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Effect of a Therapeutic Intervention for the Hemiplegic Upper Limb in the Acute Phase After Stroke

A Single-Blind, Randomized, Controlled Multicenter Trial

Hilde M. Feys, PT; Willy J. De Weerd, PT, PhD; Beat E. Selz, MD; Gail A. Cox Steck, PT; Ruth Spichiger, PT; Luc E. Vereeck, PT; Koen D. Putman, PT; Gustaaf A. Van Hoydonck, PT

Background and Purpose—Arm function recovery is notoriously poor in stroke patients. The effect of treatment modalities, particularly those directed at improving upper limb function, has been studied primarily in chronic stroke patients. The purpose of this study was to investigate the effect of a specific therapeutic intervention on arm function in the acute phase after stroke.

Methods—In a single-blind, randomized, controlled multicenter trial, 100 consecutive patients were allocated to either an experimental group that received an additional treatment of sensorimotor stimulation or to a control group. The intervention was applied for 6 weeks. Patients were evaluated for level of impairment (Brunnström-Fugl-Meyer test) and disability (Action Research Arm test, Barthel Index) before, midway, and after the intervention period and at follow-up 6 and 12 months after stroke.

Results—Patients in the experimental group performed better on the Brunnström-Fugl-Meyer test than those in the control group throughout the study period, but differences were significant only at follow-up. Results on the Action Research Arm test and Barthel Index revealed no effect at the level of disability. The effect of the therapy was attributed to the repetitive stimulation of muscle activity. The treatment was most effective in patients with a severe motor deficit and hemianopia or hemi-inattention. No adverse effects due to the intervention were found.

Conclusions—Adding a specific intervention during the acute phase after stroke improved motor recovery, which was apparent 1 year later. These results emphasize the potential beneficial effect of therapeutic interventions for the arm. (*Stroke*. 1998;29:785-792.)

Key Words: clinical trials ■ rehabilitation ■ stroke

Several studies have been conducted to examine the recovery of the hemiplegic arm in stroke patients. Up to 85% of patients show an initial deficit in the arm. Three to six months later, problems remain in 55% to 75% of patients.¹⁻⁴ While recovery of arm function is poor in a significant number of patients, leg function has proven to be less of a problem. Seventy-five to eighty-three percent of surviving stroke patients learn to walk again.^{5,6} This discrepancy might be due to several reasons. Three quarters of strokes occur in the region supplied by the middle cerebral artery.⁷ As a consequence, the upper limb will be affected in a large number of patients. Functional recovery of the arm includes grasping, holding, and manipulating objects, which requires the recruitment and complex integration of muscle activity from shoulder to fingers. In contrast, a minimal amount of recovery of the hemiplegic leg may be sufficient to obtain functional ambulation. Furthermore, secondary complications

such as inferior subluxation of the glenohumeral joint, shoulder-hand syndrome, soft tissue lesions, and painful shoulder frequently hinder rehabilitation of the hemiplegic arm. Another factor that might decrease the probability of return of upper limb function is the lack of spontaneous stimulation during functional activities. Each transfer and each attempt to stand or walk will require bilateral activity in the legs. In performing upper limb activities, the patient may use the nonaffected side exclusively.

The rehabilitation of the upper limb is a challenge. Many therapeutic approaches are currently available. However, considerable controversy exists about their effectiveness. Controlled studies designed to compare neurophysiological treatment approaches, such as proprioceptive neuromuscular facilitation, neurodevelopmental treatment, and the Brunnström technique with conventional treatment, failed to detect any differences in general outcome⁸⁻¹⁰ and in upper

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From the Department of Rehabilitation Sciences, Faculty of Physical Education and Physiotherapy, University of Leuven (H.M.F., W.J. De W.); the Department of Rehabilitation and Geriatric Medicine, Bürgerspital, Solothurn (B.E.S., G.A.C.S., R.S.); the Department of Physical Medicine and Rehabilitation, University Hospital, Antwerpen-Edegem (L.E.V.); the Department of Physiotherapy, O.L.Vr. Hospital, Aalst (K.D.P.); and the Department of Physiotherapy, Rehabilitation Center Hof ter Schelde, Antwerpen (G.A. Van H.), Belgium.

