Forced Use of the Upper Extremity in Chronic Stroke Patients
Results From a Single-Blind Randomized Clinical Trial

Johanna H. van der Lee, MD; Robert C. Wagenaar, PhD; Gustaaf J. Lankhorst, MD, PhD; Tanneke W. Vogelaar, PT; Walter L. Devillé, MD; Lex M. Bouter, PhD

Background and Purpose—Of all stroke survivors, 30% to 66% are unable to use their affected arm in performing activities of daily living. Although forced use therapy appears to improve arm function in chronic stroke patients, there is no conclusive evidence. This study evaluates the effectiveness of forced use therapy.

Methods—In an observer-blinded randomized clinical trial, 66 chronic stroke patients were allocated to either forced use therapy (immobilization of the unaffected arm combined with intensive training) or a reference therapy of equally intensive bimanual training, based on Neuro-Developmental Treatment, for a period of 2 weeks. Outcomes were evaluated on the basis of the Rehabilitation Activities Profile (activities), the Action Research Arm (ARA) test (dexterity), the upper extremity section of the Fugl-Meyer Assessment scale, the Motor Activity Log (MAL), and a Problem Score. The minimal clinically important difference (MCID) was determined at the onset of the study.

Results—One week after the last treatment session, a significant difference in effectiveness in favor of the forced use group compared with the bimanual group (corrected for baseline differences) was found for the ARA score (3.0 points; 95% CI, 1.3 to 4.8; MCID, 5.7 points) and the MAL amount of use score (0.52 points; 95% CI, 0.11 to 0.93; MCID, 0.50). The other parameters revealed no significant differential effects. One-year follow-up effects were observed only for the ARA. The differences in treatment effect for the ARA and the MAL amount of use scores were clinically relevant for patients with sensory disorders and hemineglect, respectively.

Conclusions—The present study showed a small but lasting effect of forced use therapy on the dexterity of the affected arm (ARA) and a temporary clinically relevant effect on the amount of use of the affected arm during activities of daily living (MAL amount of use). The effect of forced use therapy was clinically relevant in the subgroups of patients with sensory disorders and hemineglect, respectively. (Stroke. 1999;30:2369-2375.)

Key Words: arm | clinical trials | disability | hemiplegia | rehabilitation

Stroke is a major cause of disablement in many western countries. In the Netherlands, the standardized annual incidence rate for stroke in men and women is 1.74 and 1.96 per thousand, respectively.1 Approximately 80% of stroke patients survive the acute phase, and although most patients regain their walking ability, 30% to 66% of the survivors are no longer able to use the affected arm.2 The recovery process of upper extremity function is often slower than the recovery process of lower extremity function.3,4 According to the theory of “learned nonuse,” repeated disappointment in attempts to use the affected arm in the acute and subacute phase can lead to negative reinforcement of using the affected arm.5 Although motor function may gradually return as the result of a combination of spontaneous recovery and rehabilitation, actual use often seems to be much less than potential use.6

Rehabilitation methods have been developed in which patients were either forced to use the affected arm, by means of immobilization of the unaffected arm (forced use),5,7,8 or strongly encouraged to do so by a therapist who constantly corrected the patient when he/she tried to use the unaffected arm (constraint induction).9,10 In 1993, Taub et al5 reported promising results of forced use therapy in a randomized clinical trial involving 9 patients. The contrast between the experimental and the reference interventions consisted of both specific factors (ie, use of a splint and a sling) and cointerventions (eg, intensive outpatient therapy, only applied in the experimental group), which differed substantially between the experimental and the reference interventions. In the present study the effects of forced use therapy were investigated in a larger group of stroke patients, with similar cointerventions in both treatment conditions.

The main research question addressed in the present study is whether forced use therapy for 2 consecutive weeks is more
effective than bimanual training based on Neuro-Developmental Treatment (NDT)\textsuperscript{11} in restoring dexterity and improving activities of daily living (ADL) functioning in chronic stroke patients. Although the NDT method has never been proven to be more effective than other treatment modalities in stroke patients,\textsuperscript{12,13} it is widely applied in stroke rehabilitation in the Netherlands. Therefore, it appears to be an adequate reference condition.

