A Self-Administered Graded Repetitive Arm Supplementary Program (GRASP) Improves Arm Function During Inpatient Stroke Rehabilitation

A Multi-Site Randomized Controlled Trial

Jocelyn E. Harris, MSc; Janice J. Eng, PhD; William C. Miller, PhD; Andrew S. Dawson, MD

Background and Purpose—More than 70% of individuals who have a stroke experience upper limb deficits that impact daily activities. Increased amount of upper limb therapy has positive effects; however, practical and inexpensive methods of therapy are needed to deliver this increase in therapy.

Methods—This was a multi-site single blind randomized controlled trial to determine the effectiveness of a 4-week self-administered graded repetitive upper limb supplementary program (GRASP) on arm recovery in stroke. 103 inpatients with stroke were randomized to the experimental group (GRASP group, n=53) or the control group (education protocol, n=50). The primary outcome measure was the Chedoke Arm and Hand Activity Inventory (CAHAI), a measure of upper limb function in activities of daily living. Secondary measures were used to evaluate grip strength and paretic upper limb use outside of therapy time. Intention-to-treat analysis was performed. Group differences were tested using analysis of covariance.

Results—At the end of the 4-week intervention (approximately 7 weeks poststroke), the GRASP group showed greater improvement in upper limb function (CAHAI) compared to the control group (mean difference 6.2; 95% CI: 3.4 to 9.0; \(P<0.001\)). The GRASP group maintained this significant gain at 5 months poststroke. Significant differences were also found in favor of the GRASP protocol for grip strength and paretic upper limb use. No serious adverse effects were experienced.

Conclusion—A self-administered homework exercise program provides a cost-, time-, and treatment-effective delivery model for improving upper limb recovery in subacute stroke. (Stroke. 2009;40:2123-2128.)

Key Words: stroke, rehabilitation, upper limb

Stroke is the leading cause of serious long-term disability in older adults with approximately 750 thousand individuals in North America experiencing a new stroke each year.1 The annual cost to the economy is $68 billion with approximately 70% attributed to hospital services incurred during inpatient stay.1 More than 70% of individuals experience upper limb paresis poststroke.2 In a qualitative study of upper limb recovery after stroke, participants stated that use of the paretic upper limb is critical to life engagement but is neglected by health care professionals.3 Further, a strong relationship between upper limb function and ability to perform activities of daily living, social, and recreational activities has been found.4,5

There is evidence that early admission to stroke units and thus involvement in rehabilitation is strongly associated with improved functional recovery.6,7 In reviews of early rehabilitation treatment for the paretic upper limb, it is apparent that increased treatment intensity using repetitive task oriented methods improves motor and functional recovery compared to facilitative approaches.8,9 Despite the knowledge that increased therapeutic activity leads to better outcomes post-stroke, patient inactivity during inpatient rehabilitation is a concern. Studies in acute and subacute settings have shown that individuals were involved in therapy for 5.3% of the day (approximately 47 minutes/d) with upper limb treatment accounting for only 4 to 11 minutes.10,11 In addition, these individuals spend more than 60% of the day resting and alone.10 These findings indicate considerable time during the day when individuals could engage in therapeutic activity outside of standard therapy time.

A possible way to engage individuals in activity during this time is by developing a self-administered homework-based exercise program that is supplemental to what is received in therapy. Self-administered exercise programs have been successfully prescribed for the upper limb for the home setting with favorable results for improved upper limb function in chronic stroke.12,13 Studies which evaluate supplemental inpatient exercise programs are rare. One exception was a
self-administered quadriiceps strengthening program which was initiated during inpatient care for anterior cruciate ligament reconstruction with results of better knee joint outcomes.

We designed an innovative self-administered program for upper limb recovery that increased the hours of repetitive goal-oriented tasks without increasing costly therapy time or requiring expensive equipment. Our primary hypothesis was that individuals with subacute stroke who received the supplemental GRASP protocol would attain greater upper limb function at the end of 4 weeks compared with those who received only usual inpatient care. Self-administered treatment outside of regular therapy has never been evaluated during inpatient stroke rehabilitation.

Methods

This was a multi-site randomized, single-blind, controlled trial. Four sites participated in this study. Each site was assigned an onsite coordinator and assessor. Standardized protocols were developed and all site coordinators, and assessors were trained.