Correspondence and reprint requests to Hilde Feys, Faculty of Physical Education and Physiotherapy, Tervuursevest 101, B-3001 Heverlee-Leuven, Belgium.

E-mail Hilde.Feys@flok.kuleuven.ac.be

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limb function.^{11,12} Although no therapeutic advantage could be demonstrated for one approach over another, conclusions should be carefully interpreted in the light of some methodological shortcomings. In most studies, a limited number of patients were included, reducing the power and thus decreasing the chance of detecting a statistically significant difference. Insensitive or inappropriate measures precluded detection of small improvements, either in function or in quality of movement. On the other hand, several studies of treatment modalities especially directed at improving upper limb function (such as the use of slot machines,¹³ home therapy programs,¹⁴ strategies to overcome the learned nonuse of the hemiplegic arm,^{15,16} electromyographic biofeedback applications,¹⁷⁻²¹ and different types of electrical stimulation²²⁻²⁴) did show positive results. Some of these experiments had a small sample size, and nearly all therapeutic interventions were applied to chronic stroke patients. However, they do suggest that upper limb function can be improved by therapeutic input. To the best of our knowledge, only two randomized controlled trials have been set up after acute stroke. In the study of Crow et al,¹⁹ electromyographic biofeedback facilitated recovery of arm function. However, the beneficial effect did not persist at follow-up. Sunderland et al²⁵ proved that motor recovery could be improved and maintained by an enhanced therapy regimen. There is a need for further studies in this early period, when the surviving brain tissue has the greatest plasticity.

The present study investigates the effectiveness of a therapeutic intervention for the upper limb in the acute phase after a stroke, which emphasized motor and sensory stimulation and normalization of muscle tone. The treatment modality originates from Johnstone²⁶ and is an application of one of the current neurophysiological treatment approaches.

The primary objective of the study was to evaluate the effect of additional sensorimotor stimulation on the motor and the functional recovery of the hemiplegic arm in stroke patients. Other objectives of the study were (1) to examine if the specific effects of the therapy (motor and sensory recovery or changes in muscle tone) could explain the underlying mechanism of the therapeutic intervention, (2) to assess eventual side effects, and (3) to identify subgroups of patients who are more likely to benefit from this type of therapy.

Subjects and Methods

Subjects

All stroke patients admitted consecutively to an acute medical ward over 2 and 1/2 years—from March 1994 till September 1996—were screened for entry into the study. The criteria for inclusion in the trial were (1) diagnosis of ischemic brain damage or intracerebral hemorrhage, (2) an obvious motor deficit of the upper limb (Brunnström-Fugl-Meyer²⁷ score on the subscale of the upper limb lower than 46), (3) ability to sit independently or with a minimum of support, and (4) ability to perform the experimental treatment independently. Patients were excluded if they had a diagnosis of a subarachnoidal or subdural hemorrhage, a previously completed stroke on the same side, or a prestroke disability affecting the arm function. Patients were recruited from several centers in Belgium (University Hospitals of Leuven, University Hospital and Rehabilitation Center Hof ter Schelde in Antwerpen, and O.L.V. Hospital in Aalst) and from the Bürgerspital in Solothurn in Switzerland. All these centers use a comparable multidisciplinary rehabilitation approach.

Study Design

For the purpose of the present study, a single-blind, stratified randomized, controlled design was used. Patients who met the entrance criteria were admitted into the trial between 2 and 5 weeks after the onset of stroke. To obtain two comparable groups, patients were then stratified according to their initial motor score on the Brunnström-Fugl-Meyer test.²⁷ Subjects were assigned to group 1 if the Brunnström-Fugl-Meyer score was between 0 and 10, and to group 2 if the score was between 11 and 45. In addition, stratification was applied based on the type of stroke to achieve an equal distribution of patients with hemorrhage and ischemia (subgroups A and B). Within these four strata (1A, 1B, 2A, and 2B), patients were randomly allocated to either an experimental or a control group. This schedule was applied separately for each of the hospitals involved.

The number of patients needed for the study was calculated a priori to ensure sufficient statistical power. The variance and effect size needed to calculate the number of patients were estimated from the results of a long-term follow-up study on arm recovery after stroke.²⁸ This revealed that a sample of 82 patients was necessary to achieve a 90% chance (power=.90) of detecting a 10% difference ($\alpha=.05$) in improvement between the two groups in the main outcome measure (Brunnström-Fugl-Meyer test). This number was increased to 100 in anticipation of inevitable defaulters.

