Original Research

Lessons Learned: The Difficulties of Incorporating Intensity Principles Into Inpatient Stroke Rehabilitation

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Abstract

Objective: The objective of this study was to determine the feasibility of a rehabilitation approach focusing on cardiovascular, strength, and gait training intensity in the inpatient rehabilitation setting after a new onset of stroke. We additionally aimed to determine the efficacy of this intensity-based program on rehabilitation outcomes compared with usual care.

Design: Participants were pseudo-randomized to an intensity-based program focusing on gait, cardiovascular, and strength training or to usual care. Outcomes included FIM, 10-meter walk, 2-minute walk test, 5-time sit-to-stand test, and Tinetti balance assessment.

Intervention: The intervention consisted of 6 20-minute sessions per week dedicated to intensity of activity: 2 each for walking, cardiovascular training, and strength training.

Participants: Patients (N=49) with new onset stroke admitted to inpatient rehabilitation over the course of 1 year.

Setting: Four inpatient rehabilitation facilities with comprehensive neurologic rehabilitation teams.

List of abbreviations: 2MWT, 2-minute walk test; 10-mw, 10-meter walk test; 5xSTS, 5 times sit to stand; CFIR, Consolidated Framework for Implementation Research; SSWS, self-selected walking speed.

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AnMed Health Rehabilitation Hospital is now Encompass Rehabilitation Hospital, Columbia, SC, and HealthSouth Rehabilitation Hospital is now Encompass Rehabilitation Hospital, Charleston, SC.

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Stroke is the most common disabling condition in the United States today, with approximately two-thirds of the 795,000 individuals experiencing stroke each year requiring comprehensive, interdisciplinary therapy to promote functional independence. Individuals poststroke often experience severe deconditioning secondary to direct impairments from the stroke, as well as subsequent sedentary lifestyle. Initiating and progressing capacity-building exercise programs to combat the acute and long-term effects of stroke should be imperative during poststroke rehabilitation. Intensity of interventions, which we define as dosing and progressing according to prescribed standards associated with maximum heart rate, 1-repetition maximum resistance, and self-selected walking speed (SSWS), is critical if improved physical function is to be achieved. Intensity of training, a primary principle of neuromuscular plasticity, is consistently a major factor associated with success in improving function and driving neurologic recovery.

Although intensity is recognized as an important factor in poststroke recovery research, it is rarely practiced in real-world environments. Translating new interventions, such as high intensity rehabilitation, to the clinical setting can be challenging, but it is critical to the advancement of best practice in neurologic rehabilitation. Surveys indicate that although 88% of physical therapists in the United States responded that intense aerobic exercise should be incorporated into stroke rehabilitation, 84% identified at least 1 barrier inhibiting implementation, and heart rates reach aerobic training zones for less than 5% of total physical therapy treatment time. Knowledge of sedentary activity reduction being critical to neurologic recovery has not changed the fact that patients with stroke in inpatient rehabilitation only spend 10 hours a day out of bed, with 87% of that time being sedentary (including 61.6% of their time participating in physical therapy). An urgent need exists to translate laboratory-tested interventions to real-world environments and to identify and ameliorate obstacles to comprehensive intensity-based programs capable of promoting walking recovery.

Previous rehabilitation trials focused on the intensity of interventions have primarily examined a single intervention, such as aerobic training, walking interventions, or strengthening. In a review of strength training after chronic stroke, appropriately intense resistance training (at 75% of the 1-repetition maximum) produced improvements in strength, gait speed, functional outcomes, and quality of life. Importantly, there were no reports of increased spasticity or synergistic movement patterns. Intense cardiovascular training, defined as reaching a target heart rate or target rating of perceived exertion for a total of at least 20 minutes, produced significant gains in walking speed, distance walked, balance, and cognition compared with a non-targeted exercise control intervention. High intensity walking (training faster than SSWS) yielded significant improvements in SSWS, fastest comfortable walking speed, and 6-minute walk test distance.

