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Developing complex interventions: lessons learned from a pilot study examining strategy training in acute stroke rehabilitation

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Abstract

Objective—To examine the feasibility of a strategy training clinical trial in a small group of adults with stroke-related cognitive impairments in inpatient rehabilitation, and to explore the impact of strategy training on disability.

Design—Non-randomized two-group intervention pilot study

Setting—Two inpatient rehabilitation units within an academic health center

Participants—Individuals with a primary diagnosis of acute stroke, who were admitted to inpatient rehabilitation and demonstrated cognitive impairments were included. Individuals with severe aphasia; dementia; major depressive disorder, bipolar, or psychotic disorder; recent drug or alcohol abuse; and anticipated length of stay less than 5 days were excluded.

Intervention—Participants received strategy training or an attention control session in addition to usual rehabilitation care. Sessions in both groups were 30–40 minutes daily, 5 days per week, for the duration of inpatient rehabilitation.

Main Outcome Measures—We assessed feasibility through participants' recruitment and retention; research intervention session number and duration; participants' comprehension and

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Declarations of Conflict of Interest
There are no conflicts of interest to disclose.

Author Contributions
Dr. Skidmore conceived, designed, and implemented the study, as well as analyzed the data, and drafted the manuscript. The remaining authors contributed to the conceptualization of the study, providing expertise on the conceptualization and implementation of the intervention (Dawson, Grattan, Holm), selection and assessment of participants (Becker, Butters, Whyte), and clinical trial design (Becker, Dew, Holm). All authors contributed to the interpretation of data, and contributed to the revision of the manuscript.

engagement; intervention fidelity; and participants' satisfaction. We assessed disability at study admission, inpatient rehabilitation discharge, 3 and 6 months using the Functional Independence Measure.

Results—Participants in both groups (5 per group) received the assigned intervention (>92% planned sessions; >94% fidelity) and completed follow-up testing. Strategy training participants in this small sample demonstrated significantly less disability at 6 months [*M(SE)*=117 (3)] than attention control participants [*M(SE)*=96 (14); t_8=7.87, p=.02].

Conclusions—It is feasible and acceptable to administer both intervention protocols as an adjunct to acute inpatient rehabilitation, and strategy training shows promise for reducing disability.

Rehabilitation practitioners routinely employ complex interventions to promote improvements in a variety of functional and health-related outcomes. The Medical Research Council defines complex interventions as "interventions that contain several interacting components [including] the number and difficulty of behaviors required by those administering and receiving the intervention, the number of groups or organizational levels targeted by the intervention, the number and variability of outcomes addressed by the intervention, and the degree of flexibility or tailoring of the intervention permitted" (Craig et al., 2008, p. 7).[1] Thus, by definition, developing, evaluating, and implementing complex interventions is challenging. Nonetheless, this process is critical to the effective and ethical conduct of rehabilitation.[2]

The lack of rigor in the development and evaluation of rehabilitation interventions is well-documented.[3] There are a dearth of preliminary studies that 1) specify the theoretical foundations and mechanisms of complex interventions and 2) validate intended outcomes.[4] As a result, there have been several premature and costly efficacy and effectiveness studies (in the form of large-scale randomized controlled trials) that yield ambiguous findings.[4] Furthermore, sparse reporting on scientific methods (e.g., specification of active ingredients, manualization of procedures, definition and measurement of intervention fidelity, and development of valid and acceptable control or comparison conditions) impedes reproduction and weakens confidence in the robust nature of intervention in clinical practice.[4–7] To address these concerns, the Medical Research Council has published revised guidelines on the development and evaluation of complex interventions.[1]

