An evaluation of two different exercise regimes during the first year following stroke.

A randomised controlled trial.

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ABSTRACT

Objective: To evaluate effects of two exercise approaches during the first year after stroke on instrumental activities of daily living (IADL), gait performance, balance, grip strength and muscle tone and to investigate explanatory factors for some IADL activities.

Design: A double-blind longitudinal randomised trial of first-time-ever stroke patients.

Setting: cute hospital and community.

Participants: Seventy-five patients: 35 in an intensive exercise group and 40 in a regular exercise group.

Interventions: The intensive exercise group received intensive functional endurance, strength and balance training. The regular exercise group was not recommended any specific training.

Main Outcome Measures: Instrumental Activities for Daily Living according to Fillenbaum, 6- Minute Walk Test, Berg Balance Scale, Timed Up and Go, grip strength, Modified Ashworth Scale, and pulse monitoring.

Results: One year post stroke both groups showed higher participation in all items of the Instrumental Activities for Daily Living Test and improved in the results of 6-Minute Walk Test, Berg Balance Scale, Timed-Up-and-Go and grip strength. At 3, 6 and 12 months follow-ups there were some significant differences in favour of the regular exercise group. A multiple regression analysis revealed that scores of Berg Balance Scale were the strongest explanatory factor for Instrumental Activities of Daily Living item 2 "get to places out of walking distance" at both 3-month and 1-year follow-ups and that ($R^2 = 0.63$ / 0.67 and that 6-Minute Walk Test was the strongest explanatory factor for item 7 "can you handle your own money" at the 1-year follow-up.

Conclusion: Both groups improved to similar degrees in IADL, gait, balance and grip strength. The test occasions themselves were strong motivators for training, irrespective of group allocation. IADL was to a higher degree explained by the results of 6-Minute walk test and Berg Balance Scale than Timed-Up-and-Go and grip strength.

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Key words: balance, exercise, gait, participation, stroke, tone

INTRODUCTION

In stroke rehabilitation outcomes are often considered in relation to body function and levels of activity, such as muscle function, muscle tone, personal activities of daily living and walking. Instrumental activities of daily living (IADL) and participation are not so often mentioned in the rehabilitation of stroke patients, and even less so associations between body functions, activities and participation. The ability to walk has been shown to be related to independent living (1-3). A reduced walking capacity might lead to a decrease in endurance, muscle power and postural control, which in turn may lead to problems both with transfers and with personal and instrumental ADL (4). It is not known, however, whether improvements in walking ability, balance and strength are related to more independence in IADL, as has been demonstrated for personal ADL (5-8)? The few studies of IADL have shown that stroke patients are dependent to a great extent upon relatives (9), that IADL are related to leisure activities (10), and that being male, unmarried, of high age, ADL can be predictors of social inactivity 12 months post stroke (11). The influence of therapy on IADL is not well documented (12-13), nor is the association between IADL, gait, postural control, muscle power and tone.

Our main objective in this study was to evaluate the effect of two different exercise approaches during the first 12 months post stroke, and to study the possible effects of these two regimes on IADL, the 6-Minute Walk Test, Berg Balance Scale, Timed-Up-and-Go, grip strength and Modified Ashworth Scale.

A second objective was to find out to what extent parameters such as gait performance, postural control, grip strength and muscle tone could be considered explanatory factors of IADL 3 months and 12 months post stroke.

METHODS

SUBJECTS

The study was designed as a double-blind, intention to treat, longitudinal randomised controlled stratified trial. Randomisation took place at discharge from the acute hospital. Patients were randomised into two different groups, an intensive exercise group and a regular exercise group by a person not involved with the patients or the treatment on the ward. Neither the investigator nor the patients knew to which group the patients were allocated. Stratification was done according to gender and hemisphere of lesion. The protocol was sealed for 1.5 years from the start of the study, until the last patient included had been tested at the12- month follow-up. Inclusion criteria were first-time-ever stroke, confirmation of stroke by neurological signs and computer tomography, and voluntary participation. Exclusion criteria were subarachnoid bleeding, tumour, other serious illness, and brain stem or cerebellar stroke. Patients who fulfilled the inclusion criteria were included in the trial consecutively as they were admitted to the hospital.

On the basis of an earlier study (14) a power calculation was made and it was estimated that 29 participants were required in each group to detect a difference in motor function with a significance level of 0.05 and a power of 80 %.

Informed consent was given by all participants through methods approved by the Regional Committee of Medical Research Ethics of Norway.

Data collection

A test protocol was set up, consisting of well-known clinical measurements that could be implemented anywhere without laboratory equipment. Instruments included were Instrumental Activities of Daily Living tested according to Fillenbaum (15), 6-Minute Walk Test (16 -17), Berg Balance Scale (18), Timed-Up-and-Go (19), grip strength (Martin vigorimeter) (20), and Modified Ashworth Scale (21). Pulse monitoring during activities was also included, with the aim of obtaining complementary information on perceived energy expenditure.

Instrumental Activities of Daily Living Test according to Fillenbaum, 6-Minute Walk Test, Berg Balance Scale and Timed-Up-and-Go can be said to represent measures of activity and participation level, according to the International Classification of Function (ICF), World Health Organisation (22). Grip strength and muscle tone, on the other hand, are tests on the body organ/body structure level, according to the same classification (22).

