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Does functional strength training of the leg in subacute stroke improve physical performance? A pilot randomized controlled trial

Marte Bale Section of Physical Therapy, Førde Central Hospital (FSS), Førde and **Liv Inger Strand** Section for Physiotherapy Science, Department of Public Health and Primary Health Care, University of Bergen, Norway

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Objective: To examine the effect of functional strength training in subacute stroke.
Design: A single-blinded randomized controlled trial.
Setting: Two rehabilitation units.
Subjects: Eighteen patients in the subacute phase post stroke, randomly allocated to a functional strength training (intervention) group ($n=8$) and a training-as-usual (comparison) group ($n=10$).
Intervention: The functional strength training group participated in functional progressive strength training of the affected lower extremity. The training-as-usual group had traditional training, excessive muscle power being avoided to prevent associated reactions. All trained 50 minutes five days a week for four weeks.
Main measures: Maximum weight-bearing in standing (primary outcome), isometric muscle strength, gait speed and items of Motor Assessment Scale.
Results: Maximum weight-bearing on the affected leg improved more in the functional strength training group (mean 17.4% of body weight) than in the training-as-usual group (mean 5.6% of body weight), but taking test data at inclusion into consideration, the difference in change was not statistically significant ($P=0.056$). More patients in the functional strength training group (57%) could weight-bear on the affected leg while stepping forward, than in the training-as-usual group (17%). Improvement was clinically significant in 7 of 9 outcome measures in the functional strength training group (effect size $\geq$0.80, large), but in only 3 of 9 in the training-as-usual group. All patients in the functional strength training group and 70% of the patients in the training-as-usual group rated their overall status as 'much' or 'very much' improved.
Conclusions: This pilot study indicates that functional strength training of lower extremities improves physical performance more than traditional training.

Introduction

Stroke is a major cause of disability in Norway, as well as in other Western countries.[1] Hemiplegia is registered in 70–85% of first-ever case stroke,[2] and reduced muscle strength is considered a major

Address for correspondence: Marte Bale, Førde Sentralsjukehus (FSS), Vie, 6807 Førde, Norway.
e-mail: marte.bale@c2i.net

Los Angeles, London, New Delhi and Singapore

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cause of motor disability.[3] The gait pattern tends to be asymmetric in hemiplegic patients,[4] and gait speed slow.[5] A moderate to strong relationship has been demonstrated between gait speed and strength in different muscle groups of the affected leg,[6] and between gait speed and maximum weight-bearing on the affected leg in standing.[7] Patients with sequels from stroke bear less weight on the affected leg in rising from sitting to standing compared with healthy adults.[8] When attempting to maximum weight-bear on one leg at the time when standing, the patients tend to transfer less weight on the affected leg.[9]

Progressive resistance strength training has been found to strengthen paretic muscles after stroke.[10–12] Whether strength training is also effective in improving functional activities has been questioned.[13,14] Randomized controlled trials (RCTs) using strength training as intervention have shown inconsistent results regarding the effects on gait speed and sit-to-stand activities.[11,15,16] However, interventions that included task-oriented strength training, or used strength training in combination with training of balance, endurance, flexibility and functional activities, have resulted in improved performance of everyday activities.[10,12,17–19]

The effect of strength training on functional activities for patients in the subacute phase (between two weeks and six months post stroke), has only been examined in a few RCTs,[10,16,20] showing inconsistent results. Physical performance did not improve more by adding isokinetic strength training of knee muscles to traditional training[16] or by using weights around the waist or leg during functional movements in standing,[20] but Moreland *et al*.[20] suggested that their negative results might be due to lack of adequate outcome measures. Subacute stroke patients used proprioceptive neuromuscular facilitation patterns (PNF) or Theraband to strengthen the muscles as a part of a multidimensional progressive training programme targeting endurance, balance, flexibility and muscle strength in the study by Duncan *et al*.[17] The intervention was found to improve gait speed more than usual care did.

The purpose of the present pilot study was to test the following hypothesis: Patients in the subacute phase after stroke who receive progressive functional strength training will improve more in maximum weight-bearing and muscle strength of the affected leg, and in functional weight-bearing activities, than patients who receive training-as-usual with no focus on muscle strength.

