How balance task-specific training contributes to improving physical function in older subjects undergoing rehabilitation following hip fracture: a randomised controlled trial.

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ABSTRACT

Objective. To evaluate the efficacy of a rehabilitation programme including balance task-specific training in improving physical function, pain, activities of daily living (ADL), balance, and quality of life in subjects after a hip fracture.

Design. Randomised controlled trial.

Subjects. 52 older subjects selected for internal fixation due to extra-capsular hip fracture were randomised to be included in an experimental (n=26) and control group (n=26).

Interventions. The experimental group underwent a rehabilitation programme based on balance task-specific training. The control group underwent general physiotherapy, including open kinetic chain exercises and walking training. Both groups individually followed programmes of 90-minute sessions five times/week for three weeks.

Outcome measures. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), a Pain Numerical Rating Scale, the Berg Balance Scale, the Functional Independence Measure, and the Short-Form Health Survey. The participants were evaluated before and after training, and after twelve months.

Results. Significant effects of time, group and time by group were found for all outcome measures in favour of the experimental group. A clinically important between-group difference of 25 points was achieved after training and at follow up in

terms of the primary outcome (WOMAC function before, after treatment and at follow up was 84.8 (3.7), 39.8 (4.9) and 35.7 (6.2) for the experimental group and 80.9 (5.7), 65.2 (7.1), and 61.0 (11.1) for the control group).

Conclusion. An in-patient rehabilitation programme based on balance task-specific training is useful in improving physical function, pain, ADL and quality of life in older patients after hip fracture.

INTRODUCTION

Evidence suggests that rehabilitation plays a crucial role in guaranteeing recovery and enhancing quality of life following hip fracture (1). However, there are still doubts about its efficacy, timing and duration, as well as which exercises are best (2,3).

Adequate balance training is expected to contribute to the reduced risk of falling and safer return to walking, and is receiving more and more interest among the exercises to be proposed to patients. A rehabilitation programme conducted in 2007 showed that inpatients with femoral neck fracture reduced falls (4) and improved independence in activities of daily living (ADLs) and indoor walking ability (5) in subjects with femoral neck fracture. Nevertheless, at the end of the one-year follow-up it was not possible to detect any between-group significant difference in terms of falls, while ADLs performance and mobility were preserved (5). Another trial demonstrated that an individualised fall-prevention education programme reduced the rates of falls in older hip fracture subjects who entered rehabilitation hospital-units (6). However, the actual impact of balance training on physical function was never investigated within a more comprehensive programme.

Over the course of time, programmes of care and rehabilitation after hip fracture have been developed in either inpatient or ambulatory rehabilitation settings (7). Despite no conclusive evidence of their effectiveness, there is a trend towards all outcomes in

favour of inpatient rehabilitation (7), which is more associated with functional improvement and reduced length of hospital stay in elders (8).

Hence, we hypothesised that an in-hospital rehabilitation programme including balance task-specific training can contribute to improving physical function (primary outcome), pain, ADL, balance, and quality of life (secondary outcomes) in elders with hip fracture treated surgically. The aim of this randomised controlled study was to compare this programme with general physiotherapy mostly including open kinetic chain exercises in supine position and walking training.

METHODS

This randomised, parallel-group superiority-controlled trial was conducted at the Scientific Institute of Lissone of the Clinical and Scientific Institutes Maugeri. The staff involved have documented skills in orthopaedic rehabilitation and attend a theoretical and practical refresher course on the management of post-surgical treatment of hip fractures annually. The study was approved by the Ethical Committee of the University Hospital of Cagliari (PN/2016/7626/2.12) and was conducted in conformity with ethical and humane principles of research. The study was registered in the ISRCTN registry with the ID number ISRCTN 61449514.

Participants

The selection criteria were patients who had an internal fixation due to extra-capsular hip fractures such as trochanteric, subtrochanteric, pertrochanteric, intertrochanteric, basal and lateral femoral fractures 7–10 days before admission to our Rehabilitation Unit, a good understanding of Italian, and an age of >70 years. The exclusion criteria were, previous hip and lower limbs surgery, systemic illness, cognitive impairment (Mini Mental State Examination <24 (9)), recent myocardial infarctions, cerebrovascular events, chronic lung or renal diseases, or were excluded on the basis of their case histories.