The patients were tested on admission, at discharge, and after 3, 6 and 12 months after the stroke incident by an experienced investigator, blinded to group allocation. The tests were performed in the general hospital, in the patients' homes or in community service centres.

Information about IADL was recorded according to The Duke Older Americans Resources and Service Procedures (OARS) Multidimensional Functional assessment of Older Adults by Fillenbaum, where the part of self-care capacity captures the dimensions of PADL and IADL (15). The information was collected by a structured interview with the stroke patients and their carers. They were asked ten questions about use of the telephone, getting to places out of walking distances, which requires a car or a bus, purchasing of groceries / clothes, cooking capacity, housework in general, medication, care of economy and bank transfers, and whether they received help and from whom. The answers were divided into three levels: independent = 2, some help = 1 and totally dependent = 0. The part concerning self-care capacity has been tested for validity (r =0.89) and reliability (r=0.87), with satisfactory results (15).

Walking capacity was monitored by 6-Minute Walk Test using a standardised protocol (16-17). Distance walked (m) and gait velocity (m/s) were measured by the investigator. The 6-Minute Walk Test was performed in an 85 m long corridor in the hospital and institutions. In patients' homes, this test was preferably performed outdoors on an 85 m long stretch.

Indoors in patients' homes the longest stretch was chosen, but this was done only twice with two patients, 6 and 12 months post stroke. Patients were encouraged to walk as fast and as long a distance as they could in 6 minutes. The 6-Minute Walk Test is also used to assess exercise tolerance (23-24), thus measuring functional exercise capacity. Gait velocity has been tested among elderly individuals for validity and reliability, with satisfactory results (25) and it has also been used in several stroke studies.

Berg Balance Scale is a balance test, consisting of 14 items, scored from 0 to 4. It has been used in many studies and has been found to have satisfactory reliability and validity (25). Berg Balance Scale is especially sensitive for detection of risks of falls in frail elderly persons. An overall score of less than 45 points, out of a maximum of 56, is associated with a 2.7 times increase in the risk of a future fall (26).

Timed-Up-and-Go is a functional mobility test that is used in the clinic to evaluate dynamic balance, gait and transfers. The patient is asked to get up from a chair (46 cm high), with support for the arms, walk three meters, turn, go back and sit down. The physiotherapist monitors the time taken from the start to the end, when the patient is seated. The test is valid and reliable and has been used in several studies including stroke studies (16, 19, 25).

Strength was evaluated by monitoring grip strength in the paretic and the non- paretic hand. It was measured with a *Martin vigorimeter,* consisting of a manometer with rubber tubing and three rubber squeeze bulbs of different sizes: male-, female/young- and child size. The manometer gives the respective reading in bars (1 bar = 1,019 kp (kp/cm^2). When taking the test, the patient has to squeeze the vigorimeter three times with all possible strength without seeing the gauge. The averages of the three squeezes are then used. Normal values for healthy people are 0.8 to 1.3 kp for male adults, and 0.7 to 1.2 kp for female adults (20, 27-28). The Jamar dynamometer and Martin vigorimeter have been compared regarding validity, and Pearson´s product-moment correlation was found to be r = 0.89 for the right hand and 0.90 for the left (27). Test-retest reliability showed intra-class correlation coefficients of 0.96 for the mean of three measures on the dominant hand and 0.98 on the other (29).

The Modified Ashworth Scale is a clinical measure of muscle tone with an ordinal scale to grade the resistance encountered during passive muscle stretch, graded 0, i.e. no increase in tone, to 4, when the affected part is rigid in flexion or extension. The inter- and intra-rater reliability is reported to be very good to fair (21) for some muscle groups, but the reliability and validity have not been established for all muscle groups. The reliability seems to be better in the upper limb (30). There is some controversy as to what component of muscle function the scale is measuring, and its validity as a measure of spasticity or muscle tone is hence unclear (30-32).

Pulse rate was measured with a pulse monitor, Sport tester™ PE 3000, made by Polar Electro, Finland. The pulse monitor consists of a belt placed around the patient´s thorax and a wrist pulse monitor, which was in the hands of the examiner during the test. Pulse at rest was monitored at the beginning of the test procedure after 15 minutes´ rest and pulse in activity was recorded during 6-Minute Walk Test, where the mean of three measurements of the highest pulse rates was recorded.

Treatment

Both groups received functional task-oriented training tailored according to their specific needs during the acute period of rehabilitation. The amount of such training was equal in the two groups, with two periods per day, a total of one hour of physiotherapy, in combination with other specialised therapies as required.

Patients allocated to the intensive exercise group were scheduled after discharge to have four periods of physiotherapy during the first year after their stroke, with a minimal total amount of 80 hours. This was distributed into a minimum of 20 hours every third month after their initial incident (Fig.1). The first intervention period started immediately after discharge with sessions 2 or 3 times weekly, up to a total of at least 20 hours, if the patients were at home in their own home or in a private physiotherapy practice. If they stayed in a rehabilitation ward they had daily exercise sessions. This intervention was repeated after 3, 6 and 12 months. The exercises in the intensive exercise group were focused on intensive functional endurance, strength and balance exercises. The intensive exercise group patients were also encouraged to keep their activity levels up, not only in training sessions but also at other times. A protocol with suggestions of types of exercises and levels of intensity was developed in discussion with all physiotherapists involved. The individualised training programmes were aimed at functional improvements but with variations, for example training in getting up from a chair, walking in-doors, Nordic walking outdoors, stationary bicycling, and stair walking, where the physiotherapist monitored the level of intensity through Borg's Scale or the pulse rate. The goal of these exercises was to improve and maintain the body functions grip strength and muscle tone, the activities walking capacity and balance, and participation in IADL (Table 2).