Our laboratory has been applying these guidelines to the development and evaluation of a complex intervention, meta-cognitive strategy training (hereafter referred to as strategy training),[8–9] in an effort to improve rehabilitation outcomes for adults with stroke-related Developing Complex Interventions cognitive impairments enrolled in acute inpatient rehabilitation. Individuals who sustain moderate to severe cognitive impairments experience significantly greater disability compared to individuals who sustain minimal or no cognitive impairments.[10–11] Strategy training shows promise for reducing disability, particularly when administered early in recovery. Consistent with the Medical Research Council Guidelines, we previously reported the development (i.e., evidence base, theoretical model)[12] and the feasibility of strategy training for an adult with cognitive impairments enrolled in inpatient rehabilitation.[13] The current study expanded our pilot testing to address the feasibility and acceptability of both strategy training and an attention control intervention in a small group of adults with stroke-related cognitive impairments enrolled in acute inpatient rehabilitation. We also explored the impact of strategy training on activities of daily living disability within the first 6 months after admission to acute inpatient rehabilitation.

Methods

We recruited participants from consecutive admissions to two inpatient rehabilitation units in the same academic health system over an 18 month time frame. We obtained informed consent or proxy consent consistent with approved Institutional Review Board procedures, and screened potential participants for the following criteria: 1) primary diagnosis of acute stroke (within 30 days); 2) admission to inpatient rehabilitation; 3) impairment of cognitive functions (indicated by a score of 11 or higher on the Executive Interview);[14] 4) absence of severe aphasia (indicated by a score of 0 or 1 on the Boston Diagnostic Aphasia Examination 3rd Edition Severity Rating Scale);[15] 5) absence of pre-stroke diagnosis of dementia (indicated in the medical record); 6) absence of current major depressive disorder, bipolar, or psychotic disorder (indicated by the Primary Care Evaluation of Mental Disorders);[16] 7) absence of drug and alcohol abuse within 3 months of study admission (indicated by the Mini-International Neuropsychiatric Interview);[17] and 8) anticipated length of stay greater than 5 days. Eligible participants were assigned to one of two intervention groups, strategy training or attention control. To avoid cross-contamination within unit, participants on one unit received strategy training, and participants on the other unit received the attention control intervention (decided through coin toss).

Intervention

Participants in both groups engaged in research intervention sessions in addition to their usual inpatient rehabilitation sessions. The research sessions were 30–40 minutes and were administered daily 5 days per week for the duration of the length of stay. Research sessions were administered according to manualized procedures by trained occupational therapy personnel who were naïve to the opposing research intervention protocol (1 strategy training therapist; 1 attention control therapist). All research intervention sessions were videotaped and rated for fidelity to the respective manualized procedures.

The strategy training protocol is described elsewhere.[13, 18–19] In this study, strategy training addressed four critical ingredients (self-selected goals, self-evaluation of performance, strategy development and implementation, and therapeutic guided discovery) using four steps. Briefly, the strategy training therapist solicited self-selected goals from the participants using the Canadian Occupational Performance Measure (Step 1: Self-Selection of Goals).[20–21] This measure is a standard tool used to generate goals for rehabilitation, by helping participants identify activities of daily living that are 1) important to them based on their "typical" routine before the stroke and 2) likely to be problematic after the stroke. The strategy training therapist then asked participants to prioritize these problematic activities and identify the highest priority activities as a starting point. Once participants identified the first problematic activity to address, the strategy training therapist asked participants to perform the activity and identify barriers to performance (Step 2: Self-Evaluation). Next, the strategy training therapist taught participants the "Goal-Plan-Do-Check" strategy,[9] asking participants to set a goal to address the barriers (i.e., identify a criterion for performance), develop a plan to address the goal, do the plan, and check whether the plan worked or required revising (Step 3: Strategy Development). This process was repeated iteratively until the participant's criterion for the goal was met (and thus participants moved on to the next activity) (Step 4: Generalization and Transfer). The strategy training therapist used a therapeutic tool known as guided discovery,[22] guiding participants using prompting questions, as well as workbooks that aid the participants in implementing the process.

The attention control protocol was designed to control for the non-specific effects of strategy training (i.e., dose, attention). The attention control therapist administered standardized and dose-matched sessions, using scripted open-ended questions designed to promote participants' reflections on their rehabilitation activities and experiences. In lieu of strategy

training workbook materials, participants in the attention control group completed a daily journal detailing their thoughts and feelings about their stroke and their rehabilitation, and discussed these entries during the attention control sessions. We validated the attention control protocol in the course of this pilot study.