In spite of mounting evidence supporting dosing and progressing intensity-based interventions by clinically available metrics (age-based maximum heart rate, strength gauged as percentage of the 1-repetition maximum, SSWS), to date, no study has combined these approaches as part of a comprehensive inpatient rehabilitation treatment regimen. Combining all 3 areas into a comprehensive intervention offers the possibility of coalescing their individual effects into a therapy capable of maximizing mobility. In addition, therapists may be more likely to implement an intervention that not only meets the comprehensive needs of those in inpatient rehabilitation facilities but that also demonstrates the high probability of a clinical effect. The purpose of this study was to determine the feasibility of implementing an evidence-based rehabilitation approach focusing on cardiovascular, strength, and gait training intensity in the inpatient rehabilitation setting. We also aimed to determine the efficacy of an intensity-based program on inpatient rehabilitation outcomes compared with usual care.

Methods

Study design

The Systematic Collection of Objective and Progressive Exercise (SCOPE) trial was a multicenter, pseudo-randomized...
pragmatic trial that included patients admitted to inpatient rehabilitation during 2017 for management of new stroke. All participants participated in the informed consent process and completed an informed consent form approved by the institutional review board at the Medical University of South Carolina, which functioned as the institutional review board for all sites. Study participants were considered for enrollment after admission to 1 of 4 different inpatient rehabilitation facilities: (1) HealthSouth Rehabilitation Hospital, Charleston, SC (currently Encompass Health Rehabilitation Hospital of Charleston); (2) AnMed Health Rehabilitation Hospital, Anderson, SC; (3) HealthSouth Rehabilitation Hospital, Rock Hill, SC (currently Encompass Health Rehabilitation Hospital of Rock Hill); and (4) HealthSouth Rehabilitation Hospital, York, PA (currently Encompass Health Rehabilitation Hospital of York).

Inclusion criteria included (1) admission to inpatient rehabilitation for new stroke, even if there was an incidence of previous stroke; (2) stroke weighted FIM motor score between 26.15 and 51.05 (FIM group 3-9); and (3) ability to provide informed consent. Exclusion criteria included: (1) neurologic comorbidities other than stroke; (2) severe dementia (unable to follow motor commands or provide a rating of perceived exertion); (3) cardiovascular diagnosis other than stroke preventing intensity of rehabilitation; and (4) severe hypertension with systolic blood pressure greater than 200 mmHg and diastolic blood pressure greater than 110 mmHg at rest. Patient eligibility and group assignment was determined by the Director of Therapy Operations at each facility. Successive admissions were assigned to either the intervention or control group in an alternating pattern. This pseudo-randomization occurred according to clinic needs. Enrollment was completed by the treating physical therapists. Assessments were performed by the treating physical therapist within 3 days of admission and were repeated before discharge (within 24h of discharge). The study design was to be part of clinical practice and reflect a more pragmatic approach rather than serve as a true randomized controlled trial.

Patients assigned to the intervention group underwent a standardized intensity-based physical therapy rehabilitation program. The program was guided by a customized REDCap® survey tool developed by investigators at the Medical University of South Carolina. The REDCap tool provided therapists guidance on the intensity-based interventions by using patient assessment findings to specify individualized intensity dosing and progression targets. However, the REDCap tool was not prescriptive for the specific exercises or activities to be delivered during treatment sessions. The goal was for participants to receive 2 20-minute intensity-based intervention sessions per week to address each of the following: gait training, strength training, and cardiovascular training. Intensity of gait was prescribed as training performed between 110% and 125% of the patients’ SSWS, assessed at the beginning of each gait training bout, and could be completed either over ground or on a treadmill. Walking activities progressed as walking speed increased to consistently maintain 110% to 125% of SSWS. Strength training intensity prescription was based on 75% of the 1-repetition maximum, which is the equivalent of the 10-repetition maximum, and exercises progressed when the patient was able to complete more than 10 repetitions without fatigue. Specific strengthening activities were not prescribed by the protocol. Clinical decision-making regarding strengthening modalities was left to the treating therapist. Cardiovascular training was prescribed as maintaining heart rate within a target zone set at 60% to 80% of the age-predicted maximum heart rate (220 beats/min — age). For those participants demonstrating a compromised cardiovascular response to activity or exercise (eg, those on a beta-blocker or experiencing sympathetic nervous system dysfunction), an alternative intensity target of 11 to 15 on the Borg rating of perceived exertion scale was used. In the postacute stroke population, gait and strength training often produce increases in heart rate or rating of perceived exertion into the target zone. If target values were sustained for 20 minutes during gait or strength training sessions, these sessions were also counted as cardiovascular training.