Clinical evaluations were performed by independent assessors who were blinded to group assignment and not involved in the routine treatment of the patients. As the study was multicenter, several assessors performed the clinical evaluations. For reasons of uniformity, the assessors practiced jointly to standardize the assessment procedures. In addition, a detailed instruction booklet was developed.

The procedures followed were in accordance with the ethical standards of the responsible institutional committee on human experimentation of each hospital. Informed consent was obtained from all patients participating in the study.

Treatment Conditions

The therapeutic intervention was carried out on a daily basis (5 days/week) during a period of 6 weeks. Each treatment session lasted 30 minutes. The intervention was in addition to the usual rehabilitation procedures.

The experimental treatment was applied with the patient positioned in a rocking chair. An inflatable splint was used to support the affected arm. The shoulder was positioned in 80° flexion and slight abduction. The elbow was in extension and the wrist in dorsiflexion. The distal part of the splint was fixed with two straps in a gutter. The patients were asked to perform rocking movements for 30 minutes, pushing with the heels and/or the hemiplegic arm. The chair was balanced in such a way that during the rocking movements patients fell slightly forward and had to actively push backward. Patients were encouraged to do this with their hemiplegic arm. Initially, the therapist guided the movements of the rocking chair. Once the patient could control the movements, he/she performed them independently.

The experimental intervention was hypothesized to contain three major elements. Motor stimulation through the repeated movements would facilitate muscle activity. Sensory stimulation was applied through approximation of different joints (proprioceptive) and through the varying pressures exerted on the arm through the splint during repeated movements (exteroceptive). The placement of the arm in a position contrary to the typical pattern of spasticity was thought to contribute to a reduction of muscle tone.

The patients in the control group were also positioned in a rocking chair and rocked for the same period of time. The arm was rested on a cushion on the patient's lap, and no additional stimulation was given. To allow for attention, motivation, and expectations regarding the placebo treatment, patients in the control group received fake short wave therapy on the shoulder during the 30 minutes of rocking.

The additional therapeutic intervention was performed by the same therapists for patients in the control and experimental groups to prevent bias that could be introduced by personality of therapists. All patients of both groups received the full 30 sessions of treatment.

Evaluation

At entry to the study, patient characteristics such as age, sex, side of paresis, type and onset of stroke, and associated medical conditions were documented.

The main outcome parameters were evaluated before, midway, and after the intervention period and during a follow-up, 6 and 12 months after the onset of stroke. The section assessing arm recovery of the Brunnström-Fugl-Meyer test²⁷ was used to evaluate motor recovery, a measure of the level of impairment. The test includes items related to movements of the shoulder, elbow, and forearm (proximal part) and wrist and hand (distal part). The total scores can vary between 0 and 66. The scale has proven to be sensitive, reliable, and valid.^{27,29,30} At the level of disability, the Action Research Arm test³¹ was used to measure upper extremity function, and the Barthel Index³² to evaluate activities of daily living. The Action Research Arm test consists of four subscales: grasp, grip, pinch, and gross movement. The total test contains 19 movement tasks, and each task is graded on a four-point scale (score range, 0 to 57). The Barthel Index contains 10 items that measure performance in self-care and mobility (score range, 0 to 100). Both the Action Research Arm test and Barthel Index meet the criteria of reliability and validity.^{30,31,33}

Several additional parameters were evaluated to investigate specific effects of the intervention. All measures were taken before and after the intervention and at 6-month follow-up. The proximal and distal scores of the Brunnström-Fugl-Meyer test were used to evaluate the effect of the intervention on the proximal versus the more distal musculature. Sensory function, exteroceptive and proprioceptive, was assessed in the proximal, intermediate, and distal sections of the arm, according to the guidelines described by Bickerstaff.³⁴ The Ashworth scale³⁵ was used to evaluate muscle tone of the internal rotators and adductors of the shoulder; the flexors and the extensors of the elbow; the pronators of the forearm; and the flexors of wrist and fingers. A total score of the tone in the seven muscle groups was made (score range, 0 to 28).

