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Translating animal doses of task-specific training to people with chronic stroke in one hour therapy sessions: a proof-of-concept study

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Abstract

Objective—The purposes of this study were to: 1) examine the feasibility of translating high repetition doses of upper extremity (UE) task-specific training to people with stroke within the confines of the current outpatient delivery system of 1 hr therapy sessions, and 2) to gather preliminary data regarding the potential benefit of these doses.

Methods—Fifteen subjects with chronic (> 6 mo) UE paresis due to stroke underwent 3 weeks of baseline assessments followed by 6 weeks of the high repetition intervention (3 sessions/wk for 6 wks). During each 1 hour session, subjects were challenged to complete 300 or more repetitions of UE functional task training (3 tasks \times 100 repetitions). Assessments during and after the intervention were used to measure feasibility and potential benefit.

Results—For the 13 subjects completing the intervention, the average number of repetitions per session was 322. The percentage of sessions attended was 97%. Subject ratings of pain and fatigue were low. Action Research Arm test scores improved an average of 8 points during the intervention, and the improvement was maintained at the 1 month follow-up. Secondary measures of activity and participation also showed improvement while the measure of impairment did not.

Conclusions—It is feasible to deliver hundreds of repetitions of task-specific training to people with stroke in one hour therapy sessions. Preliminary outcome data suggest that this intervention may be beneficial for some people with stroke.

Keywords

stroke; UE; task-specific training; function; translational research

INTRODUCTION

Converging evidence suggests that task-specific practice may be the best way to promote functional recovery after stroke ^{1, 2}. Repeated practice of challenging movement tasks results in larger brain representations of the practiced movement ^{3, 4}. These findings and others from the neuroscience literature ^{5, 6} indicate that extended, task-specific practice is critical for producing lasting changes in motor system networks, motor learning, and motor function. Paradigms designed to investigate neural adaptations in animal models often

require "subjects" to engage in hundreds of daily repetitions of functionally-important upper extremity (UE) task practice ^{3, 7, 8}. Studies designed to investigate motor learning in humans also employ large amounts of practice, although usually for fewer sessions. The numbers vary, but different studies have used ranges between 300 and 800 repetitions per session ⁹⁻¹¹. While a definitive number of repetitions need for optimal human learning is unknown, these paradigms collectively suggest that hundreds of repetitions of task-specific practice may be required to optimize function post stroke.

The reality of stroke rehabilitation is that there is limited task-specific practice taking place ^{12, 13}. In a small pilot study and a larger, multi-site study, we observed that most UE practice during rehabilitation was devoted to basic exercises, including both active and passive movements. Substantially less practice was devoted to movements in functional, task-specific contexts. Task-specific UE training occurred in only 51% of the therapy sessions that involved UE rehabilitation and the average number of repetitions of task-specific training was 32 ¹³. Thus, the current dose of task-specific practice provided during stroke rehabilitation is an order of magnitude lower than what is currently provided in animal models of stroke and in human motor learning studies.

This proof-of-concept study was an attempt to translate the high repetition doses of task-specific training from animal models to people with stroke. Constraint-induced movement therapy (CIMT) was one of the first successful translations of a rehabilitation intervention, from deafferented, non-human primates to people with stroke. CIMT has been found to be beneficial for those with mild-to-moderate motor deficits later $^{14-17}$, but not more immediately after stroke $^{18, 19}$. Three components of CIMT include: constraint of the unaffected upper limb, a behavioral agreement (transfer package) and high doses of movement training $^{20, 21}$. The high doses of movement training, counted in minutes and hours not repetitions, are provided in 3-6 hour therapy sessions. Because CIMT has three components, the specific benefit of the movement training is unclear. Additionally, the requirement of multi-hour therapy sessions makes it challenging to implement these high doses in routine clinical practice 22 .

The purposes of this study were to: 1) examine the feasibility of translating high-repetition doses of UE extremity task-specific training to people with stroke within the confines of the current outpatient delivery system of 1 hour therapy sessions, and 2) to gather preliminary data regarding the potential benefit of these doses. We started this line of investigation in people with chronic stroke (operationally defined as \geq 6 months) because their motor deficits and UE function are relatively stable $^{23-25}$. We hypothesized that people could repeatedly achieve \geq 300 repetitions per session without inducing pain or significant fatigue and that performing these high repetition doses would improve UE function. We chose a target of 300 or more repetitions because 300 is the lower end of the number of repetitions achieved in the animal and human studies cited above. Furthermore, we believed this was likely the upper limit of what could be achieved in one hour and still make the practiced movements sufficiently challenging to an individual's motor capacity.

METHODS

This proof-of-concept study was a within-subjects, repeated measures design (Figure 1). Subjects participated in three baseline assessments, one week apart prior to starting the intervention. The intervention was one hour/day, three days/week for six weeks (18 total sessions). During the intervention, brief weekly assessments were used to gather data on the time course of changes. Post-intervention assessments occurred at the end of the intervention and one month later. The study was approved by the Washington University Human

Research Protection Office and all subjects signed an informed consent document prior to participating.

Subjects

People with chronic UE paresis post stroke were recruited from the St. Louis metropolitan area via the Cognitive Rehabilitation Research Group Stroke Registry, local outpatient stroke rehabilitation clinics, and from the community. Inclusion criteria for participation in the study were: 1) clinical diagnosis of stroke, meeting ICD-9 criteria; 2) time since stroke \geq 6 months; 3) sufficient cognitive ability to participate, as indicated by scores of 0-1 on the Questions and Commands items of the National Institutes of Health Stroke Scale (NIHSS); and 4) unilateral UE paresis, as indicated by a score of 1 – 3 on the NIHSS Arm item. Exclusion criteria for participation in the study were: 1) severe hemi-neglect, as indicated by a score of 2 on the NIHSS Extinction and Inattention item; 2) inability to follow 2-step commands; 3) history or current diagnoses of any other neurological or psychiatric conditions; 4) concurrent participation in other UE stroke treatments (e.g. Botox); or 5) if the subject would be unavailable for assessment or treatment sessions.