Ethical approval was given by all health authorities involved and the university board of ethics. Participants were inpatients recruited from September 2006 to December 2007 from consecutive hospital admissions. Retention data collection was completed by March 2008.

The inclusion criteria were:

1. Confirmed infarct or hemorrhage by a neurologist using either magnetic resonance (MRI) or computed axial tomography (CT scan);
2. Presence of active scapular elevation (shoulder shrug) against gravity and palpable wrist extension (grade 1);
3. Fugl-Meyer Upper Limb Motor Impairment Scale score between 10 and 57.

The exclusion criteria were unstable cardiovascular status, significant upper limb musculo-skeletal or neurological condition other than stroke, a Mini Mental Status examination <20, or receptive aphasia.

Individuals were admitted to an acute care facility and then transferred to 1 of the 4 participating sites for rehabilitation at approximately 2 weeks poststroke. All individuals who sustained a stroke and were admitted to 1 of the 4 sites were screened for study eligibility and interest within 72 hours. Participants who met inclusion criteria and who consented were randomly assigned to either the control or experimental group using a computerized program which generated random blocks of varying sizes. Concealment of group assignment was done by using an independent data management consultant. Participants were not blinded to group assignment, however the principle investigator was blinded to group assignment. Participants in the study were told not to reveal to the unit clinicians whether they were involved in the research project. Clinicians on the rehabilitation unit (eg, physicians, physical therapists) were aware that a study was occurring but were unaware of group assignment.

Note, in some cases, patients did not meet study eligibility criteria at rehabilitation admission (because of absence of arm and hand movement), but regained adequate movement within ten days of rehabilitation admission and were entered at this point in time.

Measures

Several measures of participant characteristics (eg, age, type of lesion, and neglect) were recorded for descriptive and comparative purposes. We tested interrater reliability for all outcome measures between the site assessors on inpatients with stroke who met eligibility criteria for this study and found intraclass correlation coefficients between 0.97 to 0.99. A site assessor who was blinded to group allocation evaluated participants at baseline, postintervention, and retention. Three of the site assessors were external to the hospitals, and one was external to the rehabilitation unit; all had no contact with study participants outside of the designated evaluation time.

Postintervention testing was the primary planned comparison taken after 4 weeks of the allocated program because no study has ever assessed the feasibility of a self-administered inpatient program.

To inform future studies, retention testing was taken 3 months after the postintervention test session, but the study was not designed nor powered for the retention analysis.

Primary Outcome Measure

The Chedoke Arm and Hand Activity Inventory-9 (CAHAI) was used to evaluate the performance of the paretic upper limb in the completion of activities of daily living (ADL). Tasks involved use of both upper limbs (eg, doing up buttons, putting toothpaste on a tooth brush) as the majority of ADL tasks require bilateral upper limb.

Scoring is based on the percentage of contribution to each task by the paretic upper limb with higher scores meaning greater use. Strong measurement properties have been established for this measure in stroke.

Secondary Outcome Measures

The Action Research Arm Test (ARAT) is a measure of upper limb function poststroke. It is a 19-item scale divided into 4 subscales (grasp, grip, pinch, and gross movement) that measure movement of the paretic upper limb only. The reliability and validity of this measure has been well established.

The Motor Activity Log-14 (MAL) was used to measure each participant’s perception of how much (Amount of Use) and how well (Quality of Movement) they used their paretic upper limb activities of daily living (ADL). Uswatte and colleagues established satisfactory measurement properties of the MAL in individuals with stroke.

Isometric strength of the paretic hand was tested using a hand grip dynamometer. The average of 3 trials was used to determine the final recorded score. Reliability and validity has been well established for hand held dynamometry in the stroke population.

The Medical Outcomes Study Short Form–12 was used to measure health related quality of life. The reliability and validity of the SF-12 in the stroke population has been established.

A pain analogue and fatigue severity scale was used to monitor adverse effects. The participants were required to mark on a diagram the region of upper limb pain and then rate the pain on a visual analogue scale from 0 (no pain) to 10 (extreme pain). Fatigue was monitored using the Fatigue Severity Scale, which has 9 items rated on a 7-point Likert scale with the total ranging from 1 to 7 (worst fatigue). In addition we asked each participant to fill out a questionnaire to rate the programs on ease, equipment and kits, exercises, benefit, and overall satisfaction based on an ordinal scale of 1 to 5 (eg, 1=poor, 3=good, 5=excellent).