Measures

All clinical assessments were administered by trained and reliable assessors who were masked to group assignment. We collected demographic (age, gender, race, ethnicity, education, vocation, and social support) and medical information (stroke etiology and onset, comorbidities, medications) from the medical record at study admission. We characterized stroke severity with the National Institutes of Health Stroke Scale.[23]

We assessed the feasibility of both research interventions by examining several indicators. For both groups, we examined the number of participants recruited and retained; the number and duration of research intervention sessions; participants' comprehension of information; and participants' engagement in the research intervention sessions. We rated participants' understanding of information using a 3-point scale (1=minimal understanding, 2=some understanding, 3=good understanding). We rated participants' engagement in the research sessions using the Pittsburgh Rehabilitation Participation Scale, a 6-point valid and reliable scale assessing effort and motivation during intervention sessions (1=no engagement, 6=excellent engagement).[24] Both measures were scored during each research session by the research therapist. Mean understanding and engagement scores were used in data analyses.

We further assessed feasibility by developing and validating fidelity checklists for both research interventions, and applying these checklists to assess fidelity in a random 20% of sessions in each treatment group. We examined two facets of fidelity: 1) treatment integrity, and 2) treatment differentiation. To address treatment integrity, independent raters trained in the respective protocols assessed adherence to specified principles in each protocol (yes, no), and competence in execution (inadequate, adequate, exceptional). To address treatment differentiation between the two protocols, raters assessed adherence of both research interventions to the strategy training protocol to determine the degree to which the strategy training sessions adhered to the planned protocol, and the degree to which the attention control sessions did not include elements of the strategy training protocol. The two protocols were considered differentiated if adherence ratings were significantly higher for strategy training sessions compared to attention control sessions.[25]

We assessed the acceptability of both research interventions with the Client Satisfaction Questionnaire (8-item version)[26] at the time of discharge from acute inpatient rehabilitation. Total scores were computed and dichotomized into two categories: poor to fair satisfaction (0 – 23) and moderate to high satisfaction (24–32).

We compared differences in length of stay. We also collected information on usual rehabilitation after acute inpatient rehabilitation (setting, disciplines, and duration) from the medical record and through participant interview. Finally, we interviewed members of the clinical rehabilitation team after the participant was discharged from the hospital to ascertain whether the research sessions influenced usual rehabilitation care. These data were gleaned to inform the design of future trials, indicating whether randomization within unit would be feasible, or randomization with stratification by unit would be necessary.

We assessed activities of daily living disability using the Functional Independence Measure.[27] We administered the Functional Independence Measure at study admission, discharge (from acute inpatient rehabilitation), 3 months after study admission, and 6 months after study admission.

Data Analyses

To assess feasibility and acceptability, we computed descriptive statistics and *t*-tests, as appropriate. To assess reduction in disability, we analyzed data according to group membership regardless of study completion. We began by examining relevant baseline characteristics, testing for baseline differences between groups, and correlations between significant characteristics and the dependent variable (Functional Independence Measure). Next, we conducted a repeated measures analysis of variance examining group (strategy training, attention control) and time (baseline, discharge, 3 and 6 months) as main effects, including the group by time interaction.

Results

Figure 1 illustrates enrollment, allocation, and retention of participants. We assigned 10 participants to the two intervention groups (Figure 1).

All participants received the allocated intervention and completed follow-up testing. Strategy training participants completed 96% of intended sessions (48 out of 50), and attention control participants completed 92% of intended attention control sessions (46 out of 50). There were no statistically significant differences between groups in the number of research intervention sessions (strategy training M=11.2; attention control M=9.5; t_8=−0.53, p=0.61), the average duration of research intervention sessions in minutes (strategy training M=37.7; attention control M=36.8; t_8=−0.19, p=0.86), participants' understanding of information (strategy training M=2.2; attention control M=2.6; t_8=0.84, p=0.43), or participants' engagement in research intervention sessions (strategy training M=4.3; attention control M=4.0; t_8=−0.31, p=0.77).