The number of subjects enrolled was chosen based on a reasonable number to make an assessment of feasibility and an a priori power estimate using a repeated measures ANOVA. Based on the parameters entered, estimated effect sizes ranged from 0.63 - 2.0, with potential subject numbers ranging from 8 - 44. During the one year period of the study, 27 people were screened and 15 were enrolled to test feasibility and to obtain preliminary estimates of the effect size of the intervention.

Measures

General characteristics (Table 1) were collected on all subjects for descriptive purposes. Feasibility measures were assessed at each treatment session by the therapist providing treatment. Measures to assess preliminary benefits were assessed at baseline, during the intervention, and after the intervention (Figure 1), by the treating therapist or by another trained assessor. Because all subjects received the intervention, none of the assessors were blinded with respect to the intervention. All assessments were video-taped and video-tapes were reviewed periodically by all assessors together to check agreement on grading criteria.

Measures of feasibility—The <u>number of repetitions</u> of task-specific training was recorded for each treatment session and was the primary measure of feasibility. For any given task, a single repetition was operationally defined as reaching to, grasping, moving or manipulating, and releasing an object.

The <u>percentage of sessions attended</u> was used as a measure of compliance with the intervention. The number of treatment sessions attended was divided by the number of possible treatment sessions (18) and expressed as a percentage.

The <u>duration</u> of each treatment session was tracked in order to compare the dose of treatment provided here with previous and ongoing UE stroke rehabilitation studies that report dose in minutes. Rest breaks longer than 1 minute and breaks between tasks were not counted as part of the duration. While each session was scheduled for 60 minutes, the duration was recorded as the number of minutes that the subject was performing task-specific practice.

Ratings of $\underline{\text{pain}}$ in the UE were used to assess side effects of the intervention. The Wong-Baker FACES Pain Rating Scale 26 was used to determine the presence and severity of pain at the beginning and at end of each treatment session. Subject ratings were an overall

measure of upper extremity pain and not pain at individual joints. Pain ratings presented in the Results are the change scores for each treatment session: the rating at the end of the session minus the rating at the beginning of the session.

Ratings of <u>fatigue</u> were used to assess tolerability and side effects of the intervention. The Stanford Fatigue Visual Numeric Scale (www.patienteducation.stanford.edu/research/) was used to determine the presence and severity of mental and physical fatigue at the beginning and end of each treatment session. This scale was chosen because it was the only one that considered mental and physical fatigue, both of which we thought might be important in this high dose intervention. While reliability and validity of the Stanford scale have not been published, the psychometric properties of general numeric rating scales are well-established ^{27, 28}. Fatigue ratings presented in the Results are the change scores for each treatment session: the rating at the end of the session minus the rating at the beginning of the session.

Measures of preliminary benefit—Action Research Arm Test (ARAT) was the primary measure used to assess benefit of the intervention ²⁹. The ARAT was chosen as the primary measure because it: 1) has a low testing burden; 2) has strong psychometric properties in people with stroke ^{25, 30, 31}; and 3) is widely used in UE rehabilitation trials around the world.

<u>Grip strength</u>, measured on a Jamar hydraulic hand-held dynamometer ³², was used as a secondary measure to capture changes in UE impairment ³³, ³⁴. Three measurements were taken at each assessment and the average of the three measurements, reported in kilograms, was used to represent grip strength.

Two subscales of the <u>Stroke Impact Scale</u> (SIS) were used to capture self-perceived UE function in everyday life, outside of the clinic or laboratory ³⁵⁻³⁷. The SIS-Hand and SIS-ADL subscales were used. The two SIS subscales were administered by face-to-face interview at baseline and post-intervention assessments.

The <u>Canadian Occupational Performance Measure</u> (COPM) was used for two purposes: as a goal setting tool to aid in choosing appropriate tasks to practice during the intervention, and as an individualized measure of potential treatment benefit. The COPM is designed to detect changes in a patient's self-perception of their own occupational performance over time ³⁸. It is a structured interview that assesses patient-specific areas of concern and progress in 3 domains: self-care, productivity, and leisure. The interview results in a list of activities the individual wants, needs or is expected to perform ^{38, 39}. The COPM's 10-point rating scale is then used to indicate the importance, performance, and satisfaction of these everyday activities. At the post-intervention assessments, subjects were asked to repeat the rating of performance and satisfaction. On both scales, higher scores indicate better performance and greater satisfaction with performance on specific, individualized activities.

Treatment protocol

The intervention was delivered in one hour treatment sessions by an occupational or physical therapist, or by an occupational therapy student supervised by one of the licensed therapists. All therapists were trained and monitored to ensure fidelity to the protocol. Task selection, task grading, and task progression were discussed and documented for each subject by the treating therapists. The Principal Investigator reviewed the selected tasks, the grading of each task, and the decisions to change tasks or progress to a more challenging version of the same task on a weekly basis.

The high repetition intervention consisted of supervised, massed practice of functional daily tasks which were appropriately graded and progressed for each subject. Most functional UE tasks require four essential movement components: reaching for, grasping, moving/manipulating, and then releasing an object. What varies across the repertoire of daily UE tasks is how the combinations of the components are strung together and the specifics of the component (e.g. direction of reach, type of grasp, manipulative forces required). We provided progressive training of these essential components through repeated practice of various tasks, with the desired goal of building the subject's capacity to perform a multitude of UE functions.

Subjects were given the COPM to assist in determining activities of interest and specific tasks to address during treatment sessions. An individualized approach to task selection 40 and not a general one (all subjects do the same tasks), was selected because severity of paresis and personal interests vary across people with stroke. Additionally, being given a choice of tasks may enhance motivation and participation in rehabilitation 41,42 . The general target number of repetitions of task-specific training was ≥ 300 per session, from practice of three specific tasks each session. Three tasks per session (≥ 100 repetitions per task) were selected to allow for variability in task practice and to avoid the boredom that might come from performing ≥ 300 repetitions of a single task.

