Effects of a Community-Based Intensive Motor Training Program Combined With Early Supported Discharge After Treatment in a Comprehensive Stroke Unit
A Randomized, Controlled Trial

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Background and Purpose—Increased amount of therapy seems to be beneficial for motor recovery after stroke. The primary aim of the present study was to evaluate the effect of a 4-week community-based intensive motor training program combined with early supported discharge after initial treatment in a comprehensive stroke unit on balance. Secondary aims were to evaluate the effect on other functional outcome measures.

Methods—This was a single-blind, randomized, controlled trial with a 26-week follow-up. Sixty-two patients were recruited within 14 days after stroke and were randomly allocated to a standard treatment group (n=32) or to an intensive motor training group (n=30) receiving 3 sessions of physical therapy and a structured home exercise program in addition to standard treatment every week for the first 4 weeks after discharge from hospital. Primary outcome measure was Berg Balance Scale. Secondary measures were Barthel Index, Motor Assessment Scale, Step Test, 5-meter Walk Test, and Stroke Impact Scale.

Results—The mean (SD) minutes of physical therapy per week was 171.0 (65.8) in the intensive motor training group vs 85.6 (69.9) in the standard treatment group. There were no statistical significant differences between the groups on any measure at end of follow-up except for a trend toward higher Motor Assessment Scale score (P=0.059) and gait speed (P=0.095) in the intensive motor training group.

Conclusion—In this randomized, controlled trial, a community-based intensive motor training program, doubling the amount of physical therapy during the first 4 weeks after discharge, did not show significant improvement of balance or any other functional outcomes. (Stroke. 2010;41:1697-1703.)

Key Words: balance ■ intensive motor training ■ physical therapy ■ randomized controlled trial ■ rehabilitation

Stroke unit care with focus on early rehabilitation (comprehensive stroke units) improves functional outcome after stroke.1,2 Time from onset until first mobilization and amount of rehabilitation during hospital stay are 2 important factors for this improvement, showing positive association between early and intensive rehabilitation and good functional outcome.3,4 An additional beneficial effect on functional outcome is seen when stroke unit care is followed by an early supported discharge service.5,6 Both stroke unit care and early supported discharge service are based on a multidisciplinary approach, and this chain of care is recommended for patients with the diagnosis of acute stroke in Norway.

Physical therapy is an important part of the multidisciplinary approach, and it is suggested that early implementation of physical therapy is associated with enhanced and faster improvement of functional recovery after stroke.7,8 It is also evident that augmented exercise therapy within the first 6 months after stroke has a small but favorable effect on activities of daily living,9 and task-specific training improves walking distance, gait speed, and sit-to-stand activity.10 The most appropriate timing of intensive motor training (IMT) after acute stroke is still unknown, but the subacute phase might be a good period for increasing the dosage of physical therapy. The gains of IMT in the subacute phase probably also depend on the dosage administered in the acute phase.

Reduced balance is a common motor impairment after stroke11 and a major cause of falls.12 It is therefore of great interest to evaluate the effect of increased amount of motor

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training to improve balance after early and intensive rehabilitation in a stroke unit.

The primary aim of the present study was to evaluate the effect of a 4-week community-based IMT program combined with early supported discharge after initial treatment in a comprehensive stroke unit on balance. Secondary aims were to evaluate the effect of this treatment on other functional outcome measures. We hypothesized that patients receiving a 4-week community-based IMT program combined with early supported discharge after initial treatment in a comprehensive stroke unit would have greater improvement on balance than standard treatment (ST).

Materials and Methods

Participants

Patients admitted to the Stroke Unit at St. Olavs Hospital, Trondheim, Norway, between April 2004 and September 2007, were screened for inclusion 4 to 14 days after stroke and were included if they fulfilled the following criteria: diagnosis of acute stroke according to WHO’s definition, modified Rankin Scale score <3 before admission,13 Berg Balance Scale score <45 points, Scandinavian Stroke Scale (SSS) score >14 points, Scandinavian Stroke Scale leg item <6 points or Scandinavian Stroke Scale transfer item <12 points, Mini-Mental State Examination14 score >20 points, and able and willing to sign informed consent. Patients were excluded if they could not tolerate the increased amount of motor training because of serious cardiovascular diseases, defined as incompensated heart failure with dyspnea or angina pectoris with chest pain during rest or other functional impairments, such as severe rheumatoid arthritis or Parkinson disease.