Patients were also assessed for eventual adverse effects of the treatment, such as soft tissue lesions, shoulder-hand syndrome, subluxation, and shoulder pain. These secondary complications were evaluated before and after the treatment period. Shoulder pain was also measured at the 6-month follow-up test. Inferior glenohumeral subluxation was evaluated by means of an x-ray. Shoulders were judged as subluxed or not on the basis of a reliable categorization of Van Langenberghe et al.³⁶ In all cases of clinical suspicion of a shoulder-hand syndrome, a triple-phase bone scan was taken to verify the diagnosis. Capsulitis and impingement were evaluated with the standard shoulder examination according to Cyriax.³⁷ Capsulitis was diagnosed if at least a clear movement limitation was found in external rotation and glenohumeral abduction of the shoulder and if the movement restriction followed the typical capsular pattern (external rotation of the arm most limited, followed by abduction and internal rotation). If clinical signs suggestive of impingement were present, an ultrasound echography was requested. The diagnosis of impingement included tendinitis of M. supraspinatus or M. biceps brachii, bursitis subacromialis, or rotator cuff rupture. Shoulder pain was judged as being present or absent at rest and during five passive movement tests as described in the Cyriax evaluation.³⁷ A total score of the pain experienced during five movements was made (score range, 0 to 5).

Data were collected at the initial evaluation for the following characteristics: degree of motor deficit, level of muscle tone, sensory loss, hemianopia, or hemi-inattention and cognitive function. This allowed us to determine if certain patients would benefit more from the experimental intervention than others. For each factor, patients were classified into two subgroups. Patients were classified as having a severe (less than 14 points on the Brunnström-Fugl-Meyer test) or mild (14 points or more) motor deficit, a low (total Ashworth score <8) or high (score=8 or more) level of muscle tone, a deficit on tactile sensation or proprioception or not, presenting hemianopia, or hemi-inattention or not, and presence of a cognitive deficit (score on Mini Mental State Examination³⁸ lower than 24) or not.

Statistical Analysis

The characteristics of the patients in the control and experimental groups were compared through the use of χ^2 db² square tests (nominal data) or unpaired *t* tests (continuous data).

Several statistical procedures were used to test differences in improvement over time between the two groups. The statistical test used depended on the type of measure. A repeated measures ANOVA using a mixed model approach³⁹ was applied if rating scales were continuous and met the assumptions of normality. A mixed model approach allows several covariance structures and provides a mechanism for handling missing values. For some parameters (Brunnström-Fugl-Meyer test, total and proximal score), a logarithmic transformation was performed to obtain a normal distribution. If the data were not normally distributed and could not be transformed to normality (Action Research Arm test and Brunnström-Fugl-Meyer test, distal score), the generalized linear mixed model³⁹ was applied as an alternative. In this analysis, the scores were approximated by a Poisson distribution. A categorical model with repeated measurements⁴⁰ was used for dichotomous or categorical ordinal data (sensory function, secondary complications).

To identify the patients who had benefited most from the treatment, an ANCOVA for repeated measures was used, with pretreatment scores serving as covariate and the prognostic factor (degree of motor deficit, level of muscle tone, sensory loss, hemianopia, or hemi-inattention and cognitive function) added to the model as an independent variable. The ANCOVA allowed adjustment for initial differences between control and experimental groups for some of the prognostic factors as well as identification of differences between both study groups after the therapeutic intervention started.

All statistical procedures were performed with the SAS System.

Results

Subjects

Approximately 1000 patients with a presumed diagnosis of stroke within the study period were considered for the trial. A major portion of the patients died, were in a state of coma, or fully recovered in the first 2 weeks after the onset of stroke. Other patients were excluded because they were too old and frail or demented for intensive therapy, they had other serious diseases, or they were referred to other hospitals early on or sent back to their homes. A final total of 108 patients entered the trial. Eight patients discontinued the treatment for various reasons. One patient died, another patient had a second stroke, and for a third patient, the general medical condition deteriorated to the extent that the treatment was discontinued. In addition, there was 1 patient with a humerus fracture and 1 with extreme shoulder pain. Finally, 2 patients were unable to perform the treatment autonomously, and 1 patient was discharged during the intervention period. These patients were excluded from further analysis. The control and experimental groups each consisted of 50 patients. Of the 100 subjects, there were 4 and 10 defaulters, respectively, at the 6- and 12-month follow-up tests. Of the defaulters at twelve months post-stroke, seven belonged to the control group and three to the experimental group. Death (*n*=3), recurrence of stroke (*n*=1), refusal (*n*=2), and inability to trace (*n*=1) accounted for the missing scores in the control group. In the experimental group, 2 patients died and 1 patient got a second stroke.