Using information from the baseline assessments, selected tasks were graded to match the motor capabilities of the subject. The job of the therapist was to grade tasks such that they challenged, but not over- or underwhelmed, the motor capabilities of each subject. In other words, we did not want subjects simply repeating tasks that they were already skilled at performing, nor did we want them to repeatedly fail at a task. Guiding principles for delivering the intervention were derived from the animal rehabilitation paradigms and motor learning literature, and are provided in detail in the Appendix. An example of a frequently used task was "lifting cans on shelves". This task simulated the real world activity of storing and retrieving objects on shelves, such as putting away groceries. This task could be graded by: 1) changing the size, weight, or shape of the cans; 2) changing the height of the shelf; 3) changing the location of the shelves with respect to the subject; and/or 4) changing the depth of the cans on the shelves. Algorithms were developed to determine when to progress a task, i.e. grade up or grade down, and when to switch tasks. During each session, the treating therapist documented the tasks and specific grading levels, the number of repetitions, and subject ratings of pain and fatigue. More information and examples regarding task selection, grading and progression are provided in the Appendix.

Statistical analyses

Statistica version 6.1 software (StatSoft Inc, Tulsa OK) was used for all analyses and the criterion for statistical significance was set at p < 0.05. Data were found to be normally distributed. Means, standard deviations, and 95% confidence intervals were generated for the feasibility data. For the number of repetitions, calculated averages excluded the first week of treatment (first 3 sessions) because we expected that subjects would require a few sessions to build up to the 300 repetition target. Repeated measures ANOVAs were used on the repetitions, pain, and fatigue data to evaluate if they increased over the course of the intervention. Our a priori criteria for determining if the intervention was feasible were that the average number of repetitions per session would be \geq 300 and that average percentage of sessions attended would be \geq 85%. We anticipated that the major consequence of increased pain or fatigue ratings would be a reduction in the number of repetitions completed or sessions attended.

Within-subject, repeated measures ANOVAs were used to determine if the intervention provided benefit to subjects. Planned contrasts were as follows: 1) comparison of baseline

assessments to evaluate the stability of the initial motor and functional deficits; 2) comparison of the baseline assessments and the 1st post intervention assessment to evaluate benefit; and 3) comparison of the 1st and 2nd post intervention assessments to evaluate any persisting benefit. Since baseline scores were not significantly different, baseline scores for each variable were averaged and used in further statistical analyses. Comparisons with only two time points were done with paired t tests. Spearman and Pearson correlation coefficients were used to explore relationships between the feasibility and outcome data.

RESULTS

Fifteen subjects were enrolled and 13 subjects completed the study. Table 1 provides descriptive information about the sample. The sample was heterogeneous with respect to age, time since stroke, initial UE functional limitations (as measured by the ARAT), and the presence of deficits in other domains.

Feasibility data

Two subjects dropped out: R001 and R004. R001 completed four treatment sessions prior to withdrawing for personal reasons. R004 completed eight treatment sessions before withdrawing. He achieved 300 or more repetitions by the fourth treatment session. Around this time, he began to report painful leg cramps that hindered his ability to walk and move around his house. Despite the intervention targeting his UE, overflow contractions in his affected lower extremity were noted during UE task-specific practice. The increased activation of lower extremity muscles could have contributed to the leg cramps. The decision to withdraw was made jointly by the subject and the research team. All subsequent feasibility and outcome data presented are from the 13 subjects who completed the intervention.

After the first three sessions, the average number of repetitions per session was 322 (95% CI: 285 - 358). Figure 2 shows group and representative, individual data for the number of repetitions. As a group (Figure 2A), the number of repetitions increased over the course of the intervention (main effect of time, $F_{17,136} = 7.72$, p < 0.0001). Figure 2B is an example of someone who achieved nearly 300 repetitions right away, and then fluctuated around 400 repetitions per session. Figure 2C is an example of someone who took much longer to achieve the target number of repetitions. The total repetitions during the intervention ranged from 3849 - 7568 with a mean of 5476 ± 1088 (SD). The average duration of treatment was 47 ± 3 minutes out of the scheduled 60 minute session (78% of the scheduled time).

The percentage of sessions attended was 97% (95% CI: 94 – 100). Ratings of pain (Figure 3A) were low, with an average of 0.3 (95% CI: -0.2 – 0.9) out of 10. Ratings of fatigue (Figure 3B) were somewhat higher and more variable across subjects and sessions, with an average of 1.9 (95% CI: 0.9 - 2.8) out of 10. We recorded numerous instances where subject ratings of pain and fatigue decreased from the beginning to the end of the session as represented by negative change scores. Neither pain nor fatigue ratings increased over the course of the intervention (main effects of time: pain, $F_{17,102} = 1.26$, p = 0.23; fatigue, $F_{17,102} = 0.80$, p = 0.69). No subjects reported missing sessions due to pain or fatigue.

Preliminary outcomes

ARAT data (Table 2) showed a significant repeated measures effect overall ($F_{4,48} = 14.19$, p < 0.0001). Initial deficits were stable, as indicated by no differences between the baseline ARAT scores ($F_{2,24} = 0.26$, p = 0.77). ARAT scores were higher after the intervention ($t_{12} = 3.66$, p = 0.003). The average change score from baseline to the first post-intervention assessment was 8 points (95% CI: 4 – 12 points). No differences were found between the

first and second post-intervention assessments ($t_{12} = 0.23$, p = 0.82), indicating that the benefit of the intervention was largely retained one month later. The secondary measures showed similar results (Table 2), except for grip strength which did not change after the intervention.