**Subjects and Methods**

**Design**

In an observer-blinded randomized clinical trial, patients were randomized individually into 2 groups by means of computer-generated randomly permuted blocks of 8. Treatment allocation was performed by one of the authors, who was unaware of the information obtained during the intake examination. One group of patients received forced use treatment for 2 weeks; the other group received an equally intensive bimanual training based on NDT for 2 weeks. All patients were treated in groups of 4. Because the experimental and reference treatments could not be applied simultaneously, the time intervals between treatment allocation and the start of the intervention varied. The sequence of the 2 treatment modalities within a block of 8 patients was determined by chance (coin-tossing) to avoid a systematic difference in the time interval between allocation and the start of the treatment. This procedure also helped to ensure that the observer was unaware of the treatment allocation.

Baseline measurements were performed 2 weeks and 3 to 5 days before the start of the treatment (M1 and M2, respectively). During the first and the second weeks of the treatment phase, measurements were performed in the second half of the week (M3 and M4, respectively). Follow-up assessments took place 3 and 6 weeks after the start of the treatment period (short-term follow-up; M5 and M6, respectively) and again after 6 months and 1 year (long-term follow-up; M7 and M8, respectively).

**Subjects**

Patients were recruited from the files of the Department of Rehabilitation Medicine of the University Hospital Vrije Universiteit in Amsterdam and the 4 nearest located rehabilitation centers in that area. In addition, the research project was advertised in the newsletter of the national stroke patient organization. From these sources, 66 chronic stroke patients were included; they all met the following inclusion criteria: (1) a history of a single stroke, at least 1 year before the start of the study, resulting in a hemiparesis on the dominant side; (2) a minimum of 20 degrees of active wrist extension and 10 degrees of finger extension; (3) Action Research Arm (ARA) test score \textless 51 (maximum score, 57);\textsuperscript{14} (4) age 18 to 80 years; (5) ability to walk indoors without a stick, indicating no major balance problems; (6) no severe aphasia (score \textgreater P50 on the Stichting Afasie Nederland (SAN) test);\textsuperscript{15} and (7) no severe cognitive impairments (Mini-Mental State Examination score \textgeq 22.\textsuperscript{16} All patients gave their written informed consent. The research protocol was approved by the medical ethics committee of the University Hospital Vrije Universiteit.

**Treatment**

Patients were treated in groups of 4 in the outpatient clinic of the Department of Rehabilitation Medicine of the University Hospital Vrije Universiteit. All 4 patients in each group received the same treatment for 2 consecutive weeks, 5 days a week, 6 hours a day. All patients in the experimental groups had their healthy arm immobilized by a resting splint and a closed arm sling, which was attached to the wrist. Patients were encouraged to wear the splint at home during the 12 days of treatment, whereas the sling was only used during treatment hours. Every day the use of the splint at home was registered by the patients in a logbook. As instructed, the patients did not wear the splint when traveling, sleeping, dressing, or during toilet activities. In the reference groups the patients were treated according to the NDT method.\textsuperscript{11} All activities were performed bimanually and, if necessary, the affected arm was supported with the unaffected hand. Symmetry of posture and inhibition of inappropriate "synergistic" movements were emphasized.

The contrast between the intervention conditions was focused on the presence or absence of forced use. Therefore, the counterinterventions, consisting of group activities, exercises, and therapist attention, were kept equal between groups. In accordance with the concept that practice should be aimed at functional goals,\textsuperscript{17} the treatment was focused on housekeeping activities, handicrafts, and games. Physical therapists selected the most appropriate activities for each individual patient on the basis of the patient's residual sensorimotor capacity. The groups were always supervised by 1 or 2 physical or occupational therapists, and patients received continuous verbal feedback and stimulation and, if necessary, hands-on facilitation of movements and inhibition of inappropriate muscle contraction. Much attention was paid to the avoidance of associated proximal movements and to relaxation, by means of verbal guidance. A more detailed description of the schedule of activities can be obtained on request from the corresponding author.