Eligible patients were evaluated by two physiatrists coordinated by the principal investigator, and those satisfying the entry criteria were then given further information and asked to declare their willingness to comply with whichever treatment option they were randomly assigned to, and to attend all of the follow-up visits.

Immediately after the patients had given their written consent to participate, the physiatrists e-mailed the principal investigator, who randomised the subjects to one of the two treatment programmes using a list of blinded treatment codes, generated in Matlab, and an automatic assignment system made in Matlab to conceal the allocation.

The principal investigator obtaining and assessing the data and the biostatistician making the analyses were both blinded to the treatment allocation. The physiatrists, the physiotherapists, and the patients were not blinded. To partially limit expectation bias and to reduce problems of crossover, patients were not made aware of the study's hypothesis, and were told that the trial was intended to compare two common approaches to hip fractures post-surgical rehabilitation, whose efficacy had not yet been established.

Interventional programmes

These involved two physiatrists equally experienced and four physiotherapists equally experienced. The staff involved was separately responsible for the physical training in

the two interventional programmes (one physiatrist and two physiotherapists in each group, respectively). The staff has also documented skills in rehabilitation following hip fracture and attends annual theoretical and practical refresher courses on their management.

Experimental group. The subjects performed balance task-specific exercises while standing with open and closed eyes with the objective of looking for a symmetrical load on their legs, while standing and keeping proprioceptive pillows under their feet, while standing by shrinking the support base, or maintaining the tandem position, or maintaining their position with and without the use of a proprioceptive bubble. Subjects were asked to walk on a rectilinear trajectory with or without crutches, while changing speed and direction, or while performing motor-cognitive tasks such as turning their head on the right and left side following physiotherapists' inputs. Additional exercises such as moving from a sitting to a standing position, ascending/descending stairs and climbing obstacles were also performed.

Control group. The subjects performed open kinetic chain exercises in the supine position on the couch aimed at improving the range of hip motion, increasing hip and lower limb muscle strength, and maintaining the length and elasticity of thigh tissues.

During walking training, subjects of both groups were instructed to use their crutches reciprocally to regain a symmetrical gait pattern. Furthermore, ergonomic advice was

provided to both groups by means of a booklet given to the patients during the first session of treatment in order to facilitate the modification of their daily living activities.

A complete description of all exercises performed by the two groups is reported in Appendix.

All of the subjects followed the exercise programmes individually. The physiotherapists arranged 90-minute sessions five times a week for three weeks and were all experienced at the same level.

To ensure that there was no variability in the administration of the treatment throughout the course of the study, a fidelity check, based on a treatment manual for the administration of exercise training was conducted both during each session and at the end of the programme.

No other treatments (e.g. physical modalities, nerve blocks) were offered once the patients were accepted for the programme; patients were also disallowed from taking major pharmacological agents, whilst mild analgesics (e.g. paracetamol) and NSAIDs were permitted.

Spouses, significant others or parents were asked to support patients' compliance during the study and to inform the staff promptly if any difficulty was encountered, in order to strengthen treatment adhesion and minimise drop-outs.

Outcome measures

The outcome measures evaluated physical function (primary), pain, balance, ADLs, and quality of life (secondary).

Physical function was assessed using the self-reported Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). It is a multidimensional scale consisting of three sub-scales: physical function (primary outcome), pain, and stiffness (10). The data for each sub-scale was standardised to a range of 0 (best) to 100 (worst health status). We used the Italian version, which has proved to be reliable and valid (11).

Current pain intensity was assessed using an 11-point numerical rating scale ranging from 0 (no pain) to 10 (the worst imaginable pain) (12).

Balance was assessed by using the Italian Berg Balance Scale, which ranges from 0 (high risk of falling) to 56 (no risk of falling) (13).

ADLs were evaluated by means of the Functional Independence Measure, which ranges from 18 (the greatest limitation) to 126 (no limitation) (14). We used the Italian version, which has proved to be reliable and valid (15).