Study Design

This study was a randomized, controlled trial with blinded assessment. Patients who fulfilled the inclusion criteria were included and stratified according to age, stroke severity, and affected side before block randomization to ST group or to IMT group receiving an increased amount of motor training in addition to ST every week for the first 4 weeks after discharge from the stroke unit. The block randomization was performed by a computer-based randomization program created by Department of Cancer Research and Molecular Medicine, Norwegian University of Science and Technology, Trondheim, Norway. The size of the blocks varied and we did not know the size of the blocks. A complete study protocol is available at http://www.clinicaltrial.gov (NCT00184431). The study was approved by the Regional Committee of Medical and Health Research Ethics and Norwegian Social Science Data Services.

ST

All patients were treated in a comprehensive stroke unit emphasizing mobilization to standing or sitting position out of bed within the first 24 hours after onset of symptoms and physical therapy according to a task-oriented approach, focusing on independence in activities of daily living, as described by Indredavik et al.3 The therapy was administered as 2 daily sessions of 30 minutes, 5 days per week. In addition, specially trained nurses in the stroke unit offered training in activities of daily living when appropriate during 24 hours.4 The stroke unit treatment was based on a team approach combining acute medical treatment and rehabilitation. In addition, all patients received early supported discharge, coordinated by a hospital-based multidisciplinary team.4 The multidisciplinary team worked in close cooperation with the primary health care system during the first 4 weeks after discharge. The further rehabilitation was administered as inpatient rehabilitation, outpatient rehabilitation, or as rehabilitation in the patients’ home according to the patients’ needs.

IMT

Intensity of practice has been described as “amount of external work,” “frequency of repetition of desired movement,” or “amount of time that is dedicated to practice.”16 In the present study, intensity was defined as ‘increased frequency of repetition of desired movement” and “increased amount of time dedicated to practice.”

The IMT group received 3 additional sessions of motor training each week for the first 4 weeks after discharge from the stroke unit and 1 additional session every week for the next 8 weeks. Each session was intended to last from 30 to 50 minutes. The patients were also encouraged to perform home exercises during this period.

The additional motor training comprised reaching tasks in sitting and standing positions, sit-to-stand, step tasks, and walking tasks. All tasks were individually adapted and varied according to base of support, speed, weight, and complexity. The patients were instructed to repeat as many repetitions of each task as tolerated. Borg rating scale of perceived exertion17 was used to ascertain a certain level of effort, and the patients were instructed to exert themselves between 13 (somewhat hard) and 15 (hard) during the sessions. The patients also partially wore an orthosis on the less affected leg during these sessions to force the use of the more affected leg.

The IMT program was provided by physical therapists in the primary health care system and was added to the standard care also provided by the same therapists. The treatment was administered in the patients’ home, at a rehabilitation clinic, or at an outpatient clinic, depending on where the patients were discharged after their hospital stay.

The home exercises consisted of 4 tasks that were individually chosen according to the patient’s functional level. The patients were told to perform 10 repetitions of each task and to repeat the exercises twice per day, 6 days per week.

Outcome Measures

Primary outcome measure was Berg Balance Scale at 26 weeks after stroke.18 Secondary measures were Motor Assessment Scale,19 Barthel Index,20 Step Test21 measuring number of steps with affected leg on a step (height, 7.5 cm) during 15 seconds, and Stroke Impact Scale.22 Five-meter Walk Test was performed at maximum gait speed23 for patients who could walk without support at inclusion.

All outcomes were assessed at baseline (4–14 days after stroke), 4 weeks, and 12 weeks after discharge from the stroke unit, and 26 weeks after stroke. The energy expenditure rated by Borg rating scale and time spent on each physical therapy session was registered by the physical therapists and the compliance to home exercises was registered by the patients in a training diary. The training diaries were collected and checked monthly by the project coordinator. The time spent on home exercises was calculated by multiplying the number of sessions registered in the training diary by 10 minutes.