**Measurements**

**Intake Measures**

In addition to the measurements related to the inclusion criteria, sensory disorders and hemineglect were also recorded during intake (2 to 64 weeks before the first baseline measurement M1; median, 11 weeks). Sensory disorders were rated on a dichotomous scale. Any sensory deviations reported by the patient during the interview, or in a test involving alternating and simultaneous touching of both hands (with eyes closed), were rated as positive. Hemineglect was defined as a difference of at least 2 letters between the unaffected and the affected side in the letter cancellation test\textsuperscript{18} or a significant (P<0.05) deviation from the center in a line bisection test consisting of 10 lines of 10 cm, assessed by means of a Wilcoxon signed rank sum test.

**Primary Outcome Measures**

The subscales of the domains Personal Care and Occupation of the Rehabilitation Activities Profile (RAP) were applied for the measurement of activities.\textsuperscript{19} The RAP is an International Classification of Impairments, Disabilities, and Handicaps–based instrument (semistructured interview) to assess disabilities and handicaps, consisting of 21 items in 5 domains. Each of the items is subdivided into a number of subitems. Items and subitems can be scored on a 4-point scale, ranging from 0 (performs activity without difficulty) to 3 (does not perform activity). The validity,\textsuperscript{20} reliability,\textsuperscript{21} and responsiveness\textsuperscript{22} of the RAP in a subacute stroke population have been established. The subitem scores of each of the domains Personal Care\textsuperscript{23} and Occupation\textsuperscript{20} were added, resulting in sum scores with a maximum of 37 and 30 points, respectively.

Dexterity was assessed by means of the ARA test,\textsuperscript{14,23} which is an observational test consisting of 19 items focusing on grasping objects of different shapes and sizes, and gross movements in the vertical and horizontal planes. The performance of each motor task is rated on a 4-point scale, ranging from 0 (no movement possible) to 3 (movement performed normally).\textsuperscript{23} The scores on the individual items are added, yielding an overall sum score; the maximum obtainable sum score is 57 points. The validity and reliability of the ARA test have been found to be high in several studies.\textsuperscript{14,23}

**Secondary Outcome Measures**

The upper extremity motor section of the Fugl-Meyer Assessment (FMA) scale was applied to measure the ability to move the hemiparetic arm outside the synergistic pattern (impairment level) on a 3-point scale (maximum score, 66 points). The FMA scale has been found to be valid,\textsuperscript{24} reliable,\textsuperscript{25} and responsive in the first 6 months after stroke.\textsuperscript{26}

Amount of use (AOU) and quality of movement (QOM) of the affected arm were assessed by means of the Motor Activity Log (MAL), a questionnaire evaluating 25 specific activities on a 6-point scale. This is an adapted version of the MAL used by Taub et al,\textsuperscript{3} which consisted of 14 items. The AOU scale ranges from 0 (never
TABLE 1. Patient Characteristics at Intake, According to the Randomization Schedule and According to Allocation

<table>
<thead>
<tr>
<th></th>
<th>Randomization Schedule</th>
<th></th>
<th>Allocation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Forced Use (n=33)</td>
<td>Bimanual (n=33)</td>
<td>Forced Use (n=31)</td>
</tr>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>60 (51.5–63.5)</td>
<td>64 (51.5–70.5)</td>
<td>59 (52–64)</td>
</tr>
<tr>
<td>(Interquartile range)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Years since stroke</td>
<td>3.1 (1.8–5.4)</td>
<td>2.9 (1.9–5.0)</td>
<td>3.4 (2.1–7.0)</td>
</tr>
<tr>
<td>Females (%)</td>
<td>16 (48)</td>
<td>14 (42)</td>
<td>12 (39)</td>
</tr>
<tr>
<td>Diagnosis of hemorrhage</td>
<td>9 (27)</td>
<td>7 (21)</td>
<td>8 (26)</td>
</tr>
<tr>
<td>Left-sided hemiparesis</td>
<td>5 (15)</td>
<td>7 (21)</td>
<td>5 (16)</td>
</tr>
<tr>
<td>Sensory disorders present (%)</td>
<td>18 (54)</td>
<td>11 (33)</td>
<td>16 (52)</td>
</tr>
<tr>
<td>Hemineglect present (%)</td>
<td>3 (9)</td>
<td>4 (12)</td>
<td>3 (10)</td>
</tr>
<tr>
<td>Mean intake ARA score (SD)†</td>
<td>28.6 (12.4)</td>
<td>29.4 (13.2)</td>
<td>32.1 (11.7)</td>
</tr>
<tr>
<td>Mean intake FMA score (SD)</td>
<td>49.1 (10.4)</td>
<td>46.6 (9.2)</td>
<td>51.1 (8.0)</td>
</tr>
</tbody>
</table>

†Information is missing for 1 case.