Quality of life was assessed using the self-reported Short-Form Health Survey (SF 36): its eight domain scores of physical function, physical role, bodily pain, general health, vitality, social function, emotional role, and mental health were calculated on the basis

of the Italian version (0= worst perceived, 100= best perceived quality of life), which has proved to be reliable and valid (16–18).

The questionnaires were completed before treatment, three weeks later (post-training), and 12 months after discharge from hospital (one-year follow-up). At baseline and post-training, the questionnaires were administered by secretarial staff who checked them and returned any uncompleted part to the patients for completion; at follow-up, the patients were met with personally or telephoned by the same secretarial staff in order to ensure the questionnaires were properly completed.

At the end of treatment, the patients were also asked to rate the efficacy of treatment using the Global Perceived Effect scale, which is a 7-point Likert scale (1=helped a lot, 2=helped, 3=helped only a little, 4=did not help, 5=made things only a little worse, 6=made things worse, 7=made things a lot worse) (19).

Using a specific form, the patients were asked to report any serious and/or distressing symptoms they experienced during the study that required further treatment.

Statistics

The primary end-point was the between-group difference after training in the WOMAC, physical function sub-scale, for which a between-group difference of 24 points was estimated to be clinically important (20). It was calculated that a sample size of 44 patients would be capable of detecting a between-group difference of 24

points in the primary end-point with a standard deviation of 15, a type I error of 5%, and a power of 95% (21,22). A total of 52 patients were included in each group to allow for a 20% drop-out rate.

The baseline characteristics of the two groups were compared by t-test for independent samples. Linear mixed model analyses for repeated measures (significance level of 5%) were made of each of the outcome measures, with group and time entered as fixed effects and the outcome measures as dependent variables. The time by group interaction term was also evaluated. Since an intention-to-treat analysis was conducted, the linear mixed model was selected in order to deal better with missing data (23,24). Because of its categorical nature, the Global Perceived Effect scale was analysed using the Mann–Whitney U test.

The data was analysed using SPSS 22.0 software.

RESULTS

The patients were consecutively included in the study during the period between July 2012 and December 2014. A total of 71 subjects were screened for eligibility and 52 met the inclusion criteria, agreed to participate and were randomised; two subjects (one for each group) dropped out from the study before the intervention ended, and a further 3 subjects were lost at follow-up. Figure 1 shows the participants' flow chart. No crossover problems arose as no patient asked to swap groups.

The patients' characteristics and the results of the statistical comparison between groups at baseline are reported in Table1. The sample had a mean age of 77 years and was characterised by a high level of physical impairment (WOMAC, higher than 80 for both groups) and a moderate level of perceived pain.

Significant effects of time, group and time by group were found for all outcome measures but Emotional Role and Mental Health sub-scales of the SF 36 (Tables 2 and 3).

After training, a mean between-group difference of 25 percentage points was found for the primary outcome (WOMAC, function sub-scale), indicating that the experimental programme was able to induce a clinically significant improvement in terms of physical function. This between-group difference was maintained at follow-up.

A clinically significant between-group difference was achieved after training also in terms of pain (WOMAC, pain sub-scale). This difference was not maintained at follow-up since a reduction of pain was perceived by the control group also.

As for balance (Berg Balance Scale), a between-group difference of 13 points was achieved after training and further increased at follow-up thanks to an additional improvement of the experimental group.

Also in terms of ADLs (Functional Independence Measurement) and quality of life the experimental group improved more and the improvements were maintained or further improved at follow-up.

A significant between-group difference was found for the Global Perceived Effect scale ($p<0.001$). Subjects in the experimental group felt that the intervention had helped them (median=2; interquartile range=1), while no improvements were perceived by the control group (median=4; interquartile range=1).

Physiotherapists' systematic checking of the exercise administration manual revealed excellent compliance rates in both groups. Minor adverse effects of transient pain worsening (experimental group: n=3; control group: n=4), autonomic and sensory problems (experimental group: n=2; control group: n=2), and mood disorders (experimental group: n=1; control group: n=2) were easily managed by means of symptomatic drugs and brief periods of rest

DISCUSSION

The results of this randomised controlled trial show that a rehabilitation programme including balance task-specific training is superior to general exercises in improving physical function, pain, balance, ADLs and the quality of life of elderly in-patients who have undergone internal fixation following hip fracture. The between-group difference was clinically meaningful for our primary outcome, physical function (>24). Improvements lasted for at least twelve months after the end of the intervention in both groups.