The patients belonging to the regular exercise group were not sent for follow-up treatment on a regular basis during the post stroke year. If the patient was in need of follow-up treatment or rehabilitation they were assigned to that according to their needs, as deemed appropriate by the rehabilitation staff at the stroke unit / rehabilitation ward or by the rehabilitation team in the community. No specific treatment was recommended to this group (Table 2). On the other hand, like the intensive exercise group they were encouraged to keep their activity levels high in general.

Compliance to the training programmes was recorded by the physiotherapists in charge of the follow-up treatment. Compliance was considered high in the intensive exercise group patients if they did the exercises at least twice a week in all four exercise periods during the year post stroke. In the regular exercise group patients any completion of follow–up treatment after the acute rehabilitation was considered as high compliance, since the expectations of follow-up were minimal in this group, as based on earlier experiences (14). The participants of both groups were also interviewed informally on each test occasion concerning their own training habits, their motivation to exercise, and whether and how they were doing exercises. The motivation was considered high if the participants did the exercises regularly, if they complied with the tests at different times during the year post stroke and if they gave positive verbal expression of the importance of exercise. In order not to compromise blinding and disclose group allocation, the project leader made notes during these interviews and kept track of information, to be able to compare these notes on training habits with the actual training information from the physiotherapists, as the seal of blinding was broken at the end of the study. This procedure was meant to be a double check on training habits and compliance by comparing subjective and objective information.

Statistical analysis

The results were analysed in an SPSS programme version 13. Descriptive statistics were used to summarise demographic, stroke and baseline characteristics. All analyses were performed on an-intention-to-treat basis. Mean and standard deviation (SD) were calculated for 6-Minute Walk Test, grip strength and Timed-Up-and-Go. Mean and median were calculated for Berg Balance Scale. A general linear model, with univariate analysis of variance (ANOVA) was performed, using change from baseline to 12 months as dependent variable for each of the scores of Instrumental Activities of Daily Living Test , 6-Minute Walk Test, Berg Balance Scale, Timed-Up-and-Go, grip strength and Modified Ashworth Scale, respectively, with treatment group as a fixed factor and time, age and gender as covariates.

For analyses within the groups, a two- way analysis of variance (ANOVA) was used for results of 6-Minute Walk Test and Timed-Up-and-Go, and the Friedman two-way analysis of variance by rank for scores of Instrumental Activities of Daily living by Fillenbaum, Berg Balance Scale and Modified Ashworth Scale. The significance level was set at $p < 0.05$.

Spearman rank correlation coefficients were calculated to search for the associations between Instrumental Activities of Daily living by Fillenbaum and other tests.

Items statistically significant at $p<0.05$ in a bivariate analyses were included in a model of regression, to analyse explanatory factors related to two different items of the Instrumental Activities of Daily Living evaluation. A stepwise linear regression analysis was performed in the two groups, with the scores of item 2 of the Instrumental Activities of Daily living Test ("can go to places out of walking distance", seen as a physical variable) and item 7 ("handle own money", seen as a cognitive variable) entered as dependent factors, and results of 6-Minute Walk Test, Berg Balance Scale, Timed-Up-and-Go, grip strength and Modified Ashworth Scale entered as independent factors on two different occasions: at 3 months and at 12 months.

RESULTS

A total 185 patients with stroke were registered at the hospital during the period of 1. September 2003 till 1. September 2004. After close screening, 75 adhered to the inclusion criteria and were consecutively included in the study, 35 in the intensive exercise group and 40 in the regular exercise group. Four patients died and four withdrew during the acute stage (flow chart, Fig.1). The reasons for the latter withdrawals were a new diagnosis, anxiety, cognitive status /dementia and advanced age (98 years), respectively, and one patient did not want to participate.

Demographic data are presented in Table 1. There were no significant differences between the groups regarding age, hemisphere of lesion and marital status at baseline on admission to the stroke unit. The main causes of stroke were thrombosis or embolism, 29 of 35 patients in the intensive exercise group and 36 of 40 in the regular exercise group.

At discharge there were 32 patients in the intensive exercise group, taking part in the compulsory training four periods during the first year after the stroke, and 35 patients in the regular exercise group, with training according to their needs. After 12 months 32 patients remained in the intensive exercise group and 31 in the regular exercise group (Fig.1). The patients in both groups were very active and highly motivated for training, and 25 patients in the intensive exercise group (71%) compared to 26 patients in the regular exercise group (65%) stated spontaneously on the test occasions that they found the exercises vital for their function and well-being. Compliance to the training programmes was also high in both groups; good compliance being noted in 28 patients in the intensive exercise group (80 %) and in 31 patients in the regular exercise group (78 %). The intensity of the programme was high in both groups, with therapeutically steered training in the intensive exercise group and self-initiated training in the regular exercise group. Between the 3-month and the 12-month follow-ups the mean number of occasions of supervised exercise in the intensive exercise group was 2.1 times per week and in the regular exercise group 2.2 times per week. This amounts to approximately 40 weeks of exercise per year in both groups, which represents the 80 hours we initially aimed at in the intensive exercise group.