Results

Statistical Analysis

The General Linear Models for Repeated Measures option in SPSS 8.0 for Windows 95 was used to analyze each outcome measure. Separate analyses were performed for 4 different periods, ie, (1) the baseline period (M1 and M2), (2) the treatment period (M2 through M5), (3) the short-term follow-up period (M5 and M6), and (4) the long-term follow-up period (M5, M7, and M8). All patients for whom data were available for all measurements within a specific period were included in the analysis of that period. Analysis of the baseline period was performed to allow for adjustment for significant changes resulting from a possible learning effect due to repeated testing or from a possible influence of the patient’s knowledge of treatment allocation. The other 3 periods were analyzed separately to obtain insight into the course of the treatment effect. An on-treatment analysis as well as an intention-to-treat analysis was performed. The covariates found to be statistically significant in the on-treatment analysis (as explained below) were also included in the intention-to-treat analysis.

At first, all associations with possible covariates were studied by means of univariate analysis of the treatment period (comprising M2 through M5). For each outcome measure, the first measurement (M1) was the first independent variable to be studied in the univariate analysis to control for baseline differences between groups. The other independent variables were as follows: (1) time since stroke; (2) presence or absence of sensory disorders; (3) side of the lesion; (4) presence or absence of hemineglect; (5) age; (6) sex; (7) diagnosis (infarction or hemorrhage); (8) FMA score at intake; and (9) ARA score at intake. The rationale for studying FMA and ARA intake scores as potential covariables was 2-fold: (1) the groups differed on these variables (although in the case of the ARA score, this was not significant at the 0.05 level) and (2) both parameters were regarded as important prognostic indicators. Only those independent variables for which the P values of the F tests between treatment conditions (to control for baseline differences) or change over time (within-subject effects) were <0.20 were selected as possible covariables in the definitive model. Covariables were retained in the model if the inclusion of the specific covariable changed the F test of treatment or if the F test of the covariable in the bivariate analysis (containing treatment) was significant (P<0.05). Subsequently, the interaction between treatment and the covariable was investigated. All covariables included in the model were taken into account in the analysis of the other 3 periods. If the repeated-measures analysis indicated a significant main or interaction effect, differential improvements between posttreatment and pretreatment (M5–M2) with 95% CIs were estimated by means of an ANCOVA, controlling for the same covariables as in the repeated-measures analysis. The level of statistical significance was set at 0.05.
the randomization schedule and according to the allocation. Statistically significant differences at intake were found between both groups with regard to time since stroke and intake FMA score.

After randomization, before the start of the treatment, 2 patients withdrew from the study because of changes in their personal circumstances, and another 2 withdrew because of serious health problems. Information about these 4 patients is included in Table 1. In the reference group, 1 patient dropped out shortly after treatment because of a second stroke, and 1 dropped out because of a hip fracture. One patient in each treatment group could not be contacted for the 1-year follow-up measurement. Consequently, data were obtained from 60 of the 62 patients who had completed the treatment period until 6 months after treatment. A complete data set (8 measurements) was obtained from 58 patients. A t test revealed no significant difference in the time interval between intake and the start of treatment between the intervention groups. Multivariate analysis of each outcome measure in the baseline period (M1 and M2) revealed no significantly different changes over time between treatment groups, indicating the absence of a learning effect, influence of a patient’s knowledge of treatment allocation, or spontaneous recovery.

Differences in Effectiveness

Table 2 shows means and SDs of all outcome measures before and after treatment, at 3 weeks, 6 weeks, and 1 year after the start of the treatment period.