Patient details of each group are shown in Table 1. The groups were comparable in terms of age, sex, and side of paresis. A significant difference between the control group and the experimental group was found in the average number

TABLE 1. Patient Characteristics of the Control (n=50) and Experimental (n=50) Group

Characteristic	Experimental Group	Control Group	P	Significance
Age				
Mean	65.62	62.78	.24 (<i>t</i>)	NS
SD	11.81	12.03		
Range	38–87	36–88		
Days between stroke onset and entry into trial				
Mean	21.40	24.02	.05 (<i>t</i>)	*
SD	5.94	6.98		
Range	13–38	13–37		
Sex				
Male	31	28	.54 (χ)	NS
Female	19	22		
Side of paresis				
Left	28	30	.69 (χ)	NS
Right	22	20		
Type of stroke				
Ischemia	50	45	.06 (<i>F</i>)	NS
Intracerebral hemorrhage	0	5		

t indicates *t* test; χ , chi square test; *F*, Fisher exact test; and NS, not significant.

* $p < .05$.

of days between the onset of stroke and entry in the trial. The mean difference between the two groups was 2.6 days, and the range was equal in both groups. This was not considered to be clinically important. A greater imbalance, although not significant, was found for the type of stroke. All patients suffering an intracerebral hemorrhage belonged to the control group.

Efficacy of the Therapeutic Intervention

Fig 1 shows the means and standard errors of the logarithmic scores on the Brunnström-Fugl-Meyer test for both the control and experimental groups at the time of the five evaluations. The figure shows a perfect randomization in the

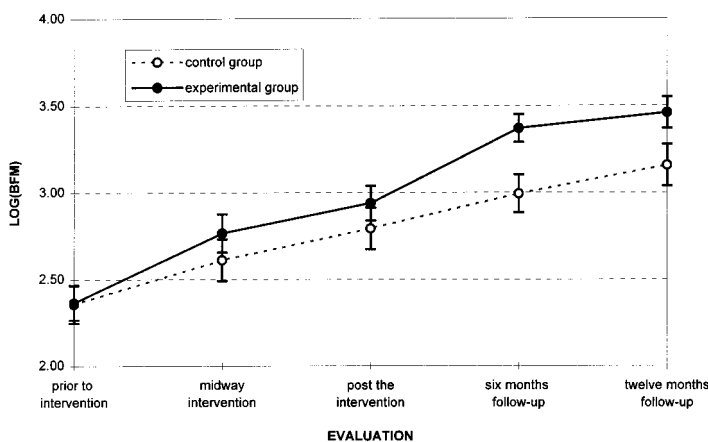


Figure 1. Means and SEs of the logarithmic scores on the Brunnström-Fugl-Meyer test (BFM) for the control and experimental groups before, midway, and immediately after (post) the intervention period and at follow-up at 6 and 12 months after stroke.

two groups for the initial score. The results of the repeated measures ANOVA are summarized in Table 2. All patients improved significantly over the test sessions (time). However, both groups showed a significantly different pattern of recovery (group by time interaction). The experimental group showed a greater improvement in the scores over test sessions if compared with the control group. Although this pattern started from the second evaluation and continued onward, post hoc comparisons revealed that differences were only significant at the 6- ($P = .004$) and 12-month ($P = .03$) follow-ups. The control group improved from 13.9 to 26.0 in the first 6 months and to 30.3 at 12 months. In comparison, the experimental group improved from 14.0 to 33.4 in the first 6 months to 36.9 at 12 months. This implies a difference in improvement of 7.3 points at 6 months and 6.5 points at 12 months in favor of the experimental group. Table 3 shows the distribution of improvement in percentage of the Brunnström-Fugl-Meyer scores in the control and experimental groups. At both 6 and 12 months poststroke, the number of patients not improving or improving by 10% or less was higher in the control group than in the experimental group.