Study Protocol

Participants in the study received rehabilitation by the unit multidisciplinary team in addition to the experimental or control group protocols. Time spent in usual therapy (physical therapy and occupational therapy) was recorded.

Experimental Group

The experimental group received the GRASP protocol, which is a self-administered homework-based exercise program designed to improve paretic upper performance, and to encourage the use of the paretic upper limb in ADL. Three exercise protocols were developed into exercise books and kits based on the Fugl-Meyer Motor Impairment Scale (mild, moderate, severe). Each exercise book contained written and pictorial instructions for each exercise, and the kits contained inexpensive equipment (eg, ball, bean bag, towel, paper clips) to complete the exercises. Each exercise was graded by varying repetitions to meet each participant’s need. Exercises included strengthening of the arm and hand (small wrist weight, putty, hand gripper), range of motion (stretching, active exercises), and gross and fine motor skills (eg, blocks, Lego, pegs). Repetitive goal and task oriented activities were designed to simulate partial or whole skill sets required in ADL (eg, folding, buttoning, pouring, and lifting).
The sample size was computed using pilot data (n=10, mean change=6, SD=12) from the Chedoke Arm and Hand Activity Inventory (our primary measure). Using a significance level of 0.05, power of 0.80, and dropout rate of 15%, a study sample of 48 individuals per group was needed. Descriptive statistics, independent sample t-test, and \( \chi^2 \) tests were used to analyze characteristics of the sample. Intention-to-treat analysis was performed for all measures and at all 3 evaluation periods. Any missing values at postintervention and retention were imputed using last-value-observed-carried-forward. Group differences for the primary variable were tested using analysis of covariance (ANCOVA), a method shown to be superior to change score, percentage of change, and repeated measure analyses.26,27 For the secondary variables, ARAT, grip, and MAL, we used multivariate analysis of covariance (MANCOVA) to control for type I error, multiple comparisons, and correlation between dependent variables. Posthoc univariate analysis of covariance was completed for the dependent variables. At each evaluation period, the baseline score was used as the covariate. All analyses were completed using SPSS 15.0 and at 0.05 significance.

**Results**

A total of 542 individuals were admitted to the 4 sites. Of these admissions, 144 (26.6%) were eligible for our study. Sites had similar rehabilitation admission and discharge criteria, therapist to patient ratio, treatment methods, time spent in treatment, and unit environment. 103 subjects were recruited and randomized to the treatment (n=53) or the control (n=50) group. Reasons for exclusion are illustrated in the Figure. A total of 9 participants withdrew from the study before postintervention testing (a completion rate of 91%): 3 from the experimental group (2 were admitted to acute care, 1 developed complex regional pain syndrome) and 6 from the control group (3 declined after being randomized to the