Methods

Subjects

Patients with hemiplegia in the subacute phase after stroke were recruited to the study from two rehabilitation units, a hospital ward and a rehabilitation centre. Each patient who entered the units during defined time periods, were considered for inclusion in the study by the staff. The criteria for enrolment were first onset of stroke with reduced muscle strength in the affected leg, ability to understand verbal information and to sit without support. Patients were excluded if they had significant sensory or cognitive sequels, arrhythmia, uncontrolled angina pectoris or hypertension, or co-morbidities that could mask the sequels from the stroke. Also patients with no motor control of the affected leg were excluded. The study was approved by the Regional Committee for Medical Research Ethics and the Data Inspectorate. The first eight patients were recruited over a period of six months, and the last 10 over a period of one year.

A sample size calculation was performed based on test results of the change in maximum weight-bearing, including the first eight patients (four patients in each group) of the present study. The functional strength training group improved by 22.6% (SD 8.7) while the training-as-usual group improved by 3.0% (SD 13.5). A mean improvement of approximately 20%, as demonstrated, was considered clinically important. With a power of 0.90 and a significance level of $P < 0.05$, at least seven patients in each group were required to be included in the study.[21]

Design

An RCT was applied. Patients who were eligible for the study were asked to participate (Figure 1). Patients who volunteered and gave written informed consent were randomly allocated to two different training groups, either a functional strength training group or a training-as-usual group by drawing lots. From a total number of 20, 10 were allotted to each training group.

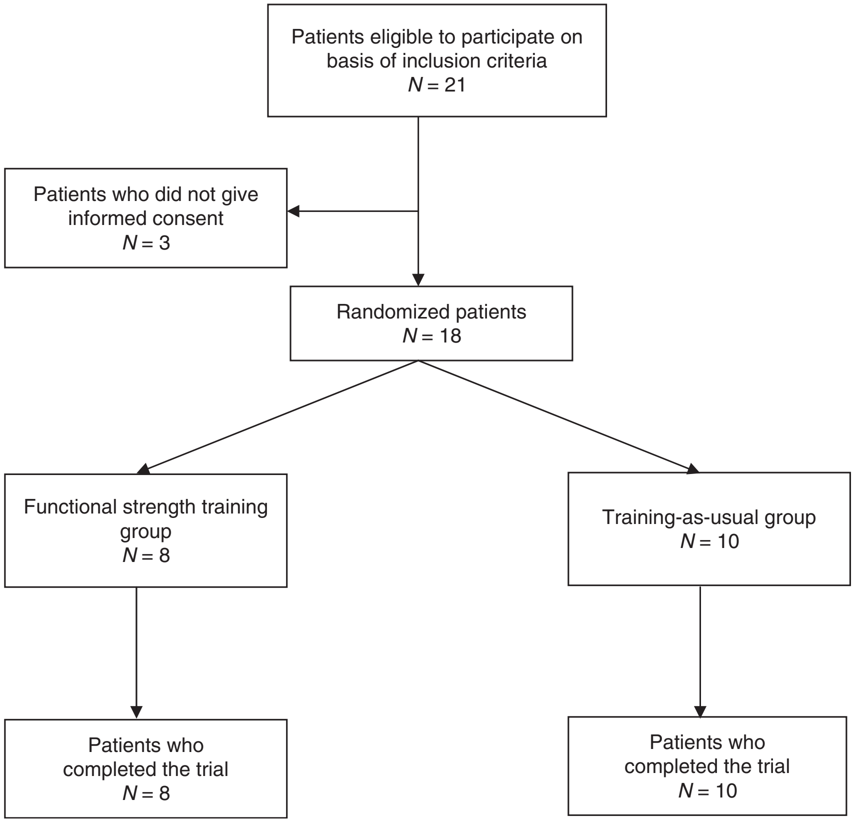

Figure 1 Flow diagram of participants in the study.

Twenty-one patients were eligible and asked to participate in the study and 18 gave written consent, eight in the functional strength training group and 10 in the training-as-usual group (Figure 1).

Intervention

The aim for both training groups was to achieve better performance of daily life activities. All participants trained with physiotherapists 50 minutes a day five days a week, for a time period of four weeks. Different physiotherapists trained patients in the two intervention groups.