In their systematic reviews (1,3), the Authors suggested early rehabilitation after hip fractures, but could not clearly recommend types and characteristics of exercises, especially based on older subjects' need of faster recovery and optimization of post-injury recovery. Rehabilitation is often too short for balance performance to recover. Therefore, we firstly chose the use of balance task-specific training over general exercises where articular motion, strength, balance and endurance are trained as separate components. As previously suggested (25–27), we found that tailored exercises for balance were more effective when performed under conditions similar to those encountered during daily life. Further, the closed chain kinetic exercises were advised to favour functional outcomes as well as faster return to ADLs in contrast to open chain kinetic exercises, mostly performed supine on the couch and in the

absence of any functional input. Our findings are in line with previous studies conducted in subjects undergoing rehabilitation after total hip replacement and after hip fracture (28,29).

At the end of the treatment period, balance and ADLs performance had improved in both groups, but the improvement was significantly greater in the experimental group. Satisfactory levels were maintained until the end of the follow-up, suggesting the possibility to adopt healthier strategies and overcoming environmental barriers. As for balance, our findings are in line with a previous study which found between-group significant difference in terms of balance recovery (5). As for ADLs, our findings are also in line with a previous study that showed an intervention based on functional exercises improved usual activities and decreased the number of environment barriers (30).

Pain perception had decreased in both groups by the end of the treatment and follow-up periods, which reflects the positive synergistic effects of surgery and active exercises (31).

The satisfactory effect of treatment on the Short-Form Health Survey physical subscales highlighted the potential benefits of the proposed intervention. Significant between-group treatment effects were also found in the mental domains of Short-Form Health Survey, suggesting the importance of this innovative approach in

enhancing aspects related to mental components such as the emotional role and social function.

The higher rates of treatment satisfaction in the experimental group indicated the superiority of the approach, probably because the proposed intervention was perceived by the subjects as providing a better solution to problems experienced after hip fractures.

Elderly subjects suffering from hip fractures tend to be frail due to cognitive problems, multiple co-morbidities, and poly-pharmacy and with limited movement ability (8). We therefore chose a well-coordinated in-patient setting involving physiatrists, geriatricians, and nurses especially devoted to medical and rehabilitative needs. Obviously, such organization is expensive, around 5000 Euros per patient is provided from the Italian health care system during the stay (32), and it has to be reserved for subjects with clinical and social characteristics as described above; however, it might potentially prevent additional costs due to long-term assistance and fall-related injuries.

This randomised controlled trial was internally valid, capable of distinguishing the effects in the two groups, and adequately sized. It was also based on concealed randomisation, blinded data collection, and the effective masking of assessors and analysts. Concerning the generalizability issues, this sample was representative of a

subset of older patients still requiring medical aids and/or having insufficient home support, preventing an early discharge from the Orthopaedic Unit to home. Hence, our data is not generalizable to younger populations, who are discharged at home after surgery. Moreover, the data cannot be generalised to subjects undergoing femoral head replacement with a prosthesis or to surgical revisions. Remarkably, there was a limited number of dropouts from either group, which suggests that the patients were highly motivated and determined to adhere to all of the phases of treatment. The support of staff and relatives probably played a crucial role in establishing a controlled and protected situation.

This study has some limitations. First of all, we did not record pre-surgery scores of physical function, pain, ADL, and quality of life, and this may limit our interpretation of the impact of the exercise protocol. Secondly, this trial was characterized by a small number of subjects although, based on the clinical relevance of our primary outcome, we properly defined the subjects' number needed to treat. Thirdly, physiatrists and physiotherapists were not blinded to treatment and, therefore, a performance bias could not be excluded (33).

In conclusion, our findings suggest a programme based on balance task-specific training as a more effective and long-lasting means to recover function, balance and daily activities rather than a programme that involves general exercises where hip

deficits are trained as separate components: general physiotherapy based on open kinetic chain exercises in the supine position on the couch should be therefore progressively avoided in clinical practice, choosing exercises favouring balance and functional outcomes in order to guarantee earlier returns to pre-fracture physical levels. Older frail subjects with limited mobility and at high risk of falling are the main target of the proposed intervention to be delivered in in-patient settings. Future research should verify the usefulness of balance task-specific training in older frail subjects undergoing total head replacement as well as in younger subjects after hip fracture.