Figure 4 shows the time course of ARAT changes during the intervention. On average, ARAT scores increased steadily during the 6 week intervention (Figure 4A). Exploratory analyses indicated that improvement during the intervention may be moderately related to both the initial deficit (baseline ARAT vs. change in ARAT, rho = 0.64, p = 0.02) and the doses of training received (change in ARAT vs. total repetitions, r = 0.46, p = 0.10). The relationship between improvement and the doses of training received is illustrated in Figure 4B. The dose of training received was not related to the initial deficit (total repetitions vs. initial ARAT, r = 0.14, p = 0.65).

DISCUSSION

Subjects with chronic UE paresis were able to achieve ≥ 300 repetitions of task-specific UE training without inducing pain or substantial fatigue. Participating in this intervention resulted in improved UE function, as measured by the Action Research Arm test. Improvements were also seen on self-report measures of UE activity and participation but not on the measure of UE impairment (grip strength).

Feasibility of the intervention

Our main finding was that the high repetition intervention was feasible in one hour therapy sessions. Numbers of repetitions attained and the time course of achieving them varied across subjects and within sessions. A common observation was that more repetitions were achieved earlier in a session. The moderate increase in fatigue at the end of each session was appropriate, indicating that participation required both mental and physical effort. Our study builds on earlier literature (see Introduction) to show that it is feasible to achieve high repetition doses of task-specific training in one hour sessions. In hindsight, we wondered if we could have asked for even higher numbers of repetitions in each session. Achieving even higher number in 1 hour sessions is unlikely for two reasons. First, subjects were fatigued at the end of the session. Many subjects provided feedback that they could not continue to work this hard for another hour. And second, achieving targets much above 350 repetitions in one hour would have required us to make the practiced tasks easier. This would mean that we would be more likely to have subjects repeat tasks they could already do quickly instead of challenging their motor capacity. It is unknown how the number of repetitions performed here compares to the number of repetitions achieved with the modified form of CIMT ⁴³⁻⁴⁶. as dose is reported only in time scheduled for therapy. Our feasibility results indicate that it is possible for rehabilitation clinicians to move from providing minimal amounts of taskspecific training ^{12, 13} to hundreds of repetitions within the current outpatient service delivery model.

Our sample contained individuals with deficits from stroke other than paresis (Table 1). Three subjects had diminished somatosensation, four subjects had aphasia, and one subject had ataxia in addition to their UE paresis. The sample was therefore consistent with the clinic presentation of stroke, where the majority of patients experience deficits in multiple domains. The manner in which the intervention was delivered was modified to fit the needs of people with the other deficits. For example, for those subjects with aphasia, conversation was limited during treatment sessions as to not distract the participant. Paper and a black marker were provided so the subject could write down any statements he or she was having difficulty verbalizing. The finding that this intervention was successfully applied to individuals with deficits beyond paresis enhances its clinical utility.

Preliminary benefit of the high repetition dose intervention

Subjects participating in this intervention improved their UE function, as measured by clinical tests of UE activity and participation. The average 8 point change seen here on the ARAT was larger than a 4 point minimal detectable change for this measure 47 and larger than its 6 point minimal clinical important change identified in people with chronic stroke 17 , but smaller than its 12-17 point change estimate in people with acute stroke 48 . The magnitude of improvement seen here is similar to the magnitude of improvement in the experimental groups of other enhanced, task-specific, or CIMT studies in people with chronic stroke 14 , 15 , 17 , 45 , 49 . As with other studies, some subjects did not respond to the intervention, and this may be partially related to the severity of their initial motor deficits. Note that the two subjects who dropped out had the most severe initial deficits (Table 1). From this preliminary data, we can only surmise that this high repetition intervention is likely no worse than other interventions tested.

We propose that the main utility of this intervention is as a vehicle for investigating the dose-response relationship between movement practice and functional improvements. The dose-response relationship is a critical issue facing neurorehabilitation clinicians and researchers ^{50, 51}. Understanding the dose-response relationship is critical as new treatments are emerging, particularly for treatments where a novel agent (e.g. drug, robot, cortical stimulation, transcranial magnetic stimulation) is paired with physical practice. Number of repetitions is a useful way to quantify dose, either session-by-session or total, as is done in animal models of stroke. The correlation analysis suggests that more repetitions may result in better outcomes. The time profiles of ARAT data indicate that subjects were improving over the course of the intervention. Because the duration was set at six weeks for practical reasons, we do not know if continuing the intervention, thereby achieving larger total doses, would have resulted in greater functional improvements. Further studies are needed to map the dose-response relationship post stroke and the potential modifiers of this relationship.

Several limitations should be considered when interpreting our data. First, we had a small sample, which limits the generalizability of the findings. Second, the sample was heterogeneous. Average data could have masked important findings in specific subgroups, if there had been sufficient subject numbers. Third, assessments were not blinded, which likely introduced bias into our measurement, particularly for the assessments of benefit. Due to the pilot nature of the project and amount of available funding, we were unable to utilize a blinded rater. Fourth, we did not have a control group. While the baseline data indicate the motor function was stable prior to the intervention, the improvements may have been due to participating in any therapy, versus participating in the specific intervention tested here.

Conclusions

This is the first attempt to translate the high repetition doses from animal models to people with stroke in one hour therapy sessions. Our data indicate that it is possible to achieve \geq 300 repetitions of task-specific UE training without inducing pain or substantial fatigue. Preliminary outcome data suggest that this intervention may be beneficial for some people with stroke. The benefit of the intervention may be a function of initial motor deficits and the dose of training provided. Further studies are needed to examine optimal dosing for people with stroke.

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APPENDIX

TREATMENT PROTOCOL FOR HIGH REPETITION TASK-SPECIFIC INTERVENTION

The high-repetition intervention consisted of supervised, massed practice of functional daily tasks which were appropriately graded and progressed for each subject. Most functional upper extremity tasks require four essential movement components: reaching for, grasping, moving/manipulating, and then releasing an object. What vary across the repertoire of daily upper extremity tasks are how the combinations of the components are strung together and the specifics of the component (e.g. direction of reach, type of grasp, manipulative forces required). We provided progressive training of these essential components through repeated practice of various tasks, with the desired goal of building the subject's capacity to perform a multitude of upper extremity functions.