**Table 1. Demographic and Clinical Characteristics of Sample at Baseline**

<table>
<thead>
<tr>
<th>Variable</th>
<th>GRASP (n=53)</th>
<th>Control (n=50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, n</td>
<td>31M/22F</td>
<td>28M/22F</td>
</tr>
<tr>
<td>Age (mean±SD), yrs</td>
<td>69.4 (11.7)</td>
<td>69.3 (15.3)</td>
</tr>
<tr>
<td>Side of Paresis, n</td>
<td>35L/18R</td>
<td>30L/20R</td>
</tr>
<tr>
<td>Dominant hand affected, n</td>
<td>16 (30%)</td>
<td>18 (36.7%)</td>
</tr>
<tr>
<td>Fugl-Meyer arm score, max=66</td>
<td>39.5 (14.2)</td>
<td>40.0 (12.6)</td>
</tr>
<tr>
<td>Type of stroke, n</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infarct</td>
<td>35</td>
<td>34</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td>Lacunar</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Location of Stroke, n</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cortical</td>
<td>31</td>
<td>25</td>
</tr>
<tr>
<td>Subcortical</td>
<td>22</td>
<td>25</td>
</tr>
<tr>
<td>Time poststroke to study start date (mean±SD), days</td>
<td>20.5 (7.1)</td>
<td>20.8 (7.0)</td>
</tr>
<tr>
<td>Mini mental status exam max=30</td>
<td>26.7 (3.3)</td>
<td>26.9 (2.6)</td>
</tr>
<tr>
<td>Star cancellation test max=56</td>
<td>51.9 (7.0)</td>
<td>51.6 (5.9)</td>
</tr>
<tr>
<td>Chedoke arm and hand activity index, (mean±SD), max=63</td>
<td>32.6 (15.3)</td>
<td>32.7 (17.2)</td>
</tr>
<tr>
<td>Action research arm test (mean±SD), max=57</td>
<td>31.1 (18.3)</td>
<td>31.0 (20.0)</td>
</tr>
<tr>
<td>Motor activity log (mean±SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amount of use, max=5</td>
<td>2.0 (1.2)</td>
<td>1.9 (1.4)</td>
</tr>
<tr>
<td>Quality of use, max=5</td>
<td>2.0 (1.1)</td>
<td>1.8 (1.3)</td>
</tr>
<tr>
<td>Grip strength (mean±SD), kg</td>
<td>9.0 (8.1)</td>
<td>8.8 (8.0)</td>
</tr>
<tr>
<td>Modified Ashworth scale, (mean±SD), max=4</td>
<td>1.0 (0.76)</td>
<td>1.1 (0.81)</td>
</tr>
<tr>
<td>SF-12 (mean±SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical health summary score, max=50</td>
<td>38.0 (7.7)</td>
<td>34.5 (7.7)</td>
</tr>
<tr>
<td>Mental health summary score, max=50</td>
<td>48.7 (10.3)</td>
<td>49.7 (10.6)</td>
</tr>
</tbody>
</table>
control group instead of the exercise group, 2 were admitted to acute care, and 1 withdrew because of arthritis pain).

For descriptive characteristics of the study sample, see Tables 1 and 2. At baseline there was no significant difference between groups on demographic, clinical, or study characteristics (Tables 1 and 2). Mean time between randomization and baseline measurement was 72 hours and (2) postintervention testing was 4 weeks for both arms of the trial.

A total of 103 individuals were included for the primary and secondary analyses. Results for the primary outcome measure are illustrated in Table 3. The GRASP group achieved a significantly greater postintervention score on the CAHAI compared to those in the control group (P<0.001, effect size $d=0.45$). Mean difference between groups for the CAHAI was 6.6 (CI: 3.7 to 9.0, $P<0.01$).

A significant MANCOVA model for the secondary variables was found in favor of the GRASP protocol (Wilk $\lambda=0.89$, $P=0.031$). Significant posthoc univariate effects were found for grip strength, paretic upper limb function (ARAT), and paretic upper limb use in daily activities (MAL) in favor of the GRASP group (Table 4). No group difference was found on the SF-12.

The retention testing took place 4 months postrandomization for both study arms. The GRASP group maintained a significantly larger score on the CAHAI than the control group at retention (50.4; CI: 49.6 to 58.5 versus 44.9 to 52.5, $P=0.037$). However, the retention results should be interpreted with caution as we had a completion rate of 58% (60/103 participants).

During the intervention, participants reported high levels of satisfaction with the GRASP protocol (Table 2). No serious adverse effects were recorded. Pain analogue scale showed 15 individuals as no wrist or hand movement was required. In contrast, constraint-induced movement therapy (CIMT) requires 20° of active wrist movement and 10° of finger movement.28 Because of the strict inclusion criteria for CIMT, a low percentage of individuals admitted to rehabilitation units (10%) are eligible for this treatment.29 In our study, 40% (212/524) of those admitted for stroke rehabilitation with upper limb impairment were eligible for the GRASP protocol, indicating a significant number of individuals who could benefit. Our effect size of 0.45 is similar to that reported in the large multi-site trial comparing CIMT to usual care (0.53).30 Additionally, our primary outcome measure is very applicable to real life situations, as it evaluates a wide variety of daily activities that incorporate the full range of upper limb movement, motor control, and coordination whereas the majority of outcomes for trials use outcomes that primarily assess reach, grasp, and unimanual skills (eg, FM, ARAT, WMFT).