The results for the Action Research Arm test and Barthel Index showed a similar pattern (see Table 2). The experimental and control groups both improved over time, but there was no significant difference between them (group by time interaction).

Specific and Side Effects of the Therapeutic Intervention

Results of statistical analyses testing the differences between control and experimental groups over time (group by time interaction) for specific and side effects of the intervention are summarized in Table 4. For some parameters, the analysis was performed on a smaller number because some patients could not be tested due to aphasia.

Testing the specific effects revealed only a significant group by time interaction for proximal and distal motor recovery. No significant differences were found between the control and experimental groups in the development of secondary complications.

Prognostic Factors of the Therapeutic Intervention

An ANCOVA for repeated measures was carried out for the logarithmic scores on the Brunnström-Fugl-Meyer test to

TABLE 2. Results of ANOVA for Repeated Measures for the Main Outcome Parameters in 100 Stroke Patients

Parameter	df (Effect)	df (Error)	Effects	F	P	Significance
Brunnström-Fugl-Meyer test	1	98	Group	2.27	.14	NS
	4	98	Time	60.80	.0001	*
	4	98	Group by time	4.54	.002	†
Action Research Arm test	1	378	Group	1.20	.27	NS
	4	378	Time	26.07	.0001	*
	4	378	Group by time	0.62	.65	NS
Barthel Index	1	98	Group	2.06	.15	NS
	4	98	Time	88.44	.0001	*
	4	98	Group by time	1.10	.36	NS

df indicates degrees of freedom; NS, not significant.
* $P < .001$; † $P < .01$.

identify the subgroups of patients that benefited most from the therapeutic intervention. A significant interaction was found between the treatment group and degree of motor recovery ($P = .04$) and the presence or absence of hemianopia or hemi-inattention ($P = .02$). The mean logarithmic scores on the Brunnström-Fugl-Meyer test obtained at the five evaluation sessions for the control and experimental groups in each of the two subgroups are presented in Fig 2a and 2b. This figure shows that differences between the control and experimental groups were larger in patients with a severe motor deficit and in patients with hemianopia or hemi-inattention.

Discussion

The results of the present study indicate that motor recovery of the upper limb in hemiplegic stroke patients can be improved significantly by additional sensorimotor stimulation in the acute phase. The mean difference in improvement on the Brunnström-Fugl-Meyer test at 6 and 12 months poststroke between control and experimental groups was 7.3 and 6.5 points, respectively. This corresponds to 11.1% and 9.8% of the total Brunnström-Fugl-Meyer score, a difference that was considered to be clinically relevant at the outset of the study. The Brunnström-Fugl-Meyer test²⁷ is based on the observation that motor recovery occurs according to predictable stages, each evaluated by a set of items. An improvement of 10% on this test implies that the patient achieved the next stage in the recovery process.

Table 3 also shows that the therapeutic effect cannot be attributed to a few outlying results. More than 40% of the

TABLE 3. Distribution of Percentage Improvement on the Brunnström-Fugl-Meyer Test at 6 and 12 Months in the Control and Experimental Groups

	Control Group				Experimental Group			
	6 mo		12 mo		6 mo		12 mo	
	n	%	n	%	n	%	n	%
≤0%	7	14.9	3	7.0	0	0	3	6.4
1–10%	15	31.9	15	34.9	7	14.3	2	4.3
>10%	25	53.2	25	58.1	42	85.7	42	89.3

patients in the control group deteriorated or showed an improvement of less than 10%. In the experimental group, 85% of the patients improved more than 10% at 6-month follow-up and 90% at 12-month follow-up. The therapeutic intervention appears to be useful for a large number of stroke patients with arm paresis.