Functional strength training

The patients in the functional strength training group had training to improve the muscle strength of the lower extremities three days a week, and trained arm functions and activities of daily living the remaining two days. The functional strength training programme was designed to facilitate appropriate power in the weak muscles of the affected leg in graded activities or sequences of activities. Most of the exercises were weight-bearing and also challenged standing balance (Appendix). Each strengthening exercise was performed according to the principle of 10–15 repetitions maximum to achieve moderate fatigue in one set.[22]

Training-as-usual

The patients in the training-as-usual group had traditional training influenced by the Bobath Concept, with a central focus on normalizing muscle tone and movements on the affected side, symmetrical use of the body and relearning activities of daily living, often using manual guiding and facilitation techniques. Use of excessive muscle power was avoided to prevent associated reactions during training. As part of their basic rehabilitation, all patients participated in multidisciplinary training programmes. Questionnaires were filled in by nurses and occupational therapists at week 3 of each patient's training period to obtain information about attendance and quantity of training in the wards, and in sessions with occupational therapists.

Outcome measures

Maximum weight-bearing

Maximum weight-bearing on each leg was performed by a procedure described by Bohannon[7] and it was used as the primary outcome measure. The patients were assessed when standing with each leg in the middle of one of two scales (Bianco EP 1130) placed side by side on the floor. The maximum ability to weight-bear on one leg at the time was registered and then converted to percentage of bodyweight. The test was performed on the affected as well as on the non-affected leg, twice each time. The mean weight of the two measurements was calculated. The difference in maximum weight-bearing between the affected and non-affected sides was calculated as a measure of symmetry. Less difference between the sides indicated better symmetry. Very high test–retest reliability of the measure in patients with stroke has been reported by Bohannon.[7] Test–retest reliability was examined in the eight first patients included in the study and found to be high, ICC(1,1) >0.80.[21]

Muscle strength

Isometric muscle strength was assessed with a dynamometer (Digital myometer; MIE Medical Research Ltd., Leeds, UK) for knee extension and flexion, on both affected and non-affected legs. The patients were tested in a seated position in a chair with 90 degrees of the hips and knees and with a fixation belt over the hips.[23] The length between the knee joint and the fixation belt for the dynamometer at the wrist, was measured in centimetres and the test parameter torque (Nm) was calculated as the force multiplied by the lever arm. The test was performed three times, and the means of the two last test results were calculated. The differences in strength between the affected and non-affected legs were calculated as a measure of symmetry in muscle strength. Less difference indicated better symmetry. Repeatability based on the last two of three measurements has been found to be very high in elderly people.[23] Test–retest reliability was found to be sufficiently high ($n = 8$) in the present study, ICC(1,1) $\geq$0.7.[21]

Gait speed

The patients were asked to walk a distance of 12 metres. The time to walk the central 8 metres was recorded by a stopwatch. The patients walked the distance twice at habitual gait speed, and twice at maximum gait speed. The mean of each gait speed was calculated in metres per second. The patients were allowed to use their usual walking-aid, if required. Measures of gait speed have been found reliable in stroke patients.[24]

Motor Assessment Scale

Two items of the Motor Assessment Scale[25] were assessed: sitting-to-standing and walking, using the Norwegian translation of the Motor Assessment Scale.[26] Each item is scored on an ordinal scale from 0 (cannot) to 6 (optimal motor behaviour). To have a score of 3 or better on sitting-to-standing, the patients must have even weight distribution on both legs while performing the activity. For the item walking, a score of 1 or better implies that the weight-bearing hip is extended while the patient stands on the affected leg and steps forward with the other leg. Inter-rater reliability for sitting-to-standing has been found to be high, and for walking very high in stroke patients.[27]

Patient Global Impression of Change

The Patient Global Impression of Change was used to assess the patients' impression of change after treatment. The following statement was posed: 'Since the start of the study, my overall status is', and the patients were to choose an answer from a 7-point ordinal scale. A score of 1 indicates 'very much improved', a score of 4 'no change', and a score of 7 'very much worse'.[28]

Test procedure

Two physiotherapists performed the physical measurements, and were blinded to the patients' group assignment. Before the study started, the testers were trained to perform the measurements based on a test protocol. To improve reliability they tested four patients independently at the same time, and discussed their scores afterwards. Eight patients of the pilot study were tested on two consecutive days both at inclusion and after four weeks. As little variability was demonstrated, the remaining patients were only tested once at inclusion, and once after four weeks of training.