Those individuals randomized into the control group received usual care, defined as the physical therapy treatment normally provided at each individual facility. Treating physical therapists of patients in the control group were given no knowledge of the intervention group design, and scheduled treatment time was equivalent to the intervention group.

Outcomes
Participants in both groups underwent a standardized battery of common physical therapy outcome measures used with the cerebrovascular accident population in the inpatient rehabilitation setting. The battery was assessed at admission and discharge by the treating physical therapist and included the following measures: 10-meter walk test (10-mw), 20-minute walk test (2MWT), timed Up and Go, 5-times sit-to-stand (5xSTS), the Tinetti Performance Oriented Mobility Assessment, and the FIM. A 2018 clinical practice guideline published by the Academy of Neurologic Physical Therapy recommends outcome measures in the following domains: balance (standing, walking, and confidence), walking speed, walking distance, and transfers with included measures reflecting all of the above recommendations. More specific measures for aerobic capacity (ie, exercise tolerance testing) and for strength training (ie, dynamometer testing) were beyond the clinical scope of this study. Patients who were unable to complete any of the standardized outcome measures at time of admission were assessed as soon as they could complete the measure without modification. For the 10-mw, 2MWT, Tinetti, and FIM, baseline scores were considered zero if they could not be completed. For the 5xSTS and timed Up and Go (where zero would reflect an impossible score), we replaced zeros at baseline with the time from the lowest performing individual on that outcome measure for statistical purposes.

Semi-structured follow-up phone interviews
We conducted follow-up phone interviews with the study physical therapists (n=5) to further understand barriers to implementation. The interviews were performed 3 months after study completion by an individual with experience collecting qualitative data who was not involved in previous
study activities. A semi-structured interview guide was developed using the Consolidated Framework for Implementation Research (CFIR). The CFIR is a comprehensive framework of constructs related to implementation organized into 5 domains: Intervention Characteristics, Outer Setting, Inner Setting, Characteristics of Individuals, and Process. The interviews were audio-recorded and transcribed verbatim. Transcripts were analyzed using a content analysis approach. Coded data was categorized by CFIR construct and characterized as a barrier or facilitator. Because of the nature of the study and the set sample size, we report barriers and facilitators identified by at least 3 of the 5 participants. Survey questions were rated on a 4-point Likert scale (Strongly Agree, Agree, Disagree, Strongly Disagree). We calculated frequencies of responses on survey questions.

Statistical analysis

All data are reported as mean ± SD unless otherwise noted. Between-group effect sizes were calculated for all variables using the formula:

$$ES_{between} = \frac{\Delta_{intervention} - \Delta_{control}}{\text{standard deviation}^{pooled}}$$

A 2 × 2 analysis of variance was performed for each of the 6 outcome measures to evaluate main effect of group, time, and the group × time interaction. Sphericity of the models was tested using Mauchly’s test of sphericity. If significant findings, Greenhouse-Geiser corrected $P$ values are reported; otherwise, sphericity was assumed. Post hoc analyses were conducted using a Bonferroni adjustment. Normality was assessed using a Shapiro-Wilk test, and all non-normally distributed data were log-transformed. Alpha was preset to 0.05. All statistical analysis was performed using IBM SPSS Statistics for Windows, Version 24.

Results

Sixteen individuals completed the intervention (10 men, 6 women; 2 black, 14 white) with an average age of 67.2 ± 17.4 years and average chronicity of 36.8 ± 72.9 days poststroke (2 patients were readmitted 251 and 186 days poststroke). Nineteen individuals were in the usual care control group (9 men, 10 women; 3 black, 1 Hispanic, 15 white) with an average age of 70.3 ± 14.2 years and 8.2 ± 5.6 days poststroke. Length of stay was 14.8 ± 5.1 days for the intervention group and 13.8 ± 4.0 days for the control group, which were not significantly different ($P$ = .635 with the Mann-Whitney $U$ test).