Adverse Events

The physical therapists were instructed to report any adverse events during both IMT and ST. Adverse events were recorded in a day-to-day record. Falls were also recorded during treatment and follow-up and inspected on a monthly basis.

Data Analysis

The sample size was computed using previously published data on Berg Balance Scale from a comparable population.24 A 6-point increase or decrease on Berg Balance Scale was regarded as a clinically significant change.24 Using a significance level of 0.05 and power of 0.9, a study sample of 30 patients in each group was needed.

At baseline, group homogeneity was analyzed with independent sample t test for continuous variables and χ² tests for categorical variables. Independent sample t test was also used to analyze differences in the amount of physical therapy between the groups. Intention-to-treat analysis was performed for all outcome measures at all follow-up assessments. Any missing values at follow-up were imputed using last-value-observed carried forward. Analysis of covariance adjusting for stroke severity was applied as a statistical
approach for all measures at the follow-ups. P<0.05 was considered as significant. SPSS version 16 was used for all analysis.

Results

In all, 834 patients were screened for inclusion (Figure 1). The main reason for exclusion was functional dependency (modified Rankin Scale >2) before the stroke, followed by no significant leg paresis or no reduction in balance after stroke. Sixty-two subjects were included in the study and 30 patients were randomly allocated to the IMT group and 32 patients were randomly allocated to the ST group.

There were no differences between the 2 groups on any features regarding patient characteristics, except there were slightly more patients with a medical history of myocardial infarction in the IMT group and slightly more patients with diabetes in the ST group (Table 1).

Mean (SD) score improved significantly (P<0.000) from baseline to 26-week follow-up in both groups on all reported outcome measures (Figure 2). Regarding between-group comparisons, results from the 26-week follow-up are reported in Table 2. Any other significant differences between the groups are reported in the text.

Analysis of covariance adjusting for stroke severity showed no significant differences between the groups on Berg Balance Scale at 26-week follow-up. There were no significant differences on any secondary measures, except for Motor Assessment Scale showing greater improvement in the IMT group at 4-week (P=0.040) and a trend toward greater improvement at 26-week (P=0.059) follow-up (Table 2).

Twenty-one patients with initial walking ability in each group were assessed on maximum gait speed. Analysis of covariance adjusting for stroke severity showed a trend toward significant faster gait speed in the IMT group (P=0.095) at 26-week follow-up (Table 2).

The mean (SD) minutes of IMT and ST per week and ratings on Borg rating scale are reported in Table 3. The IMT group received, on average, 7.5 additional hours of physical therapy compared to the ST group during the 12 weeks, and spent, on average, 15.5 hours on home exercises during the same period. Three patients received less than half of the intended dosage of IMT during the first 4 weeks because of reduced staffing during holiday seasons for 2 patients and readmission to hospital for 1 patient. The ST group exerted themselves between “somewhat hard” and “hard” (mean [SD] Borg rating was 14.2 [1.9]) during the ST, whereas the IMT group exerted themselves at the same level during the IMT but a bit lower during the ST.

Adverse Events

One patient in the IMT group experienced dizziness attributable to reduced blood pressure. Another patient in the IMT group was admitted to hospital because of a new stroke. Both patients continued the IMT program after these events. There were no serious falls in the IMT group.

Discussion

This is, to our knowledge, the first randomized, controlled trial evaluating the effect of a community-based IMT program combined with early supported discharge after
treatment in a comprehensive stroke unit. The IMT was safe and feasible but did not significantly improve balance. However, there was a trend toward greater improvement in overall motor function in the IMT group compared to the ST group.

