater proportion of responding patients who received EBT strongly felt that their overall confidence had improved (27% vs 16%; $P = .02$) in walking around the home (36% vs 28%; $P = .04$) and walking outside (27% vs 18%; $P = .02$) than of those receiving conventional treatment. A higher proportion also reported improved balance (26% vs 19%; $P = .005$). Significant differences between the two groups for these aspects persisted even when the strongly agree and agree groups were combined. There were no significant differences between the two groups for interactions with the therapy staff; an equal proportion of patients reported that they were satisfied or highly satisfied with the way they had been treated, the type of treatment they had received, and the advice they were given when talking about balance difficulties. However, nearly 72% patients receiving CT felt that they had not received enough therapy, compared with only 7% in the EBT group ($P < .0001$).

DISCUSSION

Improvements in BBS, number of falls, FHI scores, and FAI were seen in both groups after completion of therapy input (at 6 weeks) and were still present at 24 weeks. In addition, the EBT group showed significant improvements in walking speed and quality-of-life measures compared with baseline. However, there were no differences in outcome between the two groups at any time, suggesting that both treatments had equivalent effect on objective outcome measures in this study.

Table 3. Summary Scores of Patient Satisfaction Questionnaire

	Strongly Agree		Agree		Disagree		Strongly Disagree	
	EBT n = 44	CT n = 65	EBT n = 44	CT n = 65	EBT n = 44	CT n = 65	EBT n = 44	CT n = 65
Questions	n (%)							
My confidence has improved since starting the therapy.	12 (27)	12 (18)	27 (61)	40 (62)	5 (11)	11 (17)	0 (0)	2 (3)
I have been treated with kindness and respect by the physiotherapy staff.	29 (66)	44 (68)	15 (34)	21 (32)	0 (0)	0 (0)	0 (0)	0 (0)
I am satisfied with the type of treatment the therapist gave me.	19 (43)	29 (45)	24 (55)	33 (51)	1 (2)	3 (5)	0 (0)	0 (0)
The therapy has made me more confident in walking around my home.	16 (36)	18 (28)	22 (50)	37 (57)	6 (14)	10 (15)	0 (0)	0 (0)
The therapy has made me more confident walking outside.	12 (27)	12 (18)	22 (50)	30 (46)	9 (20)	21 (32)	1 (2)	2 (3)
I found the home exercises very useful.	15 (34)	16 (25)	27 (61)	43 (66)	2 (5)	6 (9)	0 (0)	0 (0)
I found it helpful talking to the therapist about my balance difficulties.*	15 (35)	27 (42)	28 (65)	36 (56)	0 (0)	1 (2)	0 (0)	0 (0)
My balance has improved.*	11 (26)	12 (19)	25 (58)	28 (44)	6 (14)	22 (34)	1 (2)	2 (3)
I have continued with my home exercises.*	8 (19)	17 (27)	24 (36)	30 (47)	10 (23)	17 (27)	1 (2)	0 (0)
I feel the physiotherapy I received was adequate for my needs. *	16 (37)	18 (28)	24 (56)	0 (0)	2 (5)	38 (59)	1 (2)	8 (13)

* n is decreased by one point in all response columns.
EBT = enhanced balance training; CT = conventional physiotherapy.

Patients' subjective experiences of outcome contrasted with objective measures. A significantly greater proportion of patients receiving EBT felt that the treatment had improved their balance and confidence in walking, both indoors and outside. This perception was not related to the way they were treated during the therapy program. Both groups reported equivalent levels of satisfaction in interactions with the therapists, but nearly three out of four patients receiving conventional care felt that they had not received enough treatment, compared with less than one in 10 in the EBT group, despite equal therapist contact.

Many reports show that some form of physical training is associated with greater functional independence and fewer falls,[22–25] but there is no evidence to support the superiority of EBT. A trial of patients randomized to one of two exercise groups (resistance/endurance plus enhanced balance training) or to a control group (EBT only) showed no difference in the number of falls.[26] The study also showed low adherence rates for both interventions.[26] Another recent study compared visual biofeedback/forceplate training systems (such as the BPM in this study) with CT in stroke patients and showed that, although performance on the BBS and mobility tests improved in both groups, there were no additional effects of visual biofeedback/forceplate training.[27] High dropout rates were also seen as the reason for failure to find a difference between seated balance training and a conventional training program on a range of outcome measures in elderly people over a 12-month period of observation.[28]

These observations suggest that important matters need to be addressed in evaluating the effectiveness of interventions in chronic disease. The first one relates to appropriate choice of outcome measures; increased confidence and well-being may be more important to patients than disease-related measures, and measuring these should complement disease-specific indicators such as walking speed or BBS in clinical studies. Most falls do not result in serious injury but cause loss of confidence, decreased mobility, social isolation, depression, and dependence.[29] EBT improved these aspects more than CT, which raises the question of whether it would be justified to provide a new treatment on the basis of perceived benefit of increased confidence and well-being, even when objective evidence of benefit is lacking.

A single-blind design is a major weakness of this study, but it would be impossible to design a double-blind trial in which therapists were unaware of the treatment they were providing. It is also possible that some patients may have guessed that they were receiving enhanced therapy, which may have biased results. Patients were required to participate in an intensive treatment program, which may have introduced selection bias favoring those able to access services. The nature of the study prevented rigorous masking, but assessment bias was reduced by using an observer who was not involved with randomization or treatment and designating the 10-meter TWT as the primary outcome measure because it was least susceptible to recording, recall, or observer bias.

The conclusions on satisfaction need to be interpreted with caution because of difficulties in blinding and high dropout rate. Only 54% of patients in the EBT group completed satisfaction questionnaires as opposed to 77% in the CT group. This raises the possibility of bias in favor of EBT because only those patients who benefited may have responded. Although it would be desirable to use existing satisfaction scales with known validity and reliability, this was not possible because the subjects found them difficult to understand and of limited relevance. Structured questionnaires may be geographically or culturally sensitive and prove inadequate in capturing the richness of patient experience. It is likely that patient satisfaction is best addressed using qualitative interview techniques and content analysis.

This study confirms that exercise programs modified to patients' requirements significantly improve balance and mobility, independent of the strategy used. Nevertheless, walking speed, quality of life, reported stability, and confidence improved more in patients receiving EBT. This suggests that there may be subtle differences between the two approaches that significantly affect patients confidence and quality of life, which need further investigation.

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