For all outcome measures, there was a significant main effect of time ($F_{18.5}, P < .001$). Post hoc analyses demonstrated that there were no significant differences between the groups for any variable at baseline ($P > .56$). Both the intervention and control groups improved significantly in each outcome measure ($P < .03$), but the change scores from admission to discharge were consistently larger in the intervention group for all variables except the 5xSTS (table 2). Both the 2MWT and Tinetti demonstrated a significant interaction when assessed with a 2-way analysis of variance ($P < .05$) (fig 1), and the FIM, 10-mw, 2MWT, and Tinetti all had between-group effect sizes that exceeded 0.60 (see table 2).

Follow-up phone interviews

Survey questions

The study physical therapists’ (n = 5) responses to survey questions are presented in table 3.

Open-ended interview questions

Barriers and facilitators to implementation of the intensity-based program organized by CFIR domain and construct are

### Table 1: Withdrawals

| Group      | Enrolled | Completed | Withdraw | Reason for Withdrawal                      |
|------------|----------|-----------|----------|--------------------------------------------|
| Intervention | n = 25   | n = 16    | n = 9    | Acute care transfer (n = 3)                 |
|            |          |           |          | Decreased activity tolerance/subjective (n = 3) |
|            |          |           |          | Unexpected early discharge (n = 1)          |
|            |          |           |          | Family request (n = 1)                      |
|            |          |           |          | Unable to perform outcome measures (n = 1)   |
|            |          |           |          | Acute care transfer (n = 2)                  |
|            |          |           |          | Unexpected early discharge (n = 1)          |
|            |          |           |          | Unreported reasons (n = 2)                   |

| Control    | n = 24   | n = 19    | n = 5    |                                            |


The reported barriers to implementation were complexity of participant selection criteria ($n = 4$), lack of clinical utility of the REDCap data entry tool ($n = 4$), lack of support from management in the enrollment process ($n = 3$), scheduling issues ($n = 3$), and lack of knowledge on use of the REDCap tool and delivery of the intensity-based program ($n = 3$). The therapists’ belief that the intervention was beneficial for their patients ($n = 5$) was a facilitator to implementation.

### Discussion

The purpose of this study was to determine the feasibility of using a rehabilitation framework focused on incorporating physiological principles of exercise for individuals poststroke in the inpatient rehabilitation setting. In addition, we aimed to determine the efficacy of this framework on inpatient rehabilitation outcomes compared with usual care. Although there were no serious adverse events associated with the intervention, treatment compliance was low, with patients only receiving approximately half of the prescribed intensive sessions over the course of their inpatient rehabilitation stay. In addition, 3 individuals in the intervention group withdrew secondary to decreased activity tolerance. None withdrew for tolerance reasons from the lower intensity control group. This intolerance for intensive activity highlights one of the challenges of encouraging exercise programs dosed on principles of exercise for those poststroke. Despite the low treatment compliance and the relatively short lengths of stay, individuals in the intervention group demonstrated gains in all outcome measures that exceeded those in the usual care control group with the exception of the 5xSTS. The lack of improved gains in the 5xSTS may reflect that sit-to-stand exercises are often part of usual care, whereas intensive cardiovascular conditioning and gait training are less common. Significant interactions were observed in both the 2MWT distance and the Tinetti balance assessment tool, demonstrating the efficacy of the intervention, even given the relatively small sample size. The FIM, 10-mw speed, 2MWT distance, and Tinetti all demonstrated between group effect sizes less than 0.60. Although treatment effects were medium to large, and efficacy was demonstrated with the 2MWT and Tinetti, the feasibility is unclear given the challenges discussed above.

Several factors served as barriers to compliance and feasibility with the protocol. In the facilities participating in the investigation, there were often coverage issues with inconsistency in therapists treating the intervention.