Outcomes

The results of the standardised interviews concerning Instrumental Activities of Daily living to the OARS Multidimensional Functional assessment of Older Adults by Fillenbaum (15) are presented in Table 3. There were no significant differences on baseline measures in any of the items of Instrumental Activities of Daily Living Test. Both groups reported a higher extent of activity in all the items at 3, 6 and 12 months post stroke compared with the discharge levels. There were no significant differences in any of the variables between the groups either on admission or at discharge. At the 3 month follow-up there were significant differences in item 1 (use the telephone) and item 4 “(cook your own food) in favour of the regular training group.

At 6 months there were significant differences in items 1 and 3 (able to do own shopping), and at 12 months in items 1 and 2 (getting to places out of walking distance), 3, 4 and 5 (do housework) and 8 (help from others with transportation, finances and housekeeping) on all occasions, in favour of the regular exercise group (Table 3). However, the two groups had an equal amount of help from relatives and the community (item 9), and there was no significant difference between the groups at any time on this item. At 3, 6 and 12 months 25 % in both groups were independent, 28 % relied on community/institutionalised help, and 47 % where dependent on their relatives.

Both the walking distance and the walking velocity, measured with 6-Minute Walk Test (16-17), improved significantly from admission to 12 months post stroke in both groups. However, on admission some of the participants could not walk, 13 in the intensive exercise group and 12 in the regular exercise group. The groups were comparable with no significant differences at baseline measure. At discharge only four in each group could not walk, and at 3 months three patients in the intensive exercise group and one in the regular exercise group were still unable to walk. At 6 months two of the patients in the intensive exercise group and one in the regular exercise group and at 12 months four in the intensive exercise group and one in the regular exercise group were unable to walk. All patients were included in the analyses on all occasions, but the non-walkers were rated 0. The differences between walkers and non-walkers were not significant at any time in either group (Table 4). There was no significant difference in 6-Minute Walk Test between the groups either for walking distance or velocity until the12- month follow-up tests when the regular exercise group walked significantly longer and faster than the intensive exercise group (Table 4).

The pulse rate at rest and during activity did not differ significantly between the groups on any of the tests. The pulse rate varied from 72 – 81 at rest and from 106 – 118 during activity.

Both groups showed significant improvement in the total balance scores, measured with Berg Balance Scale (18), from admission to 6 months post stroke, although the scores for the intensive exercise group were lower than for the regular exercise group, indicating lower balance performance in the former group (Table 5). There were significant differences in scores for items 6 (standing, eyes closed), 11 (turning 360^{o}), 12 (stepping), 13 (tandem standing) and 14 (standing on one leg) on the Berg Balance Scale in favour of the regular exercise group on admission, but not at discharge. At 3 and 6 months the score for item 14 remained significantly different, and at the 12 month follow-up the scores for all items except for items 3 (sitting, no support) and 4 (standing to sitting) were significantly more favourable in the regular exercise group. On the other hand there were no significant differences in total scores of Berg Balance Scale on admission or discharge or at 3 and 6 months. At the 12-month follow-up the difference in total score in Berg Balance Scale between the two groups was significant ($p<0.01$), in favour of the regular exercise group.

Many participants had difficulty in performing Timed-Up-and-Go (19) on admission, and only 20 of 35 patients in the intensive exercise group and 23 of 40 in the regular exercise group were able to carry out this test. The comparison of Timed-Up-and-Go results between test occasions is based on these patients (Table 6). There were no significant differences between the groups at any time. However, there were significant improvements up to 3 months of follow-up within both groups compared with the initial test values. The number of participants who were able to perform Timed-Up-and-Go had increased to 29 in the intensive exercise group and to 30 in the regular exercise group at the 12- month follow-up. The relative number of patients performing Timed-Up-and-Go in more than 20 seconds was larger in the intensive exercise group than in the regular exercise group on all test occasions. Timed-Up-and-Go > 20 s is considered the upper limit before help in transfer is needed (19).

Grip strength measured with the Martin Vigorimeter (20) improved significantly in both the paretic and the non paretic hand in each group between admission and the 12- month follow-up. The differences in grip strength between the groups were not significant at any time.

The results obtained with the Modified Ashworth Scale (21) revealed no differences in muscle tone between the two groups at any time. The majority of the stroke patients displayed no increase in tone at any time. The few who had increased muscle tone at discharge (6 patients in the intensive exercise group and 5 in the regular exercise group) maintained the same tone level of tone throughout follow-up period. The patients with slightly or marked increased tone were those with more motor loss on admission, indicating a more extensive brain injury.

There were significant associations between the results of 6-Minute Walk Test, Berg Balance Scale and the different Instrumental Activities of Daily Living items, with good to moderate correlations, r_s ranging from 0.57-0.79. Timed-Up-and-Go showed significant but moderate correlations to the Instrumental Activities of Daily Living items 2 (use of transport alone), 3 (able to do own shopping), 4 (cook own food), 5 (do house work) and 8 (help you with transport, finances, housekeeping) (r_s: -0.46 to -0.57), but poor correlations with items 1 (use of telephone), 6 (taking own medicine) and 7 (handling own money) (r_s: -0.28 to -0.41). Grip strengths of the paretic and the non-paretic hand were significantly but moderately associated with Instrumental Activities of Daily living items (r_s: paretic hand 0.48-0.64; non-paretic hand 0.36-0.49), whereas Modified Ashworth Scale scores were poorly associated with all Instrumental Activities of Daily living items.