Sampled strategy training sessions adhered to 94% of manualized procedures (85 out of 90), and the strategy training therapist demonstrated acceptable or exceptional competence for 100% of the completed procedures. Sampled attention control sessions adhered to 100% of manualized procedures, and the attention control therapist demonstrated acceptable or exceptional competence for 99% of completed procedures (89 out of 90). With respect to intervention differentiation, sampled strategy training sessions adhered to 94% of manualized procedures on the strategy training protocol (85 out of 90), and sampled attention control sessions did not contain any of the manualized procedures on the strategy training protocol, indicating good treatment differentiation. Overall, participants were satisfied with the research intervention sessions, with 100% of participants in each group reporting moderate to high satisfaction (strategy training M=29.5; attention control M=30.0; t_8=0.33, p=0.75).

There were no significant differences in the length of inpatient rehabilitation stay (strategy training M=24.2; attention control M=20.2; t_8=−0.91, p=.39). The clinical rehabilitation team did not detect any effects from the research intervention sessions in usual rehabilitation care. Anecdotally, interviews of clinical rehabilitation team members indicated a consistent inability to identify the content of research intervention sessions or allocation to groups.

Participant characteristics are provided in Table 1. The two groups did not differ with the exception of age. Participants in the strategy training group were significantly younger than participants in the attention control group. Age was modestly correlated with 6 month Functional Independence Measure scores (r=−.43), but the sample was too small to examine the effect of age on intervention response. Functional Independence Measure scores by group and by time are presented in Table 2. The repeated measures analysis of variance produced a significant group*time interaction ($F_{3, 24}$=7.53, p=0.001), as well as a non-significant main effect of group ($F_{1,8}$=0.99, p=.35), and a significant main effect of time

($F_{3,24}$=82.29, p<0.001). All statistical assumptions were met. Post hoc analyses suggest that the strategy training group demonstrated a significantly greater reduction in disability between baseline and the 6 month follow-up compared to the attention control group (t_8=7.87, p=0.02), despite the fact that both groups improved significantly over time. Groups differed by more than 20 points on the Functional Independence Measure at 6 months (Figure 2).

Discussion

Findings suggest that it is feasible to recruit and retain participants and administer both intervention protocols as an adjunct to acute inpatient rehabilitation. The therapists for each protocol demonstrated acceptable fidelity to the manualized procedures. Furthermore, we determined that both the strategy training and the attention control protocols were credible and acceptable to participants, as indicated by moderate to high satisfaction scores in each group. In fact, several participants in both groups reported anecdotally that the research intervention sessions were a very important part of their overall inpatient rehabilitation experience. Finally, strategy training participants in this small sample demonstrated significantly less disability at 6 months than attention control participants. These findings must be interpreted with caution, and are not generalizable beyond this small sample. Nonetheless, these findings are consistent with previous studies demonstrating the benefits of strategy training in individuals with chronic cognitive impairments.[18,28–31]

We learned a few lessons that will inform future clinical trials. First, 60% of consented participants were ineligible. While this proportion is comparable to other clinical rehabilitation studies (64–72%),[32–34] it raises significant concerns as to the widespread generalizability of future studies. The primary reason for exclusion in this study was insufficient cognitive impairment, defined as an Executive Interview score of 11 or higher. The Executive Interview is strongly associated with rehabilitation outcomes,[35] and the 11-point cut-off is based on normative data from healthy older adults.[36]However, many individuals, particularly younger adults, did not meet this criterion despite observed cognitive impairments. New evidence suggests that a 3-point cut-off may be more sensitive.[37] Using this new cut-off, we could have reduced the proportion of excluded participants from 60% to 28%. It remains unclear whether this change in inclusion criteria would yield similar results.