GUIDING PRINCIPLES FOR PROVIDING TREATMENT

Principles for how the treatment was implemented were developed prior to the study and are summarized below in Table 1. Information on motor learning principles and animal model paradigms are primarily derived from recent reviews and chapters.

MATCHING SUBJECT GOALS WITH SPECIFIC TASKS

Subjects were given the Canadian Occupational Performance Measure to assist in determining activities of interest and specific tasks to address during treatment sessions. Subjects were encouraged to select activities/tasks which included a primary upper extremity component. For instance, an individual who chose ballroom dancing as a goal was encouraged to identify another goal because ballroom dancing primarily is a lower extremity activity. Using the goals selected by the subject on the COPM in addition to the subscale scores on the ARAT, the study therapist, was able to choose related treatment activities even if the subject was unable to perform the whole task selected as a goal. Every attempt was made to perform the whole activity as a treatment activity. In cases where this was impossible, a component of the whole task was chosen. Examples of goals identified by subjects and the tasks chosen to address those goals are provided in Table 2.

GRADING TASKS TO CHALLENGE MOTOR CAPABILITIES

Using information from the baseline assessments, selected tasks were graded to match the motor capabilities of the subject. The job of the therapist was to grade tasks such that they challenged, but not over- or underwhelmed, the motor capabilities of each subject. In other words, we did not want subjects simply repeating tasks that they were already skilled at performing, nor did we want them to repeatedly fail at a task.

Following the selection of tasks, the subject attempts to perform each activity. For example, one participant had decreased shoulder range of motion but was able to use her hand to pick up small objects with decreased coordination. Since she enjoyed playing games with her grandchildren, the task of playing Connect 4 was selected. During the first attempts of this task, the participant was seated with the Connect 4 grid placed directly in front of her, on dycem (to prevent slipping). As she continued to improve, the grid position was moved further away from the participant to challenge shoulder range of motion. These changes to the activity did not occur until the criteria detailed in the section "Progressing Tasks" (below) were met.

Several universal ways to grade tasks were adopted:

- 1. Physical position of the participant
 - a. Sitting
 - **b.** Standing
- **2.** Changing the position of task materials
 - a. Change the height of task materials
 - **b.** Change the depth/change distance of reach (move task materials closer or further away)
 - **c.** Place task materials midline/right/left of the materials
- 3. Changing the weight of task materials
 - a. Heavy objects
 - **b.** Light-weight objects
- 4. Changing the size of objects
 - a. Use large items
 - **b.** Use small items (Ex- small buttons vs. large buttons)
- 5. Using adaptive equipment/materials
 - a. Use dycem to prevent an item from moving
 - **b.** Allow therapist to hold items in order to stabilize task materials
 - **c.** Increase the grip of objects used in tasks (ex- use cylindrical foam to increase the size of a pencil/pen for handwriting)
 - **d.** Other adaptive equipment may be used as long it encourages the performance of the selected task with the affected UE.

KEEPING TRACK OF THE TASKS, TASK GRADING, AND NUMBER OF REPETITIONS

The solution for keeping an accurate count of the tasks, task grading, and the number of repetitions in each task was for the study therapist to record repetitions on an easy-to-use form we developed. The form had a separate page for each task. At the top of the page, there were fields to write in the specific task and how it was graded that session. On the rest of the page, there were numbers from 1-150, arranged in 6 rows of 25. At the start of the session, the therapist filled in information about the task and grading. During the session, the therapist made a slash mark through each number as they watched the subject perform each repetition. Whenever possible, we grouped items used for a given task into groups of 5 or 10 to make counting the repetitions task easier. If the therapist was unsure if all repetitions were counted, the videotapes were reviewed to determine this.

PROGRESSING TASKS

The following rules were used to determine when to progress a task, i.e. grade up or grade down. Generally, tasks were graded up (made more difficult) if the subject had successfully achieved 100 or more repetitions in less than 15 minutes for a given task on two occasions. Additionally, if a subject achieved 100 repetitions at the 15 minute mark, the task was graded up for an additional few minutes to challenge the subject. After this occurred on two or more occasions, the graded up version of the task was adopted and used until the subject achieved 100+ repetitions. Tasks were graded down (made easier) if the subject was unable to achieve 50 repetitions of a task within 15 minutes. Tasks were also graded down within

the 15 minutes if the subject began exhibiting extreme fatigue or was unable to perform the task. For example, one subject, who was diabetic, experienced low blood sugar during one treatment session and was not performing the task as well as was typical. After providing her with the appropriate food, her tasks were graded down to accommodate her performance level for the rest of that session. On other occasions, a few subjects experienced fatigue from not sleeping well and did not perform at typical levels. On these occasions, the task was graded down as well for that particular session. On both instances, the next treatment session, the task was returned to the pre-event level.

CHANGING TO NEW, DIFFERENT TASKS

If a previous activity was no longer challenging or if the subject desired to do a different activity, one new task could be selected at the beginning of each week. In cases where the subject was able to perform the whole activity without difficulty (100+ repetitions in < 15 minutes on two occasions) the study therapists was permitted to choose another activity to further challenge the subject again relying on the identified COPM goals. On rare occasions, the subject stated they did not like a treatment activity. The therapist would evaluate the treatment activity to determine which movements were being addressed and select another activity to work on the same movement. Again, this activity was related to a goal selected on the COPM.

EXAMPLE TASKS AND WAYS TO GRADE THEM

See following pages.