Clinical messages

- A 3-week in-patient rehabilitation programme based on balance task-specific training improved physical function, pain, ADL and quality of life in older patients after hip fracture.
- These benefits were superior to a programme of general exercises and lasted for at least 12 months.

Author Contributions

- MM had a role in the study concept and design, acquisition of subjects and data, analysis and interpretation of data, and preparation of the manuscript; he drafted the article, and gave the final approval of the version to be published;

- EA had a role in study concept and design, acquisition of subjects and data, analysis and interpretation of data, and preparation of the manuscript; she critically revised it for important intellectual content, and gave the final approval of the version to be published;

- RB had a role in study concept and design, acquisition of subjects and data, analysis and interpretation of data, preparation of the manuscript; he gave the final approval of the version to be published;

- AC had a role in the study concept and design, acquisition of subjects (he surgically treated some of the patients included), interpretation of results, preparation of the manuscript; he critically revised it for important intellectual content and he gave the final approval of the version to be published;

- GP had a role in the study concept and design, acquisition of subjects and data, analysis and interpretation of data and she gave the final approval of the version to be published;

- GZ had a role in study concept and design, acquisition of subjects (he surgically treated some of the patients included), interpretation of results, and preparation of the manuscript; he critically revised it for important intellectual content, and gave final approval of the version to be published.

- CS had a role in the study concept and design, analysis and interpretation of data; he critically revised the manuscript for important intellectual content, and gave the final approval of the version to be published;

- SF had a role in the study concept and design, acquisition of subjects and data, analysis and interpretation of data, and preparation of manuscript; she critically revised it for important intellectual content, and gave the final approval of the version to be published;

Conflict of Interest Statement

The Authors declare that there was no conflict of interest.

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Table 1. Patients' Baseline Characteristics (n=52).

	Experimental group	Control group	p-value
Age (years)	77.2 (6.6)	77.7 (7.5)	0.785
Gender (Male/Female)	7/19	8/18	
Body mass index (kg/m^2)	36.7 (6.2)	38.5 (5.7)	0.274
Fracture side (right/left)	20/6	21/5	
Days after fracture	7.9 (2.1)	7.6 (2.5)	0.671
Smokers (yes/no)	4/22	4/22	
Married (yes/no)	16/10	17/9	
Employed (yes/no)	1/25	1/25	
Education			
Primary school	10	7	
Middle school	10	13	
High school	5	5	
University	1	1	
Comorbidity (principal)			
Hypertension	15	16	
Endocrine diseases	5	4	
Kidney diseases	1	2	
Other locomotor system diseases (e.g. shoulder, hand, spinal and knee osteoarthritis)	5	4	
Use of drugs			
Antidepressants	2	1	
Analgesics	10	11	
Non-steroidal anti-inflammatory drugs	14	14	
WOMAC			
Physical function (0-100)	84.8 (3.7)	80.9 (5.7)	0.005
Pain (0-100)	84.0 (9.3)	82.1 (10.3)	0.483
Stiffness (0-100)	73.6 (16.3)	74.5 (16.8)	0.835
NRS (0-10)	6.9 (1.6)	7.2 (1.3)	0.438
BBS (0-56)	15.3 (6.4)	16.9 (7.8)	0.419
FIM (18-126)	61.9 (9.3)	61.2 (9.1)	0.799
SF-36			
Physical activity (0-100)	12.1 (12.2)	12.3 (13.9)	0.958
Physical role (0-100)	12.8 (16.5)	15.4 (16.9)	0.583
Bodily pain (0-100)	10.3 (11.4)	9.2 (9.2)	0.680
General health (0-100)	34.8 (6.2)	33.5 (7.7)	0.492
Vitality (0-100)	44.0 (19.9)	49.4 (22.0)	0.359
Social function (0-100)	44.2 (28.8)	49.5 (32.9)	0.540
Emotional role (0-100)	34.6 (27.5)	30.8 (26.5)	0.610
Mental health (0-100)	64.8 (23.8)	62.2 (25.4)	0.703

Mean values (standard deviation)
WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index; NRS, Numerical Rating Scale; BBS, Berg Balance Scale; FIM, Functional Independence Measure; SF-36, Short-Form Health Survey

Table 2. Changes over time within and between groups in terms of Western Ontario and McMaster Universities Osteoarthritis Index, Numerical Rating Scale, Berg Balance Scale, and Functional Independence Measure (n=52).