### Table 2  
Change scores for each outcome

| Outcome Measure       | Intervention Mean Δ | Control Mean Δ | Main Effect Time | Interaction Effect | Between Group Effect Size |
|-----------------------|---------------------|----------------|------------------|-------------------|--------------------------|
| FIM                   | 49.88±7.32          | 42.70±14.95    | $P < .001$       | $P = .10$         | 0.61                     |
| 10-mw speed (m/s)     | 0.40±0.27           | 0.24±0.23      | $P < .001$       | $P = .25$         | 0.62                     |
| 2MWT distance (feet)  | 144.44±118.22       | 71.69±94.12    | $P < .001$       | $P = .02$         | 0.68                     |
| TUG time (s)          | -22.07±23.72        | -16.71±19.80   | $P < .001$       | $P = .36$         | 0.24                     |
| 5xSTS time (s)        | -6.88±5.80          | -7.90±12.26    | $P < .001$       | $P = .99$         | -0.11                    |
| Tinetti               | 10.44±4.76          | 7.29±4.98      | $P < .001$       | $P = .03$         | 0.64                     |

NOTE. Note that the intervention group had 3 individuals with decreased activity tolerance, whereas no one withdrew for that reason from the lower intensity control group.

Abbreviation: TUG, Timed Up and Go.
participants. These facilities also use a fair amount of group or concurrent treatments, making it more difficult to find the time to engage in the higher intensity treatments. Philosophically, many inpatient rehabilitation centers are very functional outcome biased because of dependency on the FIM as the primary outcome measure, and many therapists are reluctant to deviate from task-specific practice. Furthermore, in this study, the treating therapists were the only individuals in each facility involved in the investigation, and it proved too time consuming for them to consent individuals, collect all outcome measures, and perform the interventions without additional facility support. For example, only 49 individuals were consented into the study out of the approximately 700 persons admitted with stroke among the 4 participating sites. Lastly, for those individuals also receiving speech therapy, there were fewer opportunities for physical therapy sessions, as each patient received a total of 3 hours of therapy per day for all therapies, and the investigation was not funded for additional treatment time.

Semi-structured interviews yielded other interesting results from the treating therapists. Although there was

| Survey Question | Strongly Agree, n (%) | Agree, n (%) | Disagree, n (%) | Strongly Disagree, n (%) |
|-----------------|-----------------------|-------------|----------------|-------------------------|
| It was difficult to integrate the intensity-based program into my clinical practice | 0 (0) | 0 (0) | 5 (100) | 0 (0) |
| It was challenging to recruit patients to participate in the study. | 1 (20) | 3 (60) | 1 (20) | 0 (0) |
| Once enrolled, patients responded favorably to the intensity-based approach.* | 0 (0) | 5 (100) | 1 (20) | 0 (0) |
| I had sufficient resources, including time, to deliver the intensity-based program. | 0 (0) | 2 (40) | 2 (40) | 1 (20) |
| The REDCap survey tool was easy to use. | 2 (40) | 2 (40) | 1 (20) | 0 (0) |
| I consistently delivered the intensity dosage and progression generated by the REDCap tool. | 1 (20) | 4 (80) | 0 (0) | 0 (0) |
| I consistently administered the specified outcome measures to study participants at admission and discharge. | 3 (60) | 2 (40) | 0 (0) | 0 (0) |
| Upon reflection, the intensity-based approach was effective in my setting. | 3 (60) | 2 (40) | 0 (0) | 0 (0) |
| Involvement in the study positively impacted the way I practice now. | 3 (60) | 2 (40) | 0 (0) | 0 (0) |

NOTE. Four of the 6 outcome measures collected demonstrated between-group effect sizes greater than 0.60. The 2MWT and Tinetti demonstrated significant group × time interactions (P < .05).