**Action Research Arm Test**

The intake ARA score and the presence or absence of sensory disorders were significant covariables. During the intervention period, a significant main effect of treatment was found. The mean difference in gain between the intervention groups was 3.0 points (95% CI, 1.3 to 4.8) in favor of the experimental group, which is less than the MCID of 5.7 points. An interaction effect between treatment and sensory disorders was found, indicating a differential effect of treatment in patients with and without sensory disorders: F3,168 = 5.95, P = 0.001 (Figure 1). The mean improvement in patients with sensory disorders receiving forced use treatment (n = 16) exceeded the mean improvement in patients with sensory disorders who received the bimanual training (n = 11) by 6.7 points, which is in excess of the MCID. Analysis of the short-term (M5 and M6) and long-term follow-up periods (M5, M7, M8) revealed that the mean differences in gain between groups remained during the 1-year follow-up period.

**Rehabilitation Activities Profile**

The intake ARA score was found to be a significant covariable for the domain Personal Care. No significant covariables were found for the domain Occupation. Separate analyses of the treatment period and the follow-up period revealed no statistically significant differences between the 2 treatment conditions for the domains Personal Care and Occupation. In addition, no significant within-subject effects were found, indicating no significant change over time in either group.
Fugl-Meyer Assessment Scale
The intake FMA score was a significant covariable. The multivariate analysis revealed no significant differences between the 2 treatment conditions or any within-subject changes over time during any of the study periods, indicating no treatment effect on this scale.

Motor Activity Log: Amount of Use Scale
The baseline MAL AOU score and the presence or absence of hemineglect were significant covariables. During the treatment period (M2 through M5), patients in the experimental group showed significantly more improvement than patients in the reference group. The mean difference in gain was 0.52 points (95% CI, 0.11 to 0.93), which marginally exceeds the MCID of 0.50 points. Within both groups the improvements exceeded the MCID. A significant interaction effect between treatment and neglect was found, indicating a differential effect of treatment in patients with and without hemineglect: F<sub>3,165</sub> = 4.93, P = 0.003 (Figure 2). Patients with hemineglect who received forced use treatment (n = 3) showed a mean improvement that exceeded the mean improvement in patients with hemineglect who received bimanual training (n = 4) by 1.16 points, which exceeds the MCID. During the short-term (M5 and M6) and long-term follow-up periods (M5, M7, M8), no significantly different changes over time were found between the treatment groups. However, a significant interaction effect between treatment and hemineglect during both these periods indicates that the differences in MAL AOU scores in favor of the forced use treatment group were not maintained over the 1-year follow-up period.

Motor Activity Log: Quality of Movement Scale
The baseline MAL QOM score and hemineglect were significant covariables. During the treatment period (M2 through M5), improvement did not differ significantly between the treatment conditions. During the short-term (M5 and M6) and long-term follow-up periods (M5, M7, M8), no significantly different changes over time were found between the treatment groups.

Problem Score
No significant covariables were found for the Problem Score. Analysis of the separate periods revealed no statistically significant differences between the 2 treatment conditions or any within-subject changes over time. Although a gradual decrease was observed in the Problem Score during the entire short-term (M2 through M5) and long-term follow-up periods (M5, M7, M8), no significantly different changes over time were found between the treatment groups.
study period in both groups, this change did not reach the level of statistical significance during any of the time periods.

**Intention-to-Treat Analysis**
This analysis revealed no statistically significant treatment effects between the 2 groups.

**Subjective Evaluation of the Treatments**
With 1 exception, all patients in both groups expressed a very positive opinion about the treatment. The most frequently appreciated components of the treatment program were as follows: (1) intensity of the treatment; (2) no waiting times; (3) therapist attention (particularly important to patients who had not participated in a rehabilitation program for a long time); and (4) interaction with fellow patients and sharing of similar experiences. Although all patients completed the 2-week treatment period, for most of them the effort was strenuous. The reported adverse effects were second-degree burns (1 patient in the experimental group during occupational therapy and 1 patient in the reference group while ironing at home) and minor skin lesions (1 patient in the reference group who tried to shave with his affected hand at home). In 1 case a potentially harmful adverse effect could be prevented when a patient reported using his affected hypertonic hand to open the throttle of his scooter. All these adverse effects were the result of imprudent actions of the patients or overestimation of their own capabilities.