	Group	Pre-training*	Post-training*	Follow-up*	Mean difference at post-training†	Mean difference at follow-up†	F (p value) time effect	F (p value) group effect	F (p value) interaction effect
Primary outcome									
WOMAC Physical function (0-100)	Experimental	84.8 (3.7)	39.8 (4.9)	35.7 (6.2)	-25.36 (1.73)	-25.29 (2.61)	507.84 (<0.001)	112.78 (<0.001)	105.23 (<0.001)
	Control	80.9 (5.7)	65.2 (7.1)	61.0 (11.1)					
Secondary outcomes									
WOMAC Pain (0-100)	Experimental	84.0 (9.3)	16.0 (5.6)	9.6 (9.0)	-37.60 (2.76)	-26.50 (3.83)	467.84 (<0.001)	106.02 (<0.001)	63.72 (<0.001)
	Control	82.1 (10.3)	53.6 (12.6)	36.1 (16.4)					
WOMAC Stiffness (0-100)	Experimental	73.6 (16.3)	14.5 (7.8)	10.4 (9.5)	-22.50 (4.16)	-23.82 (5.27)	151.27 (<0.001)	22.78 (<0.001)	7.53 (0.001)
	Control	74.5 (16.8)	37.0 (19.3)	34.2 (23.9)					
NRS (0-10)	Experimental	6.9 (1.6)	1.6 (0.8)	1.5 (0.8)	-3.48 (0.32)	-2.93 (0.32)	120.86 (<0.001)	111.70 (<0.001)	21.17 (<0.001)
	Control	7.2 (1.3)	5.1 (1.4)	4.4 (1.3)					
BBS (0-56)	Experimental	15.3 (6.4)	39.5 (7.3)	48.9 (4.9)	13.48 (1.97)	23.87 (2.76)	147.04 (<0.001)	47.96 (<0.001)	44.72 (<0.001)
	Control	16.9 (7.8)	26.0 (6.6)	25.0 (12.5)					
FIM (18-126)	Experimental	61.8 (9.3)	97.1 (11.2)	106.9 (12.3)	16.28 (3.47)	20.75 (3.72)	138.19 (<0.001)	27.11 (<0.001)	11.94 (<0.001)
	Control	61.2 (9.1)	80.8 (13.2)	86.1 (13.2)					

* Mean values (standard deviation)

† Mean difference (standard error)

WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index; NRS, Numerical Rating Scale; BBS, Berg Balance Scale; FIM, Functional Independence Measure