Although patients in the experimental group performed better throughout the intervention period, differences were only significant at follow-up. These results are in contrast with some other studies, in which significant differences were seen immediately after the intervention but the beneficial effect disappeared at follow-up.^{19,41,42} The finding might be explained by the nature of the therapy. The intervention consisted of repeated stimulation of muscle activity, which

TABLE 4. Results of Statistical Analyses to Evaluate Specific and Side Effects of the Therapeutic Intervention

	n	Test Statistic	P	Significance
Specific effects				
1—Motor function				
1A—Proximal score BFM ^a	100	4.12 (F)	.009	*
1B—Distal score BFM ^a	100	3.03 (F)	.03	†
2—Sensory function				
2A—Exteroception ^b	90	0.69 (χ)	.71	NS
2B—Proprioception ^b	86	1.66 (χ)	.44	NS
3—Muscle tone ^a	100	1.96 (F)	.12	NS
Side effects				
1—Soft tissue lesions				
1A—Capsulitis ^b	100	0.33 (χ)	.56	NS
1B—Impingement ^b	100	1.00 (χ)	.32	NS
2—Shoulder-hand syndrome ^b	100	2.99 (χ)	.08	NS
3—Subluxation ^b	92	0.62 (χ)	.43	NS
4—Shoulder pain				
4A—In rest ^b	88	0.82 (χ)	.66	NS
4B—During passive movements ^b	92	3.03 (χ)	.55	NS

BFM indicates Brunnström-Fugl-Meyer test; NS, not significant.
^aRepeated measures, ANOVA; ^brepeated measures, categorical model approach.
* $P < .01$; † $P < .05$.

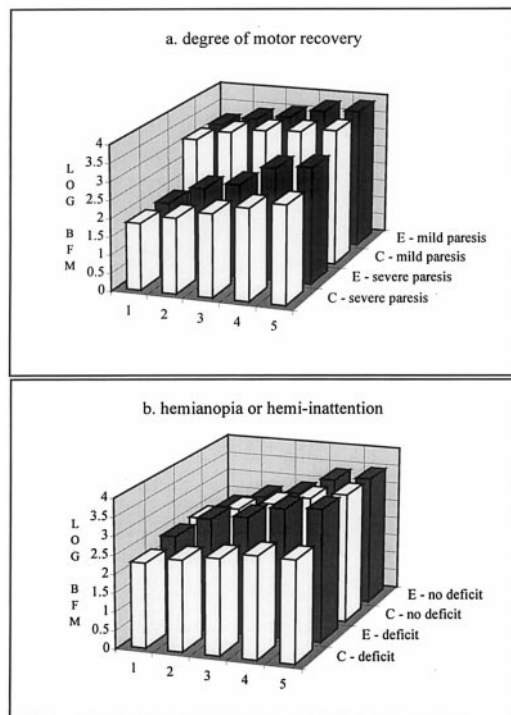


Figure 2. Means of the logarithmic scores on the Brunström-Fugl-Meyer test (BFM) for the control (C) and experimental (E) groups in each subgroup of the prognostic factor (panel a, degree of motor recovery; panel b, hemianopia or hemi-inattention) before (1), midway through (2), and immediately after (3) the intervention period and at follow-up at 6 months (4) and 12 months (5).

may not have enabled the subjects to perform voluntary movements involving the whole arm and hand. The acquired muscle activity, however, provided a necessary basis for the training of other motor activities, which continued during the rehabilitation in the follow-up period. This is a possible explanation for the significantly better outcome of patients in the experimental group at 6 and 12 months after the stroke onset.

The results on the Action Research Arm test indicate that the effect at the level of impairment was not generalized to the level of disability. The Action Research Arm test consists mainly of activities that involve grasping, gripping, or picking up objects. The intervention applied in this study was not focused on functional activities. The effect seemed to be stimulus specific, a result that was also found in other intervention studies in stroke patients⁴³ and in patients with Parkinson's disease.⁴⁴

The difference on the Barthel Index was not significant. This finding is not surprising because the Barthel Index is an overall index of functional recovery. For functions related to the upper limb, the patient may compensate with the non-hemiplegic side. It confirms that the Barthel Index is an insensitive measure for assessing the effect of an intervention on the recovery of the upper limb.

All patients with the diagnosis of an intracerebral hemorrhage were found in the control group, despite the fact that stratification for the type of stroke had been performed. This was a consequence of the fact that the randomization proce-

dures were applied in each hospital separately and the fact that so few subjects suffered a hemorrhage. Although patients with the diagnosis of hemorrhage have higher acute mortality than those with infarctions, it is generally believed that if patients survive, they have a better functional prognosis.⁴⁵ In a recent study, comparison of matched groups revealed that hemorrhagic stroke patients exhibited no better but somewhat faster functional gains than their nonhemorrhagic counterparts.⁴⁶ To the best of our knowledge, the exact impact of this factor on arm recovery has not been studied. However, statistical analyses investigating the effect of the therapeutic intervention on the main outcome measures, with and without patients with intracerebral hemorrhage, revealed the same results. Patients were also stratified according to their initial score on the Brunström-Fugl-Meyer test. An almost perfect randomization was obtained. Both groups were also comparable in the scores on the initial Barthel Index. It has been shown that the initial motor deficit is a very important prognostic factor for either general⁴⁵ or specific arm^{2,28} function outcome.