Multiple regression analyses were performed to investigate explanatory factors, on the results from the 3 and 12- month follow-ups, with two different items of the Instrumental Activities of Daily living evaluation as dependent variables, namely item 2 ("can go to places not in walking distance", seen as a physical variable) (Table 7.1) and item 7 ("handles own money", seen as a cognitive variable) (Table 7.2). The model was highly significant for item 2 at both 3 and 12 months (F = 19.2, p<0.001, and F = 22.2, p<0.001 respectively). The model, with adjusted R^2 of 0.63 and 0.67, respectively, revealed Berg Balance Scale total scores (p<0.001) as the strongest explanatory factor on both test occasions for item 2 ("Can you get to places not in walking distance?"). The model was not significant for item 7 ("Can you handle your own money?") at 3 months (F = 1.25, p=0.13) and had a low adjusted R^2 of 0.06. At 12 months the model was of better fit for item 7 (F = 7.83, p<0.001), indicating that 6-Minute Walk Test (p=0.06) was the main explanatory factor of the chosen parameters, with an adjusted R^2 of 0.40.

DISCUSSION

This is to our knowledge the first longitudinal study to be focused on the way in which IADL is influenced by two different exercise regimes in first-time-ever-stroke patients in the first 12 months post stroke.

The main results of this study point to a steady improvement in IADL, gait parameters, balance and grip strength up to 6 months post stroke, irrespective of group allocation. Both groups were very active and showed high compliance to exercises, the intensive exercise group in their compulsory training four times a year and the regular exercise group actively seeking out training possibilities but also training on their own. This was not intended and highly surprising since our experience from an earlier study indicated that activity levels were low 12 months and 4 years post stroke (14). This high compliance to training was probably triggered by the regular test occasions, of which all of the participants were aware, would be at 3, 6 and 12 months post stroke.

Although there was a general improvement in overall IADL, the results flattened out and to some extent even regressed from 6 months up to one year in both groups. These findings are in accordance with the conclusion drawn by Jorgensen et al (35); that a valid prognosis of ADL and functional recovery might be made within the first 6 months post-stroke. According to Mayo et al, by 6 months post stroke the physical recovery will have reached its maximum and in most patients the additional gains are a function of learning, practice and confidence (36). The development was especially apparent in the intensive exercise group, where measured functions on all ICF levels were lower on admission than in the regular exercise group, a fact that indicated that initial neurological impairments and disabilities have a profound impact on the prognosis. However, the results also show that high motivation and regular exercises influence the outcomes so that optimal function is maintained, as opposed to our findings in an earlier study, where no or very little follow-up training was offered post stroke, that the functional outcomes had declined at 12-month and 4-year follow-ups (14). It has also been suggested that participation parameters should not be measured sooner than 6 months post IADL improved in both groups up to 6 months, when the results began to stabilise, indicating that the social pattern had been adapted.

The results obtained with Timed-Up-and-Go (19) showed the same tendency as the scores in IADL, namely improvement in the early phase and a tendency towards stagnation after 3 to 12 months. Patients requiring more than 20 seconds to perform Timed-Up-and-Go were more frequent in the intensive exercise group than the regular exercise group on all test occasions, which could have indicated a need for help in transfer, as Timed-Up-and-Go > 20 s is considered to be the upper limit before help in transfer is required (19).

The initial stroke impact also influenced the balance, as measured with Berg Balance Scale (18), at the 12- month follow-up. Berg Balance Scale scores were decreased for the more demanding items, such as tandem standing and standing on one leg, which reduced the total score in the intensive exercise group, while the scores for the same items and the total score continued to improve in the regular exercise group. A cut-off point of 45 has been identified as an increased risk of falling (26). On admission 23 patients in the intensive exercise group and 21 in the regular exercise group had a Berg Balance Scale score of <45, and at 12 months 16 versus seven patients had a score below this level. The score was only significantly better in the regular exercise group at 12 months. The difference in total Berg Balance Scale scores, with more patients with a score < 45 on all test occasions in the intensive exercise group, can probably explain the difference in the scores of item 2 (get to places not in walking distance), item 3 (shopping for groceries), item 5 (doing housework) and item 8 (help from somebody) of the Instrumental Activities of Daily Living Test (15), where balance is one of the key components and an explanatory factor for the activity (Tables 4 and 7). On the other hand, very few stroke patients in either group did actually fall. This could be explained by the very high compliance to training in both groups, as training has been reported to be effective in reducing falls (38).

During the 12 months both groups improved their results in 6-Minute Walk Test and in the grip strength of both the paretic and non-paretic hand. The 6-Minute Walk Test results and total Berg Balance Scale score showed moderate to good correlation with all items of Instrumental Activities of Daily Living, and were explanatory factors for item 2 (get places not in walking distance) and item 7 (handling own money) (Table 6) at 6 months and 12 months post stroke. It was clear, however, that both groups had relatively low scores on Berg Balance Scale, and walked shorter distances during 6-Minute Walk Test, compared to healthy elderly people (16, 39-42). Despite the considerable continuing improvement in the results of both 6-Minute Walk Test and Berg Balance Scale, compared to the results at discharge and at 3 months, the progression was obviously too slow and not sufficient to meet the demands of daily life, as are encountered outside the home on a participation level; that is, going shopping, visiting friends, going to the theatre, and going on vacation (43-44). It is probably a wise strategy and a sign of coping skills that stroke patients let others handle many of the IADL activities, in order to avoid falls and injuries. On the other hand, this coping approach may lead to a reduction of the activity level and can give rise to secondary complications such as inactivity, lack of motivation and increased lack of function, which need to be compensated for by relevant activities and tasks (45-47).