EXAMPLE TASKS AND WAYS TO GRADE THEM

Activity: Writing

Materials:

- 1. Paper
- **2.** Pen
- 3. Pencil
- 4. Dry Erase Board
- 5. Cylindrical Foam

Method:

- 1. Patient sits at table with paper and writing utensil of choice at midline.
- 2. Patient practices free writing signature or words/sentences/paragraphs.
- 3. Patient can fill out forms similar to those used at work/school

Grading:

- 1. Increase task difficulty by increasing number of words/components of written work (ie- phone number, address, form letter)
- 2. Decrease task difficulty by using built-up writing utensil to aid with grip.
- **3.** Decrease task difficulty by using dry erase board and writing large letters, then progress to writing on a pad of paper.

Repetition Description:

1 repetition = completed signature (pick up pen – write – release pen)

or

1 repetition = 1 word

Activity: Typing on a keyboard

Materials:

- 1. Computer/Keyboard
- 2. Mouse
- **3.** Typing Program (to challenge speed/accuracy)

Method:

- 1. Patient sits at computer table with both hands on keyboard
- 2. Patient practices typing with both hands using a typing program

Grading:

- 1. Increase task difficulty by typing longer words/sentences or paragraph
- 2. Decrease task difficulty by typing single letters
- 3. Increase task difficulty by typing memos dictated from third party
- **4.** Increase task difficulty by using a speed/dexterity typing program

Repetition Description:

1 repetition = 1 word typed

or

1 repetition = 1 letter typed

Activity: Fishing (Sorting Tacklebox)

Materials:

- 1. 10 fishing lures
- 2. Various sized bobbers
- 3. Fishing weights
- 4. Tackle Box

Method:

- 1. Tackle box placed at patient's midline
- 2. Fishing weights, bobbers, and fishing lures are placed on the affected side.
- 3. Patient is instructed to pick up items and place in tacklebox
- **4.** Patient is instructed to pick up items one at a time.
- 5. Variation: patient can remove specific items from tacklebox and place on table

Grading:

1. Increase or decrease task difficulty by increasing or decreasing the size of the items in the tackle box.

2. Increase or decrease task difficulty by moving the tackle box closer or farther away from patient.

Repetition Description:

1 repetition = reach, grasp, release 1 fishing item into the tackle box

or

1 repetition = reach, grasp, release 1 fishing item from box back onto table

Activity: Playing games (Connect Four)

Materials:

- 1. Connect Four Game
- 2. Table

Method:

- 1. Connect Four game board placed on table at patient's midline. Checkers placed on table on patient's affected side.
- 2. Patient will be instructed to place checkers in Connect Four grid

Grading:

- 1. Increase or decrease task difficulty by changing the position (depth) of the grid
- 2. Increase or decrease task difficulty by changing the position of the checkers
- 3. Increase or decrease task difficulty by changing the height of table.
- **4.** Increase or decrease task difficulty by changing the patient positioning (sitting vs. standing) Decrease task difficulty by placing grid on dycem to stabilize

Repetition Description:

1 repetition = 1 Connect Four checker picked up and released in grid

Activity: Folding towels

Materials:

- 1. 20 wash clothes
- 2. 10 hand towels
- 3. 10 bath towels

Method:

- 1. Patient will sit or stand at table.
- 2. Patient will fold the towels at midline while sitting or standing.
- 3. All towels should be folded in half and then in half again using bilateral UEs.

Grading:

1. Increase task difficulty by alternating the location of the towel piles to necessitate reach to facilitate goal movements

- 2. Decrease task difficulty by decreasing the number of "folds" necessary to complete the folding task
- 3. Increase or decrease task difficulty by changing the # of towels to be folded
- **4.** Increase or decrease task difficulty by changing the size of the towels.

Repetition Description:

1 repetition = towel is folded in half and then in half again

(***note- therapist unfolds towels in order for the patient to fold again.)

Activity: Lifting cans onto shelves (Organizing kitchen shelves)

Materials:

- 1. 20 16 oz. cans
- 2. Countertop with overhead cabinet containing three shelves -OR-
- 3. Stacking shelves to simulate overhead cabinet

Method:

- 1. Therapist will place all materials on the counter.
- 2. Patient will stand at the countertop with kitchen shelves directly in front of body.
- **3.** Objects will be placed on the lowest shelf.
- **4.** Patient will be instructed to lift all objects onto the shelf one by one.
- 5. When the patient has lifted all objects onto the shelf, all objects must then be returned one by one to the counter

Grading:

- 1. Decrease task difficulty by using bilateral UE to complete task. Unaffected UE must be used as a gross assist.
- 2. Increase or decrease task difficulty by changing the height of the shelf.
- Increase or decrease task difficulty by changing placement (depth) of items placed on shelf.
- **4.** Increase or decrease task difficulty by changing the weight of objects. (light-empty vs. heavy-full cans)
- **5.** Decrease task difficulty by beginning with patient just moving objects from the shelf to the counter (downwards).
- **6.** Decrease task difficulty by stabilizing objects with therapist assist while pt. is attempting grasp.

Repetition Description:

1 repetition = reach, grasp, release 1 can onto shelf

or

1 repetition = reach, grasp, release 1 can onto countertop

Task: Sorting Silverware

Materials:

- 1. 5 of each (fork, spoons, knives) standard stainless steel
- 2. 5 of each (forks, spoons, knives) standard plastic
- 3. Sorted utensil container
- 4. Table/ Kitchen counter

Method:

- 1. Patient will sit or stand at counter with utensils placed on affected side and sorter placed on unaffected side.
- 2. Patient will pick up one utensil at a time and place in correct slot.

Grading:

- 1. Decrease task difficulty by beginning with plastic utensils before changing to stainless steel.
- Increase or decrease task difficulty by increasing or decreasing the number of utensils to be sorted.
- **3.** Increase task difficulty by alternating position of the utensil sorter to necessitate reach to facilitate goal movements.
- 4. Increase or decrease task difficulty by standing or sitting
- 5. Decrease task difficulty by using built-up utensils to aid with grip

Repetition Description:

1 repetition = reach, grasp, release 1 utensil into container

Task: Managing and manipulating coins

Materials:

- 1. Various coins (pennies, nickels, dimes, quarters)
- 2. Coin bank

Method:

- 1. Patient will sit or stand at table with the coin bank placed in midline.
- **2.** Patient will pick up coins one at a time with affected UE and place in slot on top of coin bank.