Statistical analysis

Statistical analyses were performed in SPSS, version 11.5 for Windows (SPSS Inc., Chicago, IL, USA). All *P*-values are two-sided and values ≤ 0.05 were considered statistically significant. To examine and compare demographic and test characteristics at inclusion, chi-square test, *t*-test and Mann–Whitney *U*-test for independent samples were used. Kolmogorov–Smirnov test was used to examine normality of change in outcome data, deciding use of parametric or non-parametric tests. All data, except habitual gait speed, were found to be normally distributed ($P > 0.05$). Intention-to-treat analysis was planned,[29] but was not used since there were no drop-outs from the study (Figure 1).

Change in test data from inclusion to post test after four weeks within each group was examined using paired *t*-test or Wilcoxon test for two related samples. Difference in change between the two groups was examined with ANCOVA using pre values of test scores as covariate. To compare clinical importance of change, effect sizes of change were calculated within each groups, dividing the mean change from pre to post test by the standard deviation of the change.[24] According to effect-size benchmarks of change proposed by Cohen,[30] an effect size ≥ 0.80 is large.

The percentage of patients who improved to a score of 3 or better on the Motor Assessment Scale item sitting-to-standing and to a score of at least 1 on the Motor Assessment Scale item walking was also calculated for each group as indications of clinically important change.

Results

At inclusion there were no statistical significant differences between the groups, neither in demographic variables (Table 1) nor in physical performance measures (Tables 2–4). Attendance in training sessions, rehabilitation on the ward and in occupational therapy were not found to be different between the two groups ($P > 0.05$). After treatment, mean maximum weight-bearing on the affected leg had improved more in the functional strength training group than in the training-as-usual group (Figure 2 and Table 2), but taking test data at inclusion into consideration the difference in change was not quite statistically significant

Table 1 Demographic characteristics at inclusion

	Functional strength training group ($N = 8$)	Training-as-usual group ($N = 10$)
Time since stroke (days), mean (SD)	49.4 (22.1)	32.0 (18.5)
Age (years), mean (SD)	60.8 (13.0)	64.9 (8.8)
Gender		
Men	3	4
Women	5	6
Dominant side		
Right	8	10
Left	0	0
Affected side		
Right	6	3
Left	2	7
Cerebral haemorrhage	4	2
Cerebral infarct	4	8
Blood pressure		
Normal	4	2
High	4	8
Number of other diagnosis		
1–2	8	7
3–5	0	3

Table 2 Change in maximum weight-bearing (% of body weight) and difference in maximum weight-bearing between affected and non-affected sides (percentage) within groups, and comparison of change between the groups after four weeks

Weight-bearing (% body weight)	Functional strength training group ($N=8$)				Training-as-usual group ($N=10$)				Difference in change between groups
	At inclusion Mean (SD)	After 4 weeks Mean (SD)	Change Mean (SD)	*P*-values[a]	At inclusion Mean (SD)	After 4 weeks Mean (SD)	Change Mean (SD)	*P*-values[a]	ANCOVA *P*-values[b]
Affected side	56.5 (11.9)	73.9 (8.1)	17.4 (8.8)	0.001*	63.9 (16.7)	69.5 (14.6)	5.6 (11.3)	0.153	0.056
Non-affected side	77.9 (10.9)	85.1 (6.6)	7.2 (6.3)	0.015*	76.8 (12.1)	81.4 (8.7)	4.7 (7.3)	0.072	0.194
Difference between sides	21.4 (12.1)	11.2 (4.6)	−10.3 (9.4)	0.018*	12.9 (15.0)	12.0 (13.7)	−0.9 (13.9)	0.841	0.369

[a]Paired *t*-test.
[b]ANCOVA, test results at inclusion used as covariate.
$*P \le 0.05$.