The speed and length achieved during 6-Minute Walk Test were moderate compared to age- related normative values for fast walking (Table 4) (16, 33-34). This tendency remained when stroke patients who were unable to walk were excluded from the analyses. The mean length and velocity increased in both groups, but were still lower than age-related normative values (16). It is probable that factors other than the cardio-respiratory status influence gait in stroke patients, and in order to increase the intensity during exercises this has to be considered (48). In our study the stationary bicycle was an alternative means of increasing intensity during exercise. However, according to Tanaka´s estimation of maximal heart rate, an intensity of 70 % for 72- to 76- year-old people, which was the mean age in our study, implies a pulse of approximately 110. Our stroke patients achieved this pulse during the 6-Minute Walk Test, which means that they attained pulse rates well within high intensity exercise levels just by walking as fast as they could (Table 4).

Muscle tone as measured with the Modified Ashworth Scale (21) did not differ markedly either between groups or between tests, indicating that muscle tone is not worsened by intensive training or changed in patients with stroke who carry out regular intensive exercises (49-51).

In the multiple regression analysis the results of the 6-Minute Walk Test and the Berg Balance Scale explained some activities of IADL to a higher degree than the results of Timed-Up-and-Go and grip strength in patients with stroke. This association indicates the importance of endurance and balance exercise to achieve a higher degree of social interaction. This association has not been presented in any other studies to our knowledge.

Reduction of function in stroke patients can probably be prevented by regular exercises, which will maintain and improve body functions, activity levels and social interaction. The maintenance must be seen as a life-long endeavour and in accordance with the need of healthy individuals for exercise "to keep in shape". The importance of maintaining gait capacity and balance is vital for social interaction, as this study indicates.

On the other hand, improvement of function and activity in stroke patients' is limited and relatively slow compared to that in the healthy elderly (16, 44, 48). It is therefore important that compensatory help and support are provided on a regular basis in addition to exercise and regular follow-up. Today such help and support are variable and dependent on where you live, and they are not likely to be regular. For stroke patients it is important that both possibilities of activity and supportive services are available. Physical rehabilitation needs to continue, probably for the rest of the patient's life, in order to maintain and even improve body functions and functional activities, to sustain coping and support the stroke patient and his or her partner and family. In most people who have had a stroke and are elderly, the impact of the stroke often makes it impossible to reach normative values of healthy counterparts in physical tests. The goal can therefore never be "normal function", but optimal. Programmes and opportunities post stroke need to be developed to suit people with different levels of stroke and of different ages, and that are easily accessible close to their homes or with a community transport service, and at the same time supportive services need to be implemented at the required level.

Conclusion

Regular exercises were sustained both with an organised and a voluntary follow-up regimen during the first 12 months post stroke, and the patients in these two groups improved to the same degree in IADL and results of 6-Minute Walk Test, Berg Balance Scale, Timed-Up-and-Go and grip strength, and without increasing muscle tone. Frequent, intensive and functional exercises can therefore be encouraged by regular follow-ups in the first year post stroke. The improvements in the results of 6-Minute Walk Test and Berg Balance Scale were especially important for increased activities in IADL and tests of walking capacity and balance should be incorporated in the medical services available for stroke patients, and could preferably be undertaken by physiotherapists.

Patients with stroke cannot attain the level of function of healthy counterparts, and it is therefore urgent that supportive services from the community are provided, as well as regular exercise opportunities. The possibilities for adapted physical activities and supportive services need to be strengthened and made varied and flexible, so that the services can meet the requirements of stroke patients.

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Table 1: Baseline demographic data for the two groups of patients with stroke, and significance levels for differences between the groups

	Intensive exercise group (n = 35)	**Regular exercise group (n = 40)**	**p-values**
Hemisphere of lesion:			
Right (n)	19	19	0.56
Left (n)	16	21	
Age, mean, SD (yr)	76 (12.7)	72 (13.6)	0.23
Medication Yes / No **(n)**	33 Y/2 N	37 Y/3 N	0.89
Assistive devices (n)	5	4	0.5
Self-reported health status before stroke:			
Good (n)	17	25	
Minor problems (n)	17	11	0.66
Moderate problems (n)	0	3	
Major problems (n)	1	1	
Occupation:			
Retired (n)	28	27	0,37
Working (n)	7	13	
Civil status:			
Married (n)	17	24	
Widow/-er (n)	13	11	0.42
Divorced (n)	3	2	
Single (n)	2	1	
Living together	0	2	
Children Y / N (n)	27 Y/ 8 N	25 Y/15 N	0.39