Grading:

- 1. Increase task difficulty by alternating position of coin bank to necessitate reach and facilitate goal movements.
- 2. Increase task difficulty by rotating coin bank slot, challenging wrist movements
- 3. Increase or decrease task difficulty by standing or sitting

4. Decrease task difficulty by Picking up coins and placing in another container (non-bank) Decrease task difficulty by useing dycem to stabilize coins on (prevent slipping of table)

Repetition Description:

1 repetition = reach, grasp, release 1 coin into coin bank

Task: Scrapbooking (Cutting Paper)

Materials:

- 1. Scissors
- 2. Scrapbooking paper

Method:

- **1.** Therapist will need to create (and photocopy) sheet with lines prior to treatment time.
- 2. Therapist will place paper in front of patient at midline.
- **3.** Scissors are to be placed on patient's affected side within reach.
- **4.** Patient will be instructed to cut paper.
- **5.** Patient may use unaffected UE to assist with task.

Grading:

- 1. Increase or decrease task difficulty by Increasing or decreasing size of the paper.
- **2.** Increase or decrease task difficulty by Increasing or decreasing the thickness of the paper
- **3.** Decrease task difficulty by Beginning with plastic loop scissors (child-proof scissors) and progress to standard scissors.
- **4.** Increase task difficulty by changing the type of line to cut(straight lines; zigzag; wavy lines)

Repetition Description:

1 repetition = cutting one line

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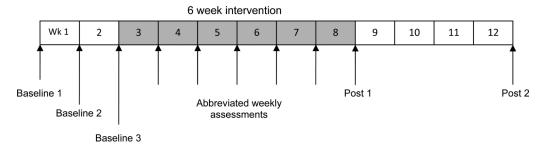


Figure 1.Schematic of experimental design illustrating the time course of assessments and treatment. Abbreviated weekly assessments included the Action Research Arm test and grip strength.

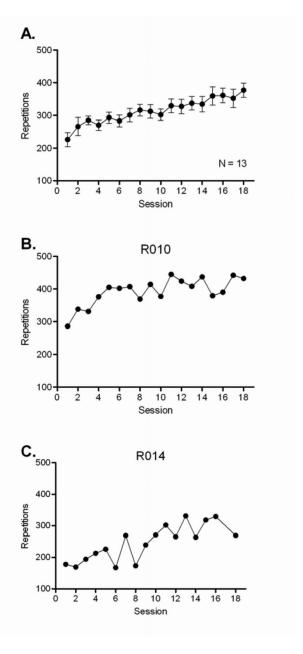
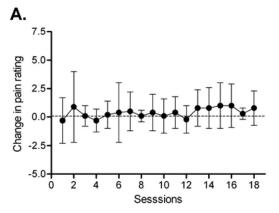


Figure 2.Number of repetitions achieved at each session for the group (A) and for two individual subjects (B-D). Group values are means and standard errors.



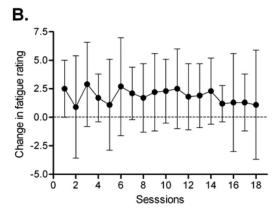


Figure 3. Subject ratings of change in pain (A) and fatigue (B), calculated from numeric scale ratings reported before and after each treatment session. Values are means \pm standard deviations. Negative values indicate that pain and fatigue diminished at the end of a treatment session compared to the beginning of that treatment session.

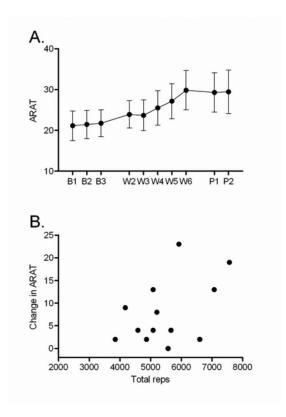


Figure 4. A: Time course of changes in the Action Research Arm test (ARAT) for the group. Values are means and standard errors. B: Scatterplot of total number of repetitions of task-specific training vs. change in ARAT score.

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Table 1

Subject characteristics

Subject	Age (yrs)	Gender	Time post stroke (mos)	Side affected	Dominant side affected	Baseline ARAT score	Spasticity [†]	Other stroke-related deficits \ddot{z}
R001	47	F	36	Т	N	3	4	↓Somatosensation
R002	50	M	19	Т	N	12	2	
R003	75	M	12	Т	N	8	2	
R004	25	M	09	R	Y	3	4	
R005	44	F	9	R	Y	38	1	
R006	44	F	36	R	Y	4	2	Aphasia, USomatosensation
R007	25	F	120	Т	Y	20	3	
R008	28	F	48	R	Y	43	0	Aphasia, Emotionally labile
R009	57	M	18	Т	N	6	3	
R010	50	F	48	R	Y	40	0	Aphasia
R011	92	F	36	Т	N	27	2	Ataxia
R012	99	M	57	R	Y	20	4	
R013	57	F	36	Т	N	15	1	
R014	06	M	48	Т	N	22	4	↓Somatosensation
R015	33	M	22	R	Y	20	1	Aphasia
Mean/%	54	53% F	40	47% R	53% Y	19	2.2	

* ARAT: Action Research Arm test, maximum (normal) score = 57; value is mean of the 3 baseline scores.

 $^{\uparrow}$ Spasticity assessed with the Modified Ashworth Scale 52 at the elbow; normal = 0, with higher scores indicating greater spasticity.

[‡] Additional motor and non-motor deficits as documented from the NIHSS, clinical examination, and/or medical records.

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Table 2

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Outcome data (n = 13). Values are means \pm SE.