($P=0.056$, Table 2). The functional strength training group also tended to improve more in muscle strength on the affected leg than the training-as-usual group (Table 3), but the difference in improvement was not statistically significant between the groups. Symmetry in muscle strength improved significantly more for knee flexors in the functional strength training group, than in the training-as-usual group (ANCOVA, $P=0.046$). Not all patients were able at inclusion to participate in the gait speed tests. Patients not able to walk the required distance were measured as having a speed of 0 m/s. The improvement was found to be larger in the functional strength training group than in the training-as-usual group for both gait speeds, and the difference in improvement between the groups was statistically significant for the habitual gait speed, but not for the maximum gait speed (Table 4). According to effect-size statistics, the functional strength training group achieved clinically significant changes (effect size $\geq$0.80) in 7 of 9 outcome variables, but the training-as-usual group only in 3 of 9 (Table 5).

At inclusion, seven patients in both training groups did not have even weight distribution on the legs (a score of 3) when rising from sitting to standing, assessed by Motor Assessment Scale. After four weeks of training, three of these patients of each group managed this requirement. At inclusion, seven patients in the functional strength training group did not meet the requirement of a score of at least 1 for walking assessed by Motor Assessment Scale, but four (57%) managed this requirement after four weeks. In the training-as-usual group one of six patients (17%) managed this higher demand after four weeks of training. According to the Patient Global Impression of Change, all patients in the functional strength training group and 70% in the training-as-usual group rated their overall status to have improved 'much' or 'very much' since the start of the study. In the training-as-usual group, 20% rated their status to be 'minimally improved,' and 10% 'unchanged'.

Discussion

Functional strength training of the legs was found to be more effective than traditional training to

Table 3 Change in isometric muscle strength (torque, Nm) within two groups receiving different training, and comparison of change between the groups after four weeks

Muscle strength (torque, Nm)	Functional strength training group ($N=8$)				Training-as-usual group ($N=10$)				Difference in change between groups
	At inclusion Mean (SD)	After 4 weeks Mean (SD)	Change Mean (SD)	*P*-values[a]	At inclusion Mean (SD)	After 4 weeks Mean (SD)	Change Mean (SD)	*P*-values[a]	ANCOVA *P*-values[b]
Knee extension: Affected side	30.3 (16.8)	47.9 (22.6)	17.7 (9.8)	0.01*	37.2 (28.7)	50.1 (40.0)	12.9 (13.5)	0.01*	0.14
Knee extension: Non-affected side	69.5 (20.7)	84.0 (31.9)	14.5 (19.0)	0.07	84.9 (53.8)	95.5 (54.8)	10.5 (13.4)	0.03*	0.61
Knee flexion: Affected side	10.6 (8.6)	17.9 (13.0)	7.3 (6.9)	0.02*	14.6 (13.8)	17.4 (16.1)	2.8 (4.8)	0.10	0.08
Knee flexion: Non-affected side	45.2 (15.1)	43.5 (15.2)	−1.7 (6.6)	0.49	42.5 (21.9)	44.9 (20.0)	2.3 (5.4)	0.20	0.19

[a]Paired *t*-test.
[b]ANCOVA, test results at inclusion used as covariate.
* $P \leq 0.05$.

improve weight-bearing on the affected side and gait speed in this pilot study of patients in the subacute phase after stroke. While improvement of isometric muscle strength of knee flexors and extensors of the affected leg did not differ significantly between the groups, the symmetry of strength in knee flexors improved more in the functional strength training group. As both patient groups had the same amount of training, the applied strength component of the functional training may seem to explain why the outcome differed between the groups.

The strong design applied in the pilot study and testers blinded to group allocation lend credit to the results of the study. The number of patients included was in accordance with sample size calculation based on the first eight patients, and should be a valid estimate. The fact that statistical significant differences in change were demonstrated between the groups in performance measures, in spite of the low number of patients, may underscore the positive effect of the functionally strength training. Also the effect-size statistics demonstrated that the functional strength training group obtained a more clinical significant change than the training-as-usual group, particularly in weight-bearing, which was the primary outcome measure of the present study. Questions may still arise concerning external validity of the findings as a relatively small number of patients were included. However, our results are in accordance with results from studies of patients in the chronic phase after stroke using task-oriented strength training of the legs or progressive strength training as a part of a broad training programme.[12,18,19] The response from strength training is specific, and the exercises should probably be as close to functional tasks as possible to enhance performance. In our study, functional strength training was integrated in the ordinary training programme, and did not cause excessive fatigue. The great attention to the limb and exerted effort during training of weight-bearing activities may seem to have enhanced muscular control of the affected leg and symmetry between the legs in functional activities.