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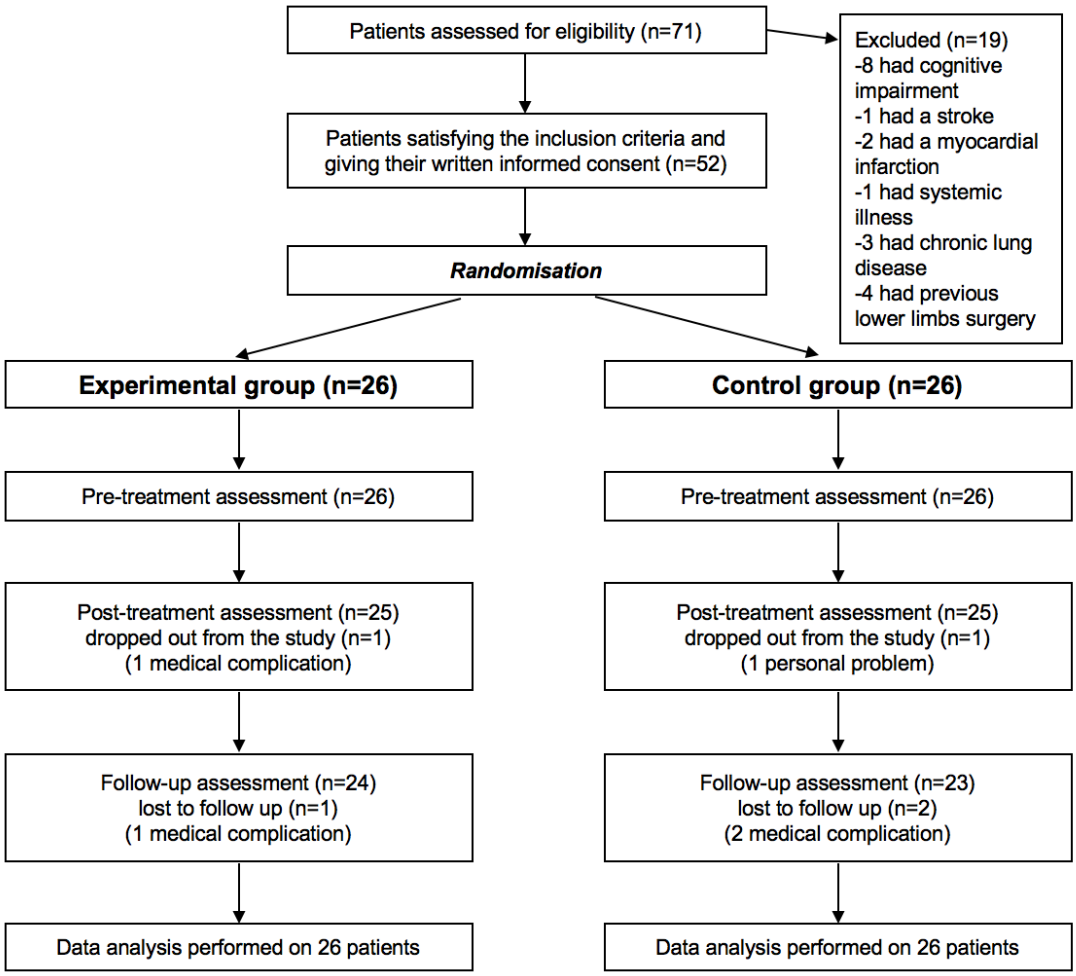
Table 3. Changes over time within and between groups in terms of sub-scales of the Short-Form Health Survey (n=52).

	Group	Pre-training*	Post-training*	Follow-up*	Mean difference at post-training†	Mean difference at follow-up†	F (p value) time effect	F (p value) group effect	F (p value) interaction effect
Short-Form Health Survey									
Physical function (0-100)	Experimental	12.1 (12.2)	56.6 (24.4)	73.3 (25.7)	18.12 (6.59)	28.12 (6.11)	92.10 (<0.001)	15.10 (<0.001)	9.84 (<0.001)
	Control	12.3 (13.9)	38.5 (22.1)	45.2 (14.4)					
Physical role (0-100)	Experimental	12.8 (16.5)	79.3 (35.1)	81.3 (37.8)	32.67 (8.46)	24.73 (8.99)	94.51 (<0.001)	14.31 (<0.001)	9.07 (<0.001)
	Control	15.4 (16.9)	46.7 (23.6)	56.5 (21.2)					
Bodily pain (0-100)	Experimental	10.3 (11.4)	63.9 (31.2)	78.4 (27.3)	26.84 (7.89)	36.98 (7.06)	78.61 (<0.001)	24.69 (<0.001)	9.44 (<0.001)
	Control	9.2 (9.2)	37.0 (24.1)	41.4 (20.5)					
General health (0-100)	Experimental	34.8 (6.2)	53.0 (17.0)	70.4 (18.6)	19.40 (4.71)	19.76 (6.11)	38.57 (<0.001)	26.64 (<0.001)	11.27 (<0.001)
	Control	33.5 (7.7)	33.6 (16.3)	50.7 (23.1)					
Vitality (0-100)	Experimental	44.0 (19.9)	61.0 (16.3)	68.5 (18.8)	16.40 (4.48)	25.93 (4.87)	3.48 (0.039)	11.62 (0.001)	11.50 (<0.001)
	Control	49.4 (22.0)	44.6 (15.4)	42.6 (14.1)					
Social function (0-100)	Experimental	44.2 (28.8)	79.0 (22.2)	87.0 (20.7)	23.00 (7.39)	36.98 (5.78)	8.63 (0.001)	15.82 (<0.001)	7.35 (0.002)
	Control	49.5 (32.9)	56.0 (29.6)	50.0 (18.8)					
Emotional role (0-100)	Experimental	34.6 (27.5)	78.7 (27.0)	84.7 (17.0)	30.67 (9.02)	22.40 (6.58)	37.18 (<0.001)	14.93 (<0.001)	2.39 (0.102)
	Control	30.8 (26.5)	48.0 (36.1)	62.3 (27.2)					
Mental health (0-100)	Experimental	64.8 (23.8)	67.7 (19.4)	70.3 (22.7)	10.24 (5.92)	20.69 (6.40)	1.25 (0.296)	5.45 (0.024)	6.47 (0.003)
	Control	62.2 (25.4)	57.4 (22.4)	49.6 (21.1)					