Measure	Baseline 1	Baseline 1 Baseline 2 Baseline 3	Baseline 3	Post 1	Post 2
ARAT	21.1 ± 3.6	21.4 ± 3.5	21.7 ± 3.3	29.2 ± 4.8	29.5 ± 4.7
Grip strength (kg)	14.0 ± 1.9	12.7 ± 1.1	12.0 ± 1.2	14.0 \pm 1.9 12.7 \pm 1.1 12.0 \pm 1.2 14.5 \pm 1.5 15.4 \pm 1.8	15.4 ± 1.8
SIS – Hand subscale	45 ± 8	40 ± 9	1	$48\pm8^{\dagger}$	49 ± 8 [†]
SIS – ADL subscale	9 = 02	67 ± 5	-	78 ± 4*	78 ± 3*
COPM - Performance	3.3 ± 0.5		1	*.5.5 ± .6	5.4 ± 0.6
COPM – Satisfaction	2.8 ± 0.4		-	5.3 ± 0.7	5.4 ± 0.8

ARAT: Action Research Arm test, 0 - 57 point scale; SIS: Stroke Impact Scale, 0 - 100 point scales; COPM: Canadian Occupational Performance Measure, 0 - 10 point scales. Higher numbers indicate better results on all scales.

For measures taken multiple times during the baseline, no significant differences between baseline assessments were found.

No significant differences were found between the first and second post-intervention assessments.

p < 0.05 for difference between baseline and post-intervention assessments

 $\dot{\tau} = 0.08$ for difference between baseline and post-intervention assessments

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Table 1
Guiding principles for the high repetition intervention

Principle	Insights & implementation in animal models & motor learning studies	Implementation in our protocol
Practice of a movement results in improvement in that movement.	Animals practice purposeful movements: reach-grasp-retrieve.	Each task incorporates the essential components of reach, grasp, move/manipulate and release.
Large amounts of practice are required to truly master a motor skill.	Animals perform hundreds of repetitions daily for up to 3 months. To date, animal studies have not determined an optimal number of daily repetitions. Brain reorganization continues for a short while after behavior plateaus.	The target number of repetitions is ≥ 300/session. Setting the target as ≥ instead of = allows us flexibility to see how much subjects can be challenged. Duration of the intervention (for future studies) should extend ~1-2 weeks beyond the anticipated behavioral plateau.
Learning requires solving the motor problem and not rote repetition of over-learned tasks.	Brain reorganization occurs with learning and not simply repetition.	Tasks have grades of increasing difficulty. Rules for progressing to more difficult grades are designed to continually challenge the subject's motor capabilities.
Learning does not occur in the absence of feedback.	Animals have clear intrinsic feedback on each trial about knowledge of results (i.e. eat the food pellet vs. or not).	Tasks have clear goals so subjects can easily determine knowledge of results.
Intrinsic feedback is optimal for promoting self-learning and generalization.		Subjects are given summary feedback on knowledge of results (number of repetitions achieved) at the end of each task.
Optimal learning occurs with high levels of motivation and engagement.	Animals are food-deprived and the task is to retrieve food, creating very high levels of motivation and engagement.	Subjects help to select tasks for practice to increase engagement and motivation. Tasks can be changed each week to minimize boredom. Subjects practice 3 tasks each session to minimize boredom.
Variable practice conditions are optimal for learning and generalization.	Animals practice a single task under limited variable conditions (e.g. changing well sizes, well locations).	Essential movement components stay the same but contexts of the components change. Variation is accomplished across tasks (e.g. practice of three tasks, change 1 task weekly) and within tasks (e.g. vary objects, location, weight, speed, accuracy, etc.).
Within-session, massed practice promotes learning better than within-session, distributed practice.	Animals continually perform their movement task throughout the session.	The environment is set up to allow for continuous practice. Subjects are given encouragement by the therapist to continue practicing. Rest breaks are only provided at the request of the subject.
Random practice of several tasks results in better learning than blocked practice of the same tasks in healthy adults. This principle is often tested as randomization of small blocks of trials of up to 3 tasks.	Animals only practice one task, so this is not an issue.	In the current protocol, task practice is done in blocks for simplicity. Future studies are needed to address this issue.
Practice of a whole task results in better learning than practice of parts of the task, unless the task can be broken down into clearly separable components.	Animals practice the whole task of retrieving and eating a pellet.	Basic underlying movement components of reach, grasp, move/manipulate and release represent a whole sequence of movements as performed in the real world.

Table 2

Examples of goals and tasks chosen to address them.

Goal	Tasks Chosen to Address the Goal	Rationale for Chosen Task
Handwriting	Practice writing; incrementally write faster to improve quality and accuracy.	Handwriting is necessary for signing documents and work duties.
Typing on a Keyboard	Practice typing	Typing is often necessary for work, including communication (e.g. email)
Fishing	Picking up fishing lures; sorting a tackle box	Fishing is an important leisure activity for many individuals. Manipulating fishing-related equipment addresses finger dexterity
Playing games	Playing Connect Four; dealing cards	Playing social games is an important leisure activity for many individuals. Different games that are of interest to the subject can be selected address motor impairments of the proximal and/or distal upper extremity.
Folding towels	Folding towels or washcloths	Folding is bilateral activity and an integral part of many household tasks. Grasping and releasing clothing is important for dressing as well.
Stacking and removing cans on shelves	Lift/remove cans onto shelves	This task mimics many common daily movements such as unloading a grocery bag, and getting out craft/hobby supplies. This task can be graded to address proximal and distal motor impairments
Sorting silverware	Pick up silverware and sort into container	Silverware is used at most meals. This activity addresses grasp and release of objects.
Managing and manipulating coins	Pick up a variety of coins and place in a metal piggy bank with slotted top.	Manipulation of money is an everyday task and addresses finger dexterity.
Scrapbooking	Cutting paper with scissors	Scrapbooking is a growing leisure activity, involving cutting, pasting/gluing, and manipulating different sized papers and photographs. The variety of movements required can be structured to address proximal and/or distal motor impairments.