Maximum weight-bearing was used as the primary outcome measure as this functional capacity was considered important in many daily life activities, and could be tested in all participating patients.

Table 4 Walking at habitual and maximum speed (m/s). Patients not able to walk are measured as having the speed of 0 m/s. *P*- values for changes within the groups, and comparison of change between groups after four weeks

Gait speed (m/s)	Functional strength training group ($N=8$)				Training-as-usual group ($N=10$)				Difference in change between groups
	At inclusion Mean (SD)	After 4 weeks Mean (SD)	Change Mean (SD)	*P*-values[a]	At inclusion Mean (SD)	After 4 weeks Mean (SD)	Change Mean (SD)	*P*-values[a]	ANCOVA *P*-values[b]
Habitual gait speed	0.13 (0.2)	0.36 (0.2)	0.23 (0.1)	<0.001*	0.38 (0.3)	0.46 (0.3)	0.08 (0.1)	0.029*	0.032*
Maximum gait speed	0.22 (0.2)	0.51 (0.3)	0.29 (0.1)	<0.001*	0.51 (0.4)	0.65 (0.4)	0.15 (0.1)	0.007*	0.067

[a]Paired *t*-test.
[b]ANCOVA, test results at inclusion used as covariate.
*$P \leq 0.05$.

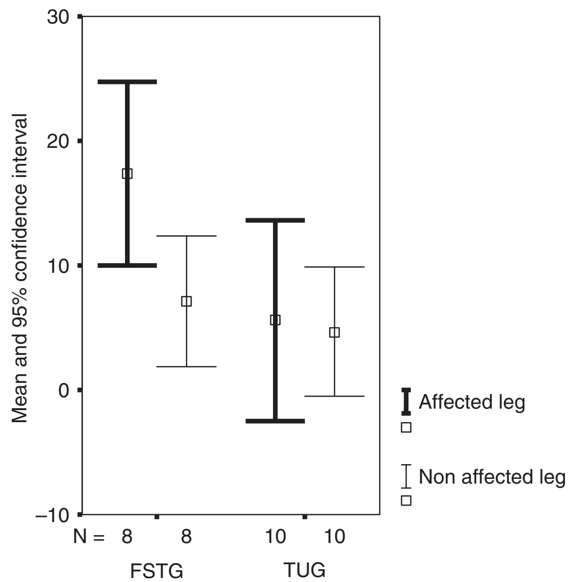

Figure 2 Changes in maximum weight-bearing (% of body weight) on affected and non-affected legs, in the functional strength training group (FSTG) and the training-as-usual group (TUG).

The maximum weight-bearing capacity improved somewhat in both groups on the affected as well as on the non-affected side. Improvement was better on the affected side in participants of the functional strength training group compared with the training-as-usual group, and the symmetry of weight-bearing also improved significantly within this group. The changes in maximum weight-bearing on the affected leg, the non-affected leg and in the symmetry of weight-bearing were considered to be clinically significant within the functional strength training group, but not in the training-as-usual group. However, pre values of maximum weight-bearing were found to have an impact on change, suggesting that patients who had little weight-bearing at inclusion were most likely to improve. As mean weight-bearing capacity was somewhat lower at inclusion in the functional strength training group, this explains some of the difference in change between the groups. The applied strength training may seem to be particularly important in patients with poor ability to maximum weight-bear on the affected leg.

Table 5 Effect size of change[a] within groups

Outcome measures	Functional strength training group	Training-as-usual group
Weight bearing (% of body weight)		
Affected side	1.98	0.49
Non-affected side	1.14	0.64
Difference between sides	1.10	0.06
Muscle strength (torque, Nm)		
Knee extension:		
Affected side	1.81	0.96
Non-affected side	0.76	0.78
Knee flexion:		
Affected side	1.06	0.58
Non-affected side	0.02	0.43
Gait speed (m/s)		
Habitual gait speed	2.3	0.80
Maximum gait speed	2.9	1.50

[a]Change from pre- to post-test/SD of the change. Change $\geq$0.80 = large.