* One participant selected “Agree” and “Disagree” and stated that it depended on the patient.

| CFIR Domain and Construct | Therapists Reporting, n = 5 |
|---------------------------|-----------------------------|
| Intervention characteristics | Therapists Reporting, n = 5 |
| Complexity | Barrier: Complexity of participant selection criteria was a barrier to enrollment. | 4 |
| Design quality & packaging | Barrier: REDCap tool did not allow entry of sufficient treatment detail or allow longitudinal tracking of patient data. | 4 |
| Inner setting | Barrier: Lack of support from management in the enrollment process. | 3 |
| Readiness for implementation, leadership engagement | Barrier: Scheduling issues were a barrier to adherence to the intensity protocol. | 3 |
| Readiness for implementation, available resources | Barrier: Lack of knowledge on use of REDCap tool and delivery of intensity program. | 3 |
| Readiness for implementation, access to knowledge and information | Characteristic of individuals | Knowledge & beliefs about the intervention | Facilitator: Therapists view the intervention as being beneficial for their patients. | 5 |
initial resistance to deviating from task-specific treatment, all participating therapists disagreed with the statement that the program was difficult to integrate into an inpatient program. However, 4 out of 5 either agreed or strongly agreed that it was challenging to recruit patients. This was partly because of the lack of institutional support, but also because of the hesitancy for individuals poststroke to voluntarily participate in more physically challenging rehabilitation, regardless of the substantial evidence supporting higher intensity treatments. Interestingly, all therapists agreed that once enrolled, patients responded favorably to the intensity-based framework, perhaps suggesting that 1 obstacle may be psychological on the part of the patients. It is possible that the word “intensity,” which was used in the informed consent form, should be replaced by “exercise guidelines,” as the American College of Sports Medicine guidelines were the basis of the theoretical framework. Three out of 5 therapists stated that they did not have sufficient resources to carry out all aspects of the investigation, even though 4 felt that they consistently delivered the required elements. All therapists either agreed or strongly agreed that administering outcome measures was not an obstacle and that the program was “effective” for their patients. However, it must be considered that all therapists involved in the investigation were graduates of a neurologic residency program and certified as neurologic clinical specialists. Thus, they may not be representative of all rehabilitation therapists.

Study limitations

As this was designed as a pragmatic trial, there were several areas of control that were not attainable in this setting, including truly randomized group assignment, blinding of evaluation, evaluators conducting treatment, and concealment of group allocation. Although this adversely affected the internal validity of the study, it emphasized the real-world aspect of the attempted translation. An unexpected limitation was a relatively small sample size considering the numbers of individuals poststroke admitted annually to each of the participating rehabilitation centers. Patient recruitment and enrollment was limited, partly because of stringent exclusion criteria, such as the requirements for intact cognition (caregiver consent was not allowed in this protocol). As the treating therapists were also responsible for consenting participants, there may have been a selection bias toward higher functioning patients, as represented by baseline mean walking speeds (control = 0.45 m/s, intervention = 0.40). However, the groups were not significantly different at baseline, so any bias would have affected the 2 groups similarly. In addition, cognitive deficits are often correlated with poststroke functional impairments, and the current study only allowed for participation if the patient could provide informed consent. As patients could likely participate in this intervention if they were able to follow a 3-step motor command, this restriction may have artificially limited enrollment, a factor which should be considered in future trials. Lastly, an additional limitation was due to the acute nature of this patient population. Those acutely admitted to inpatient rehabilitation are often unable to participate in the required treatment elements, and several patients were dropped from enrollment because of transfers back to acute facilities, a not uncommon occurrence in this treatment setting.

Future studies investigating the effectiveness of intensity-based physical therapy treatment plans should be broadened to include other diagnoses within the inpatient rehabilitation setting. An explicit approach to measuring intensity of interventions should be used in both the intervention and control groups to truly identify differences and potentially determine causative factors. The results of this study indicate a need for a larger, well-controlled examination of using exercise principles as a framework for neurologic rehabilitation. Furthermore, long-term outcomes of this intervention need to be assessed to determine the effect on quality of life, continued physical activity, and potential reduction in poststroke secondary health conditions.

Conclusions

As our health care system evolves, presenting continued reductions for reimbursement in the inpatient rehabilitation setting and effectively shortening patients’ length of stay, it is imperative to identify highly effective and efficient physical therapy treatment strategies. An increased intervention intensity during the inpatient rehabilitation stay is a simple way to maximize patient function.

Suppliers

a. REDCap; Vanderbilt University.

b. SPSS; IBM Inc.

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