Table 2 Exercise protocol

	The intensive exercise group	The regular exercise group
Frequency	2-3 times a week	No recommendations
Intensity	**Endurance**: 70-80%**,** calculated from maximal pulse **Strength:** 50-60% calculated from 1RM **Balance**: maximal or 15 – 17 on Borg's rating scale of perceived exertion.	No recommendations
Time	40 – 60 minutes	No recommendations
Type	**Endurance exercises**: -walking -treadmill -step -stationary bicycling (arm, leg or combined) -Working with balls or ballons **Strengt exercises**: 10 repetitions in 3 sets ***Extension of back****:* pulley, pull-down, "walking stick", prone- extension. ***Stomach***: ordinary sit-ups with fixation of pelvis if necessary ***Arms***: push-ups in chair, weight–lifting, water bottles, pulley ***Hips-legs***: ordinary knee flexion / extension, walking-stairs, steps ***Legs-feet***: toe-and heel rise on the floor, step, Airex mat, with or without support **Balance:** - walking on even / uneven surface - walking in 8, keeping borders - walking on a line - dual task - obstacles - dancing - tai-chi If not possible with any of the above: - sitting**:** senior dance, balls, balloons **Do light stretching of large muscles at the end!**	No recommendations

Table 3 Results of Instrumental Activities of Daily Living on five test occasions in the the intensive exercise group and regular exercise group. Scores: 2 = independent, 1 = some help, 0 = totally dependent on help. * = P ≤ 0.05; ** = ≤ 0.01; and *** =≤ 0.001 for differences between the groups. m = month.

	Intensive exercise group N = 35					**Regular exercise group N = 40**				
	Admission	Discharge	3 m	6 m	12 m	Admission	Discharge	3 m	6 m	12 m
1 Can you use the telephone?										
2	13	16	17 **	18 **	17 ***	21	20	27 **	29 **	29 ***
1	6	8	6	6	7	7	8	3	2	1
0	16	11	9	8	8	12	8	3	2	1
2 Can you make use of transport alone?										
2	11	14	16	20	17 *	17	13	20	24	23 *
1	4	10	6	2	5	8	13	8	7	7
0	20	11	10	10	10	15	10	5	2	1
3 Are you able to do your own shopping?										
2	7	8	10	15 *	14 *	13	14	15	21 *	21 *
1	5	8	9	4	4	8	5	9	8	5
0	23	19	13	13	14	19	17	9	4	5
4 Do you cook your own food?										
2	7	9	10 *	15	12 *	13	13	16 *	19	19 *
1	4	6	6	4	7	6	7	9	9	6
0	24	20	16	13	13	21	16	8	5	6
5 Do you do housework?										
2	7	9	9	15	11 *	13	12	15	17	19 *
1	5	6	7	4	8	6	8	9	11	7
0	23	20	16	13	13	21	16	9	5	5
6 Medication on your own?										
2	9	12	13	17	16	12	12	17	17	20
1	5	5	4	3	3	8	12	9	9	5
0	21	18	15	12	13	20	12	7	7	6
7 Do you do your housekeeping finances?										
2	9	10	11	15	13	12	12	15	15	19
1	4	5	6	4	6	7	9	8	8	4
0	22	20	15	13	13	21	15	10	10	8
8 Does somebody help you with transport, finances, housekeeping?										
2	7	6	9	11	10 *	12	12	11	15	17 *
1	8	12	10	10	10	7	11	15	14	8
0	20	17	13	11	12	21	13(-4	7	4	6
9 Who helps you?										
Relatives?	11	15	16	16	15	11	16	18	16	15
Institution /community services?	23	12	9	8	9	29	13	6	5	7
Private?										
Independent?	1	7	7	8	8		7	9	12	9

Table 4 Walking distance and velocity measured in 6- Minute Walk Test (6MWT), on five different test occasions, mean and SD,* = $p < 0.05$.

	Intensive exercise group N = 35					**Regular exercise group N = 40**				
	Adm	Discharge	3months	6months	12months	Adm	Discharge	3months	6months	12months
6MWT										
m/s; m	188.0	272.7	304.9	316.1	336*	221.5	279.5	376.8	395.0	479.5*
SD	211.1	188.6	206.2	227.6	260.3	197.8	191.5	228.4	224.6	234.9
6MWT										
m/s; m	0.5	0.8	0.9	0.9	1.0*	0.6	0.8	1.1	1.1	1.3*
SD	0.6	0.5	0.6	0.6	0.7	0.6	0.5	0.6	0.6	0.7

Table 5 Berg Balance Scale total scores and scores for different items; median / interquartile range (IQR) and p values on the five test occasions for the two groups. Scores for different items range from 0 - 4 and the total score ranges from 0 – 56.