Isometric muscle strength of knee extensors and flexors improved within both groups, and in particular knee extension on the affected side of the functional strength training group participants, but the improvement was not significantly different between the groups. Isometric muscle strength was not specifically trained in any of the two exercise programmes, but was expected to improve in both groups because of the spontaneous recovery that commonly takes place during the first weeks after stroke,[31] and because all patients were participating in active training. A previous RCT of stroke patients in the chronic phase using task-oriented strength training as intervention demonstrated larger differences in isometric muscle strength between the intervention and control groups.[12] However, as the patients in the control group of that study did not exercise, the difference between the groups was more likely to be substantial. Less improved muscle strength in our study may also be connected to the challenge of keeping the dose of training high enough (10–15 repetitions maximum) at this early stage after stroke. Impaired balance might have influenced the choice of dosage for strength training of the individual patient. To complete a single set during strength training is less time-consuming than using multiple sets.[22] This was taken into consideration in the present study, including subacute post-stroke patients, although the use of more sets might have given a bigger gain in muscle strength in the functional strength training group. In addition, therapists not blinded to group allocation might unconsciously have given the comparison group exercises that also challenged their muscle strength. Patients in the training-as-usual group, as well as the functional strength training group, might have used excessive muscle strength on the wards, as no restrictions were given to address this concern. The more improved symmetry of muscle strength for knee flexion in the functional strength training group versus the training-as-usual group was the result of improved muscle strength in the affected side, but also of a slight decrease in muscle strength in the non-affected side.

A weakness of our study was that not all patients had the physical capability at inclusion to be assessed regarding habitual and maximum gait speed. Patients who could not perform the tests were measured as having a gait speed of 0 m/s. Improvement was demonstrated in both groups, but greater improvement was demonstrated for the tests in patients of the functional strength training group than in those of the training-as-usual group. For habitual gait speed, the difference in change between the groups was statistically significant when the test values at inclusion were taken into consideration. Improvement on the ordinal Motor Assessment Scale's item sitting-to-standing was similar in the two groups while on the item walking, more patients in the functional strength training group managed to stand on the affected leg and step forward with the other leg after training than patients in the training-as-usual group. More patients in the functional strength training group than in the training-as-usual group reported a very satisfactory gain after the training period, in line with Oulette *et al.*[11] In our study this may be due to greater improvement in functional aspects of importance to the patients in the functional strength training group.

Clinical messages

- Functional strength training of the affected leg improved subacute stroke patients' ability to perform functional activities more than usual training with no particular focus on improving strength.
- Functional strength training implied attention to the affected leg with high demand of muscle power and weight-bearing during sequences of functional activities.

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Appendix – Exercises for affected lower extremity – Functional Strength Training Group

During the 2–3 first training sessions the strengthening exercises were individually adapted to each patient and learned.

- *Warming-up before the strength training exercises*: 5–10 minutes doing, for example, sit-to-stand exercises or walking.
- *Dose used during strength training exercises*: 10–15 repetitions maximum, to moderate fatigue, one set.
- *Progression*: by using weights, higher steps, lower bench, reducing the speed, decreasing the patient's support and/or doing more sets individually tailored, but as a rule adjusted after two weeks.

The patients trained ADLs such as walking, sitting-to-standing, stair climbing, etc. if time permitted after the strengthening exercises.

Exercise	Performance
Step-up in front by affected leg	Standing with the affected leg placed on a step in front. The patient steps up/lifts the whole body on to the step, and back down again
Weight bearing by affected leg	Standing with body weight on affected leg while lifting the non-affected leg on to a step in front and back down again
Step-up sideways by affected leg	Standing with the affected leg placed on a step beside this leg. The patient lifts the body sideways on to the step and down again
Lifting affected leg up on a step	Standing with body weight on non-affected leg, lifting the affected leg onto a step in front and back again
Standing to sitting to standing	Standing. The patient sits down until the buttock reaches the bench behind and then rises again
Heel rise	Standing with both feet on the floor. Rising up on toes and down again
Toe rise	Sitting. Dorsal flexion of affected ankle
Bridging	Supine lying with flexion in both hips and knees, and a box under the legs. Lifting and lowering the pelvis. Progression also when removing the box and with feet on the bench