**Discussion**
The present study showed a small but lasting effect of forced use therapy on the dexterity of the affected arm, as measured by means of the ARA test, in comparison to bimanual training. In patients with sensory disorders, this effect was clinically relevant. Furthermore, a positive effect was found on the subjective amount of use of the affected arm in ADL (measured by the MAL), especially in patients with hemineglect. However, this effect was no longer found during follow-up. The present study showed no significant effects of forced use therapy on the other ADL outcome measures (RAP and Problem Score) or on the impairment level (FMA score).

The positive effects found in the on-treatment analysis were not replicated in the intention-to-treat analysis. In the intention-to-treat analysis, groups were analyzed according to the randomization schedule. The rationale for an intention-to-treat analysis is to ignore protocol violations that have occurred after randomization. The protocol violations in the present study involved the randomization process itself, rendering the intention-to-treat-state to be completely virtual. However, the possibility that these violations of the randomization protocol may have had an effect on the distribution of prognostic determinants (variables that were measured as well as unknown variables) cannot be entirely precluded.

The differences in treatment effect, as measured by the ARA test in patients with sensory disorders and by the MAL AOU for patients with hemineglect, were not postulated in advance. However, it is plausible that patients with sensory disorders and hemineglect do not use the full motion potential of their hemiplegic arm and that their arm function may therefore be more amendable. These subgroup findings must be interpreted with caution because of a lack of power resulting from the small number of patients with hemineglect (n = 7) included in the study. Future research should focus on the importance of sensory disorders and neglect as determinants of recovery of upper extremity function or dexterity after stroke.

The fact that the only notable improvement was found in patients with sensory disorders suggests that patients with no sensory disorders had already reached the upper limit of dexterity. These findings are intriguing, given the fact that the learned nonuse theory was originally developed in research on monkeys that had undergone deafferentation with no permanent motor impairment but only a severe sensory deficit. In the descriptions of earlier studies on constraint-induced movement therapy or forced use, the patients included were reported to have no severe sensory disorders, or no information was provided about the presence or absence of sensory disorders in the included patients. It is conceivable that forced use can result in improvement in patients with sensory disorders if they learn to compensate for the sensory deficits, for instance, by means of visual correction. Possibly, the forced use treatment has an effect on the awareness of sensory perception, which is claimed to be liable to treatment even in chronic patients. Sensory disorders were measured in a crude way in this study, and treatment was not explicitly aimed at ameliorating sensation. Future research should focus on clarifying this issue.

The domains of the RAP (activities) and the ARA (dexterity) differ. It might be hypothesized that the lack of a differential effect on the RAP, if not due to true ineffectiveness of forced use therapy, may be due to the inadequate responsiveness of this instrument when applied to a chronic stroke population. However, in a population within 6 months after stroke, the RAP was shown to be a more responsive measurement instrument than the Barthel Index. The FMA scale also failed to reveal any difference in effectiveness. This finding may be caused by a lack of responsiveness of the FMA scale in chronic stroke patients. Its responsiveness in the first 6 months after stroke has been established. The findings of this study are in accord with the clinical knowledge that improvement at impairment level in the chronic phase after stroke is unusual.

The MAL measures the AOU and the QOM of the affected arm in ADL, as perceived by the patient. It should be noted that in both the experimental and the reference groups, mean improvement was statistically significant and greater than the MCID. In the opinion of the authors, this reflects the effect of cointervention or bimanual training; both groups received physical and occupational therapy. This may be an explanation for the greater differences found by Taub et al regarding this outcome measure, given the intervention contrast in their study. In addition, the patient ratings may have been influenced by their own ideas about the effect of treatment and by the expectations of the observer, as perceived by the patient. In general, the positive appreciation of the treatment by the patients may have influenced their assessment of their own behavior. Although the MAL has been claimed to measure "real-world arm use," its validity has not been estab-
lished, and it should be borne in mind that it is essentially a subjective measure.

The improvement in arm function a long time after stroke is an important finding of the present study, which contradicts the clinical concept that improvement in arm function is only possible within the first year after stroke. However, since the inclusion criteria were defined with the intention to select only those patients who were most likely to benefit from this treatment, the generalizability of these results is uncertain. The influence of sensory disorders and hemineglect on arm function and its apparent accessibility to treatment deserve further investigation.

Acknowledgments

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References

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