* Mean values (standard deviation)

† Mean difference (standard error)

Figure 1. Participants' CONSORT flow chart.



Appendix

INTERVENTION	BALANCE TASK-SPECIFIC TRAINING	GENERAL PHYSIOTHERAPY
EDUCATION	**Educational pamphlet**	**Educational pamphlet**
PHYSICAL EXERCISES	→**Timing, mode and setting:** five times a week; 90 minutes/session; individual-based; rehabilitation room. →**Intensity, repetitions and duration:** Medium; 10-12/exercise; 3-5 minutes each exercise (adequate periods of rest are warranted if the subject feels tired). **Day 1-5: Learning hip and lower limbs movements** (physiological hip and lower limbs patterns of movement), and **active postural control** (ideal postures when supine, sitting and standing as described in *Kendall F, McCreary E, Provance P. Muscles: testing and function. 4th ed. Baltimore: Williams & Wilkins. 1993*) **Day 3-14:** standing with open eyes in order to reach a **symmetrical load and balance on legs while standing** **Day 6-14:** standing with open and closed eyes in order to reach a **symmetrical load and balance on legs** while keeping proprioceptive pillows under feet. **Day 14-21:** standing with open and closed eyes in order to reach a **symmetrical load and balance on legs** while standing by shrinking the support base, or maintaining the tandem position, or maintaining their position with and without the use of a proprioceptive bubble. **Day 5-14: Task-oriented training** while moving from the couch to the sitting position or from a sitting to a standing position, while walking on a rectilinear trajectory with crutches, while changing speed and direction, walking while regaining a symmetrical gait pattern. **Day 15-21: Task-oriented training** (the same as above and) walking on a rectilinear trajectory with and without crutches, walking at increasing speed together with rapid way changes, ascending/descending stairs, performing motor-cognitive tasks (e.g. climbing obstacles when talking, turning their head on the right and left side following physiotherapists'	→**Timing, mode and setting:** once-weekly, hourly sessions; group-based; rehabilitation room. →**Intensity, repetitions and duration:** Medium; 10-12/exercise; 3-5 minutes each exercise (adequate periods of rest are warranted if the subject feels tired). **Day 1-5: Learning hip and lower limbs movements** (physiological hip and lower limbs patterns of movement), and **active postural control** (ideal postures (BIB*) when supine, sitting and standing. **Day 3-7: open kinetic chain exercises** of the hip and lower limbs in the supine position on the couch with **active and passive mobilization** of the hip, knee and ankle based on physiological patterns of movement. **Day 3-7: muscle strength exercises:** isometric contraction of pelvi-trochanteric and lower limbs muscles of the hip and lower limbs. **Day 1-21: maintaining the length and elasticity of thigh tissues** of the hip and lower limbs (global and segmental stretching). **Day 5-21: Walking training:** walking on a rectilinear trajectory with crutches with the aim of regaining a symmetrical gait pattern. **Day 19-21: Round-up of exercises learned,** while checking their correct execution.

	inputs, crossing the zebra crossing) and usual life prolonged activities. **Day 1-21:** Implementation of **graded exposure** to exercises and activities learned. **Day 19-21: Round-up of exercises learned** while checking their correct execution.	