The main strength of this study is the randomized, controlled design with a blinded assessor and the high-quality ST, consisting of initial treatment in a comprehensive stroke unit and further follow-up with early supported discharge, given to all patients in both groups.
The IMT group showed slightly higher scores on all outcome measures compared to the ST group (Figure 2). None of these differences was significant despite Motor Assessment Scale at 4-week follow-up and there was also a trend toward significant greater improvement at 26 weeks, indicating a possible benefit of the IMT on overall motor function. A 2-point change on Motor Assessment Scale might be the difference between dependency and independency, depending on which part of the scale the patient belongs to and, consequently, this statistically nonsignificant finding might be a clinically significant between-group difference. The improvement on Motor Assessment Scale also corresponds with a trend toward significant faster gait speed for those patients with initial walking ability, indicating that patients with initial walking ability benefit most from the IMT program. This is in line with other studies showing improvement in mobility after high-intensity therapy.

Borg rating scale of perceived exertion was used as a measure of energy spent on practice. Borg rating scale is not widely used in rehabilitation of stroke patients because this group of patients spends a lot of cognitive energy on relearning motor tasks, making the scale less feasible. However, we wanted to expand the use of Borg and asked the patients to rate their overall feeling of exertion. The mean rating on Borg was between “somewhat hard” and “hard” in both groups, although the physical therapists thought that patients in the IMT group spent less effort on performing a greater amount of exercises.

The IMT group spent, on average, 7.5 additional hours on physical therapy and 15.5 hours on home exercises during the 12-week intervention period. A general problem in training studies is that the control group has more time available for performing exercises on their own, increasing the risk of less significant difference in intensity between the groups. This could have been the case in the present study. However, the difference in additional physical therapy should be regarded as a reliable result. A meta-analysis by Kwakkel et al showed...
a small but favorable effect of augmented therapy on activities of daily living, at least if the amount of therapy is increased 16 hours within the first 6 months after stroke. This finding is not confirmed by our results, which show an equivalent improvement on Barthel Index in both groups. The dosing of therapy in the early phase after stroke appears to show a dose–response relationship, demonstrating that doses higher than optimal range may be less effective than lower doses and even may be detrimental. There was no such disadvantage of the applied dosing in the present study, indicating that the dosing was within the limits of tolerable amount, and it may have been augmented even more to achieve a greater improvement in the IMT group.

Both Step Test and gait speed showed a trend toward further improvement in the IMT group at 26 weeks, whereas the ST group showed a trend toward decrease in performance. Patients in the IMT group might have implemented some of the home exercises into their daily life, and the benefit of this change in behavior would have been more significant in the long-term. Unfortunately, there was no long-term follow-up in the present trial. Longitudinal stroke studies often show that functional level is starting to decrease at 6 months after stroke, and it is a challenge to postpone this decline. Therefore, further studies should assess if increased physical activity in these patients can reduce the decline in functional outcome between 6 and 12 months after stroke.

The lack of significant differences between the groups on the primary outcome may have several possible explanations. First, Berg Balance Scale is reported to have a ceiling effect for patients with mild stroke impairments when administered at 90 and 180 days after stroke, implying that we may have missed clinical significant gains in balance in patients with mild to moderate stroke. Second, our study was powered to detect a 6-point difference between the groups on Berg Balance Scale. Although a 6-point change on Berg Balance Scale has been shown to be a clinically important change in patients with mild to moderate stroke, a clinically significant between-group difference may be even smaller. As far as we know, the smallest clinically significant difference between groups has not been reported for Berg Balance Scale and the 6-point change is our best available estimate.

The same physical therapists provided both the IMT program and the ST. The intervention was an integrated part of their daily work and therefore, it was feasible to conduct as a part of the community practice. The very low drop-out rate (3%) also supports the feasibility of the study. Rehabilitation studies often do have a high drop-out rate, especially at long-term follow-up, and was reported up to 24% in the EXCITE trial. The low drop-out rate in the present study indicates that the inclusion criteria could have been broadened, making the intervention available for a greater proportion of the stroke population.

Conclusion

This community-based IMT program did not improve balance. However, the long-term effect of an even more intensive program should be tested out in a larger multicenter trial.

The ultimate goal of rehabilitation is to increase the number of independent stroke patients, which would be cost-effective and also improve the patients’ quality of life. It is therefore important to explore whether this goal could be achieved by defining the appropriate intensity of motor training for patients after stroke.

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Disclosures

None.

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