Second, our concern that strategy training may alter usual rehabilitation care (causing cross-contamination effects) was not supported. The clinical team was unable to correctly identify group assignment, to describe either research intervention, or to identify the impact of either research intervention on usual rehabilitation care. Future studies should randomize within unit, and more formally assess cross-contamination. This will likely address a number of the concerning issues that arose in the current pilot study, including baseline differences in age, stroke severity and cognitive impairments, as well as the potential influences of variability within usual rehabilitation (i.e., length of stay, number of usual inpatient rehabilitation sessions, duration and type of home health and outpatient rehabilitation sessions).

Future studies should examine mechanisms of action. We propose that guided discovery is a particularly potent active ingredient in strategy training that may promote changes in daily problem solving skills, and cognitive functions. Evidence suggests that guided discovery is effective in stimulating decision making and problem solving skills in individuals with and without cognitive impairments.[22,38] Examination of guided discovery and other active ingredients can be used to distill the intervention into its simplest form for maximal clinical scalability. For example, it may be that strategy training protocol in this study could be

simplified to emphasize guided discovery, and de-emphasize other active ingredients. Further study is required.

Future studies should also examine characteristics of individuals who do and do not benefit from strategy training in this venue. Potential moderators of intervention response such as age, stroke location or severity, and domains and severity of cognitive impairments may identify subgroups that require adapted or alternate intervention approaches.[10,39] One particularly important subgroup that we excluded was individuals with severe aphasia due to the languagedependent nature of the intervention. Aphasia incidence after stroke ranges from 21% to 38%.[40– 42] By excluding individuals with aphasia, we significantly limit the generalizability of the findings to the population of individuals enrolled in inpatient stroke rehabilitation. We posit that individuals with fluent aphasia may be more able to participate in and benefit from strategy training than individuals with non-fluent aphasia. However, this hypothesis remains untested.

In summary, strategy training is a feasible and acceptable adjunct to acute inpatient rehabilitation among adults with stroke-related cognitive impairments. This pilot study provides critical experiences that can be used to inform future clinical trials examining the efficacy of strategy training in inpatient stroke rehabilitation.

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Clinical Messages

- A clinical trial of strategy training is feasible and acceptable in inpatient rehabilitation among individuals with cognitive impairments after acute stroke.
- Future studies should consider broader criteria for cognitive impairments and larger randomized samples to improve generalizability.
- Future studies should also examine mechanisms, as well as moderators, of intervention response.