	Intensive exercise group					**Regular exercise group**				
BBS	Admission	Discharge	3 months	6 months	12 months	Admission	Discharge	3 months	6 months	12 months
1 Sitting to standing	3 / 4	4 / 1	4 / 1	4 / 1	4 / 1.75	4 / 4	4 / 1	4 / 0	4 / 0	4 / 0
2 Standing no support	2 / 4	4 / 1	4 / 1	4 / 1	4 / 1.75	4 / 4	4 / 0.75	4 / 0	4 / 0	4 / 0
3 Sitting no support	4 / 2	4 / 0	4 / 0	4 / 0	4 / 0	4 / 1	4 / 0	4 / 0	4 / 0	4 / 0
4 Standing to sitting	2 / 4	4 / 2	4 / 1.75	4 / 1	4 / 2.5	4 / 3	4 / 2	4 / 0	4 / 0	4 / 2.5
5 Sitting arm support to sitting no support	1 / 3	3 / 2	4 / 1	4 / 1	4 / 1.75	4 / 3	4 /2	4 / 1	4 / 0.5	4 / 0
6 Standing eyes closed	4 / 4	4 / 1	4 / 0.75	4 / 0	4 / 2.75	4 / 4	4 / 1.75	4 / 0	4 / 0	4 / 0
7 Standing feet together	0 / 4	3 / 3	4 / 2.75	4 / 2	4 / 3.5	4 / 4	4 / 4	4/ 1	4 / 0.5	4 / 0
8 Reaching forward	1 / 4	3 / 3	3 / 2.75	3..5 / 3	4 / 3	3 / 4	3 / 2.75	4 / 1	4 / 4	4 / 0
9 Picking up object from floor	1 / 4	3 / 3	3..5 / 3	4 / 2	4 / 3	3 / 4	4 / 3.75	4 / 1.5	4 / 1	4 / 1
10 Rotation left to right	3 / 4	3 / 2	4 / 1	4 / 1	3 / 1.75	3 / 4	3..5 / 2	4 / 1	4 / 1	4 / 1
11 Turning 360^0	0 / 4	2 / 4	2 / 3.75	3 / 3	3 / 3	2..5 / 4	2.5 / 4	4 / 2.5	4 / 2	4 / 1
12 Stepping	0 / 2	2 / 4	2.4 / 4	3..5 / 3.75	4 / 4	3.5 / 4	4 / 4	4 / 3	4 / 2	4 / 1
13 Tandem standing	0 / 2	0 / 3	0.5 / 2.75	1..5 / 4	1.5 / 4	1 / 4	1 / 4	2 / 4	3 / 4	3 / 3
14 Standing one leg	0 / 2	0 / 2	0.5 / 3	1 / 3.75	1 / 3	0.5 / 4	0.5 / 4	4 / 4	4 / 3.75	4 / 3
Tot. score	**23 / 46**	**36 / 28**	**45.5 / 27.3**	**46.5 / 30.3**	**45.5 / 36**	**42 / 53**	**48 / 35.5**	**52 / 21.5**	**53 / 15.5**	**53 / 9**
P values between groups	**NS**	**NS**	**NS**	**NS**	**0.01**					

Table 6 Timed Up-and-Go (TUG) on five test occasions; mean, SD and variation, min - max. Only those who were able to walk on admission are included. There were no significant differences between the groups on any test occasion.

	Intensive exercise group N = 20					**Regular exercise group N = 23**				
	Adm	Dis	3 m	6 m	12 m	Adm	Dis	3 m	6 m	12 m
TUG m(s)	17.6	12.9	11.4	11.6	11.1	14.5	9.9	8.4	8.9	8.3
SD	12.9	10.6	9.2	9.5	10.8	14.8	4.7	2.9	5.5	3.9
min – max	5-46	5-45	5-38	5-45	0-50	5-74	6-28	4-16	4-28	5-20.7
p values within groups		0.02	0.03	NS	NS		0.04	0.02	NS	0.09

Table 7.1 Multiple regression analysis showing the relationship between Instrumental Activities of Daily Living (I-ADL) item 2 (Can you make use of transport alone?) and 6-Minute Walk Test (6MWT), Timed Up and Go Test (TUG), Berg Balance Scale total score (BBS), grip strength paretic- and non- paretic hand and Modified Ashworth Scale (MAS) at 3 and 12 months of follow-up.

	Beta	**SE**	**p value**
Item 2 – 6MWT 3 months	0.11	0.001	0.5
Item 2 – 6MWT 12 months	0.19	0.001	0.2
Item 2 – TUG 3 months	0.02	0.005	0.9
Item 2 – TUG 12 months	-0.11	0.004	0.3
Item 2 – BBS 3 months	0.63	0.06	0.001
Item 2 – BBS 12 months	0.63	0.006	0.001
Item 2 – grip paretic 3 months	0.16	0.39	0.4
Item 2 – grip paretic 12 months	-0.09	0.27	0.5
Item 2 - grip non- paretic 3 months	0.001	0.35	0.9
Item 2 - grip non- paretic 12 months	0.16	0.25	0.2
Item 2 - MAS 3 months	0.02	0.11	0.8
Item 2 - MAS 12 months	0.13	0.11	0.2

Note: Adjusted R^2 at 3 months 0.63 and at 12 months 0.67.

Table 7.2 Multiple regression analysis showing the relationship between Instrumental Activities of Daily Living (I-ADL) item 7 (Do you do your household finances?) and 6-Minute Walk Test (6MWT), Timed Up and Go Test (TUG), Berg Balance Scale total score (BBS), grip strength paretic- and non-paretic hand and Modified Ashworth Scale (MAS) at 3 and 12 months of follow- up.

	Beta	**SE**	**p-value**
Item 7 – 6MWT 3 months	0.58	0.004	0.02
Item 7 – 6MWT 12 months	0.34	0.001	0.06
Item 7 – TUG 3 months	0.11	0.04	0.5
Item 7 – TUG 12 months	-0.09	0.006	0.5
Item 7 – BBS 3 months	-0.04	0.04	0.9
Item 7 – BBS 12 months	0.23	0.01	0.2
Item 7 – grip paretic 3 months	-0.05	2.8	0.9
Item 7 – grip paretic 12 months	-0.09	0.4	0.6
Item 7 - grip non- paretic 3 months	-0.16	2.5	0.4
Item 7 - grip non- paretic 12 months	0.22	0.4	0.2
Item 7 - MAS 3 months	0.04	0.77	0.8
Item 7 - MAS 12 months	-0.05	0.17	0.7

Note: Adjusted R^2 at 3 months 0.06 and at 12 months 0.40.