The minimal detectable change (MDC; ie, change representing a real improvement) for the CAHAI has been calculated as 6 points.18 The GRASP group exceeded this MDC by 8 points. Moreover there was a 6-point difference...
between the experimental and control groups. A change of 1 point on a CAHAI item represents a corresponding increase of paretic upper limb use of approximately 25%. We found individuals in the GRASP group increased use of their paretic upper limb on CAHAI items by 33%, in contrast the control group increased by 15%.

A group difference of 4.7 points in favor of the GRASP protocol on the ARAT was observed. van der Lee et al.\textsuperscript{33} found that a group difference of 3 points on the ARAT is meaningful. Furthermore, the increase on the Motor Activity Log (MAL) was equivalent to the large randomized controlled trial of CIMT by Wolf and colleagues.\textsuperscript{30} Individuals in the GRASP group achieved an average postintervention score of 3.3 on the MAL, which indicates the ability to use the paretic upper limb at least 50% as much as before the stroke.\textsuperscript{30} At baseline both groups scored in the category of “frequent use of the paretic upper limb in daily activities” on the MAL, however only the GRASP group progressed to “occasional use of the paretic upper limb in daily activities” after the intervention.

Our intervention techniques are consistent with those studies using repetitive task-oriented practice.\textsuperscript{31,34} However, our study is a homework-based self-administered protocol versus therapist-driven and -delivered. This method of treatment delivery was effective and participants adhered to the protocol with minimal time from the therapist. Despite being a self-administered program, no participants suffered any serious adverse effects and high levels of satisfaction were reported. Notably, we found that more than 50% of participants’ families were involved in facilitating the completion of the GRASP protocol. Family members had a positive reaction to the GRASP protocol and felt they were able to contribute to the recovery of their family member. Involving family in the rehabilitation process could be an important aspect of treatment delivery.

Inpatient trials that evaluated upper limb recovery using repetitive goal-oriented treatment found an additional 30 to 60 minutes of therapist time per day was required to improve upper limb performance.\textsuperscript{31,34} Positive results from inpatient trials involving CIMT have been found, but require from 2 to 6 hours of supervised therapy.\textsuperscript{35,36} Additional hours of supervised therapy time cannot be delivered feasibly by the existing parameters of most inpatient rehabilitation centers. We present a time-efficient, easy to implement, and clinically effective model for upper limb recovery in the subacute stage poststroke.

In addition, the significant improvement gained by the GRASP group was retained at retention (5 months poststroke); however, the retention results must be interpreted with caution. Although we accounted for missing data in the analysis, attrition of retention data reduced power to detect differences at this time, which may represent a distortion bias. Our planned comparison was for the postintervention time frame and the retention data simply served to assess the feasibility of continuing the protocol in the community. Individuals in the GRASP group continued to complete the upper limb exercises during the retention period without any monitoring or reminders from study personnel. However, further studies need to investigate the long-term effects of the GRASP protocol.

Contamination between groups was minimized by eliminating contact between site assessors and coordinators and by providing reminders to participants to not reveal group allocation when on the unit. In addition, we attempted to contain contamination between treating therapists and study participants by educating and monitoring the unit staff on participant anonymity. Feedback from clinicians in the rehabilitation unit (eg, physicians, therapists) suggested that they did not change their practice during the trial.

We cannot determine which component of the program, additional time during upper extremity activities or the specific homework based treatment method, contributed to the success of our findings because we matched groups for therapist attention, but we did not include a control group with an equivalent increase (35 minutes/d) of one-on-one traditional therapy time. Such a comparison was less relevant to us as it is already known that additional one-on-one therapy time does improve stroke rehabilitation outcomes.\textsuperscript{37} Given that our homework-based treatment consisted of typical exercises undertaken in rehabilitation, it is likely that the additional dedicated time practicing upper extremity activities contributed to the success of our program.

Replication of this study with a larger sample size and a third group to evaluate an equivalent increase in one-on-one traditional therapy would be beneficial. Furthermore, as our study only extended to 5 months poststroke, we were not able to determine effects which may or may not extend into the chronic phase of stroke.

In summary, the GRASP protocol was found to be a safe, time-efficient, and cost- and treatment-effective method to improve upper limb recovery in the subacute phase of stroke. These findings suggest that GRASP is an effective treatment method for stroke in inpatient settings. Further studies
should be conducted to determine the long-term effects of this protocol and its feasibility in additional settings (eg, outpatient, community).

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Disclosures
None.

References
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