Several mechanisms of neuronal plasticity have been proposed in an attempt to explain motor recovery in brain-damaged patients.⁴⁷⁻⁴⁹ However, from this type of study, it is impossible to identify the neuronal processes underlying the improved outcome. It seemed more appropriate to find an explanation based on hypothesized therapeutic elements such as motor and sensory stimulation and reduction of spasticity. However, our results indicate that the sensory stimuli did not improve superficial or deep sensation. The inhibitory position of the hemiplegic arm did not affect muscle tone as measured with the Ashworth scale. Robichaud et al⁵⁰ showed that circumferential pressure applied by an air splint around the lower leg reduced soleus muscle motoneuron reflex excitability in subjects with stroke during but not after the application. These results suggest that muscle tone might have been reduced during the 30 minutes of rocking. In fact, only motor recovery in the arm was found to be significantly better in the experimental group. Therefore, we concluded that the efficacy of the therapy could be attributed mainly to the repetitive stimulation of muscle activity in the arm. These results agree with those from two recent studies,^{51,52} in which active repetitive motor training of hand and fingers has proven to be effective. There is growing evidence that muscle weakness rather than spasticity plays a dominant role in impairment of active voluntary movements.^{53,54} The important therapeutic implication is that interventions should be directed at recruitment of muscle activity. Our results support this philosophy. In addition, it might be crucial to apply this type of intervention as soon as possible to prevent learned nonuse of the hemiplegic arm. It has been proved that even among chronic stroke patients, forced use strategies could reverse the effect of learned nonuse.^{15,16}

A limitation of this intervention is that it trains repetitive movements without any problem-solving activity. The results suggest a limited generalization to functional performance. However, more complex and skillful activities require a certain degree of muscle recruitment and control. Also from this point of view, the therapy presented optimally can be included in the acute phase of the therapeutic program. When

patients show some degree of recovery, therapeutic modalities addressing skillful and goal-directed movements may be more appropriate to obtain a maximal generalization toward function.

A complication of the therapy could be secondary damage to the shoulder joint, such as subluxation, soft tissue lesions, shoulder-hand syndrome, or shoulder pain due to possible overloading of the shoulder joint. Although complications did occur, no differences were found between the two groups. Nevertheless, applying the therapy requires careful positioning and support of the hemiplegic arm, and supervision is necessary.

Our results show that the therapeutic intervention was more effective in patients with a severe motor deficit and hemi-inattention or hemianopia. On the other hand, patients with a spastic or flaccid arm, patients with or without sensory loss, and patients with or without a cognitive deficit seem to benefit equally from this therapy. These are new and particularly interesting findings. So far, interventions for the upper limb were found to be more favorable in patients with some degree of recovery.^{14,25} In other studies, patients were only included if they showed a minimal degree of motor function and/or no serious cognitive deficit or communication problem.^{12,14–17,19} The intervention described in this study can be applied to different types of patients and appears to be particularly effective in the most severely affected subjects.

Once properly seated, the patients can practice on their own. This allows them to benefit from more therapy and facilitates a more active role and a sense of responsibility for the treatment. Only a minimum of input is needed from therapists, and a greater amount of time, available while patients are in the rehabilitation center, is spent in treatment.

The hemiplegic upper limb is affected in many stroke patients, and recovery is often poor. Adding a specific intervention to the routine treatment procedures in the acute phase after stroke proved to be effective up to 1 year after the onset of stroke. These results are encouraging for further treatment directed at stimulation of motor activity of the hemiplegic arm, and study is needed to determine how this should be done. Controlled trials are essential to evaluate critically existing or new therapeutic interventions. An attempt should be made to identify within the very heterogeneous population of stroke the most adequate treatment modalities for subgroups of patients.

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