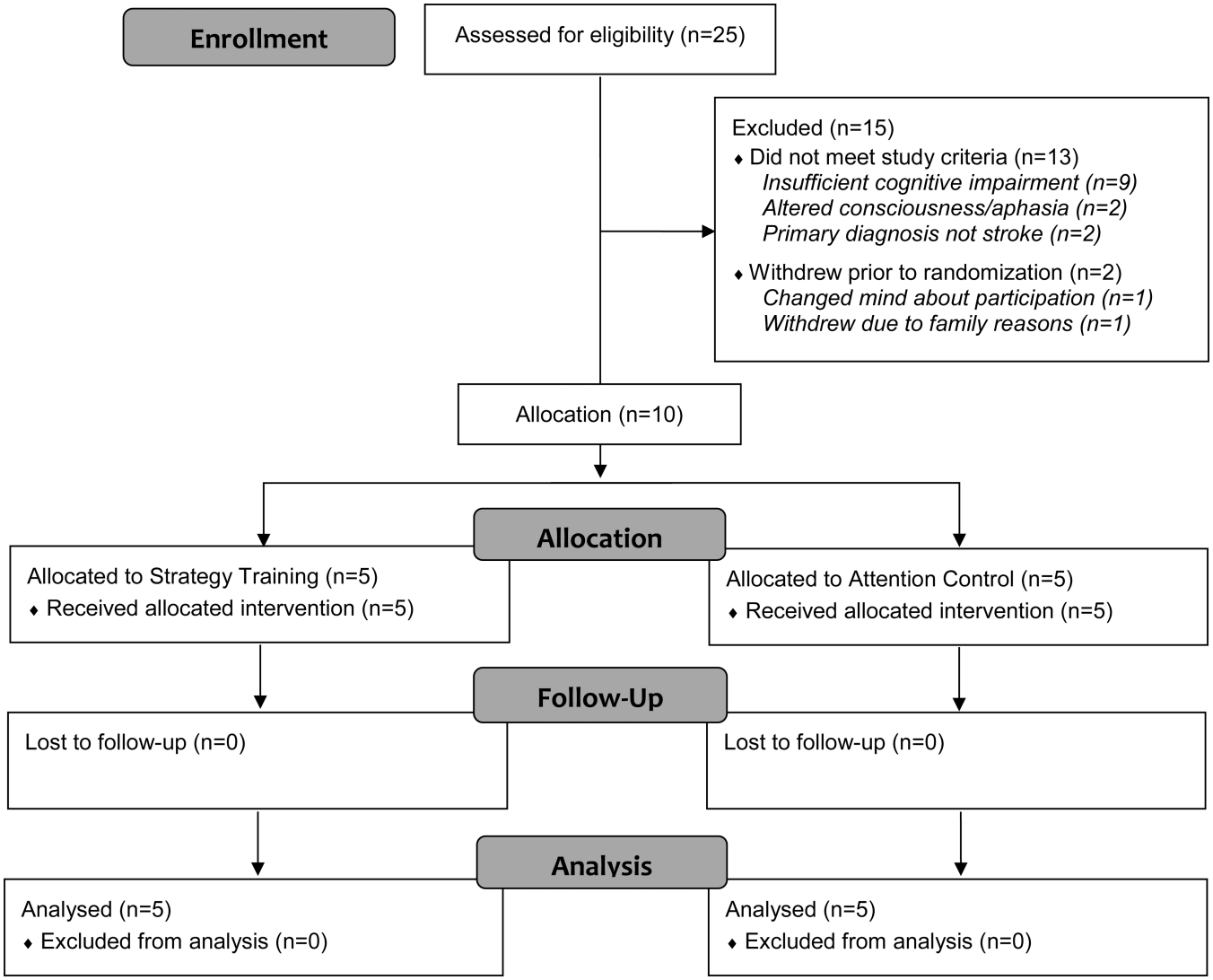

Figure 1.
CONSORT Flow Diagram

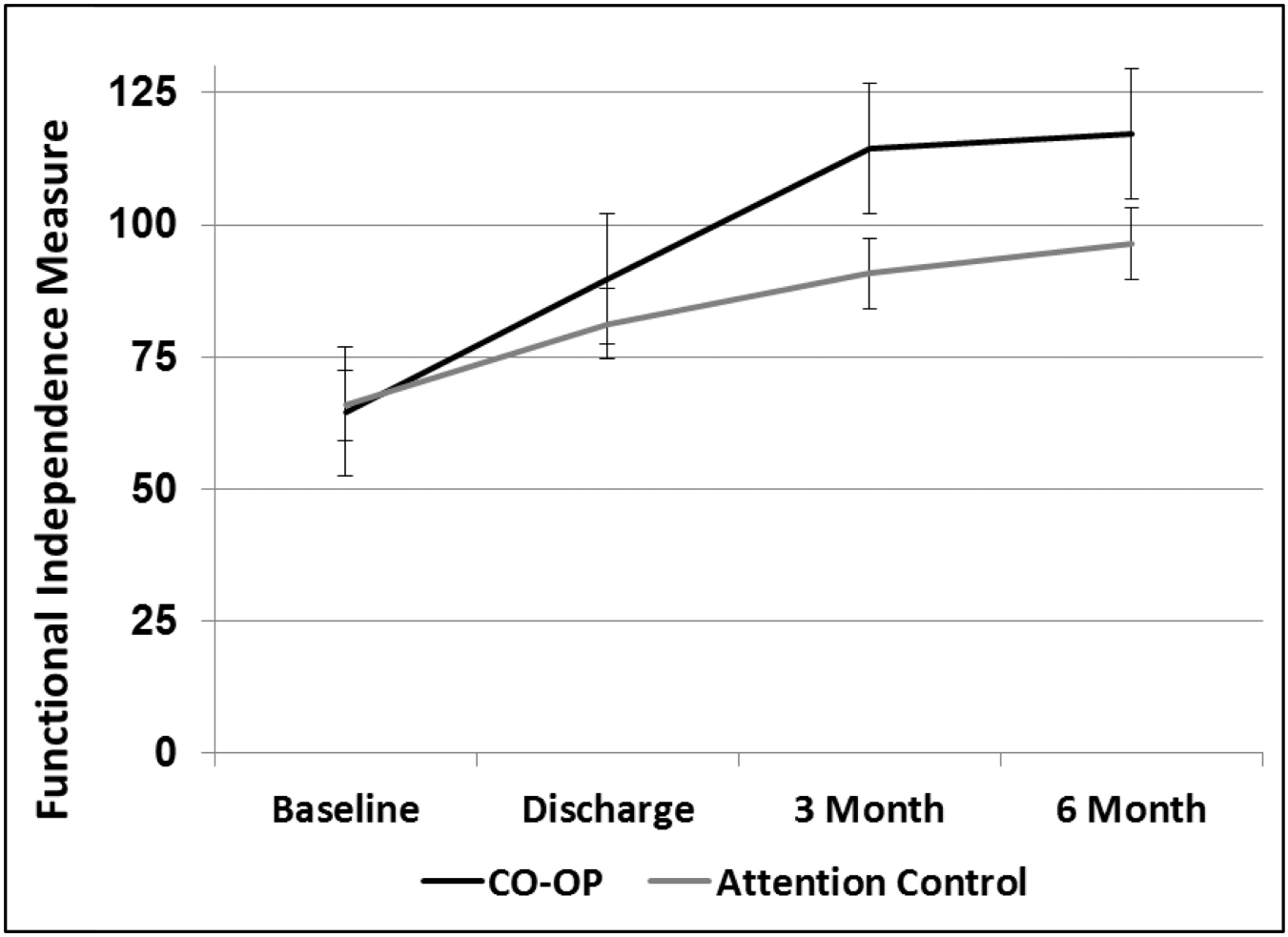

Figure 2.
Functional Independence Measure Scores

Table 1

Participant Characteristics

	Strategy Training (n=5)	Attention Control (n=5)	
Sex, Male, *n*(%)	4 (80)	3 (60)	χ^2_1=0.48
Age, Years, *M(SE)*	64 (17)	72 (13)	t_8=4.47†
Race, White, *n*(%)	4 (80)	5 (100)	χ^2_1=1.11
Stroke onset, Days, *M(SE)*	15 (8)	14 (4)	t_8=−0.12
Stroke type, Ischemic, *n*(%)	4 (80)	5 (100)	χ^2_1=0.11
Hemisphere, Right, *n*(%)	4 (80)	2 (40)	χ^2_1=1.67
Stroke severity NIHSS, *M(SE)**	9 (1)	6 (1)	t_8=−1.52
Cognitive status EXIT, *M(SE)**	12 (1)	15 (2)	t_8=1.39
Length of stay, Days, *M(SE)*	24 (5)	20 (5)	t_8=−0.91
Baseline disability, FIM, *M(SE)*	65 (4)	65 (10)	t_8=0.11

NIHSS=National Institutes of Health Stroke Scale. EXIT=Executive Interview (14-item version). FIM=Functional Independence Measure.

*Higher scores=worse performance.

†$p<.05$

Table 2

Functional Independence Measure Scores

	Strategy Training (n=5)	**Attention Control (n=5)**
Baseline	65 (4)	65 (10)
Discharge	90 (3)	81 (12)
Month 3	114 (4)	91 (15)
Month 6	117 (3)	96 (14)
Baseline to Discharge, *M(SE)*	25 (4)	15 (4)
Baseline to Month 3, *M(SE)*	50 (4)	25 (7)
Baseline to Month 3, *M(SE)*	53 (5)	31 (6)