Brain Stimulation Paired with Novel Locomotor Training with Robotic Gait Orthosis in Chronic Stroke: a Feasibility Study

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Abstract

Objectives—*1)* to investigate the feasibility of combining transcranial direct current stimulation (tDCS) to the lower extremity (LE) motor cortex with novel locomotor training to facilitate gait in subjects with chronic stroke and low ambulatory status, and 2) to obtain insight from study subjects and their caregivers to inform future trial design.

Methods—Double-blind, randomized controlled study with additional qualitative exploratory descriptive design. One-month follow-up.10 subjects with stroke were recruited and randomized to active tDCS or sham tDCS for 12 sessions. Both groups participated in identical locomotor training with a robotic gait orthosis (RGO) following each tDCS session. RGO training protocol was designed to harness cortical neuroplasticity. Data analysis included assessment of functional and participation outcome measures and qualitative thematic analysis.

Results—Eight subjects completed the study. Both groups demonstrated trends toward improvement, but the active tDCS group showed greater improvement than the sham group. Qualitative analyses indicate beneficial effects of this combined intervention.

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Conclusions—It is feasible to combine tDCS targeting the LE motor cortex with our novel locomotor training. It appears that tDCS has the potential to enhance the effectiveness of gait training in chronic stroke. Insights from participants provide additional guidance in designing future trials.

Keywords

Neuronal Plasticity; Electric Stimulation; Robotics; Lower Extremity

1. Introduction

A common theme in the motor recovery literature is that specific and intensive motor training induces central nervous system reorganization to a degree formerly thought possible only during the early post-natal period. This neuroplastic change plays a crucial role in learning and memory processes, as well as recovery of function, after neurological injuries (Dancause et al., 2005; Johansson, 2000; Kopp et al., 1999; Nudo, Plautz, & Frost, 2001). The fact that it is possible to modulate neuroplastic change has influenced modern concepts of physical therapy and research in rehabilitation.

Extensive research shows that transcranial direct current stimulation (tDCS) is a promising intervention to up-modulate neuroplasticity and improve upper extremity motor performance in neurological populations (Fregni et al., 2005; Fregni & Pascual-Leone, 2007; Fujiwara et al.; Hummel & Cohen, 2005; Nitsche et al., 2007; Pascual-Leone, Tarazona, & Catala, 1999; Schlaug, Renga, & Nair, 2008). Studies in humans over the last decade indicate that low intensity tDCS (1–2 mA) has the capacity to alter the excitability of cortical neurons (Been, Ngo, Miller, & Fitzgerald, 2007; Boggio, Zaghi, & Fregni, 2009; Boros, Poreisz, Munchau, Paulus, & Nitsche, 2008; Fregni & Pascual-Leone, 2007; Gandiga, Hummel, & Cohen, 2006; Lang et al., 2007; Nitsche et al., 2003; Paulus, 2003; Vines, Cerruti, & Schlaug, 2008). The precise mechanism of tDCS is unknown but is believed to involve either manipulation of ion channels or influence on the balance of ions inside and outside the neural membrane, which changes the threshold for neural firing (Nitsche, et al., 2003; Schlaug & Renga, 2008). Neuromodulation occurs in a polarity-dependent manner (Fregni & Pascual-Leone, 2007; Schlaug & Renga, 2008): anodal stimulation increases cortical excitability, whereas cathodal stimulation diminishes it.

While research has shown that tDCS has the potential to improve upper extremity motor recovery following stroke when paired with intensive motor training, only a few studies have examined the effects of tDCS on lower extremity motor function. One study investigating the effects of anodal tDCS in subjects with mild motor impairment after stroke demonstrated improvements in paretic ankle control (Madhavan, Weber, & Stinear, 2011). Another study of the effects of anodal tDCS on toe pinch force in healthy subjects showed transient improvement in torque (Tanaka, Hanakawa, Honda, & Watanabe, 2009). On the other hand, one study evaluating the effects of active tDCS paired with locomotor training after stroke did not yield superior results when compared to sham tDCS and identical training (Geroin et al., 2011).

Evidence to clarify and optimize the role of tDCS in locomotor restoration after stroke is needed. To this end, we designed a novel protocol for locomotor training with a robotic gait orthosis (LT-RGO) to follow the application of tDCS. Our novel approach to LT-RGO aligns most closely and comprehensively with basic principles of neuroplasticity (ie, intensive and repetitive practice; task-specificity; gradual increase in demand; motivation; attention to task; active engagement; feedback). The primary objective of this study was to investigate the feasibility of combining tDCS to the lower extremity motor cortex with novel LT-RGO to facilitate gait in subjects with chronic stroke and low ambulatory status. The central hypothesis was that application of active anodal tDCS to the cortical motor area that controls the lower extremity, paired with our novel LT-RGO protocol, would enhance gait more than a control condition (ie, sham tDCS paired with identical training). A secondary objective was to obtain insight from study subjects and their caregivers to inform future trial design.

2. Methods

The study design included both a double-blind, sham-controlled, randomized quantitative design and an exploratory descriptive qualitative design. The ethics boards of the local university and rehabilitation hospital in which the study was conducted approved the protocol. All subjects provided informed consent prior to participation. We enrolled 10 subjects as a convenience sample. Eligible subjects had impaired gait following a single stroke sustained at least 12 months prior to enrollment. Radiographic studies and medical histories were obtained to confirm diagnosis, site, and type of lesion. Exclusion criteria (eg, history of seizure; ferromagnetic material in the cranium; cardiac, neural, or medication implants; severe spasticity and/or decubitus ulcer(s) interfering with the LT-RGO harness; cognitive deficit severe enough to preclude informed consent) were largely structured to ensure subjects' safety in all aspects of participation.

Subjects were paired based on similar baseline ambulatory characteristics at eligibility screening and then randomly allocated to either the active anodal tDCS group or the control group (sham tDCS). Immediately following the tDCS, each subject participated in LT-RGO under the guidance of a physical therapist certified in use of the Lokomat (Lokomat, Hocoma Inc, Zurich, Switzerland). The intervention was repeated 3 times per week for 4 weeks. Subjects, the 2 physical therapists who administered LT-RGO, and the outcomes assessors were blinded to the tDCS condition.

2.1. Transcranial direct current stimulation

For active tDCS, stimulation current was set to 2 mA and applied for 20 minutes. The intensity and duration were selected based on previous studies demonstrating these parameters to be safe (Boggio et al., 2007; Jo et al., 2009; Kim et al., 2010) and effective to induce persistent increases in cortical excitability as measured by transcranial magnetic stimulation motor evoked potentials in the tibialis anterior muscle (Jeffery, Norton, Roy, & Gorassini, 2007). The control group received sham tDCS for 20 minutes with current set to ramp up and then down over the first 75 seconds of the session (Gandiga et al., 2006). This sham protocol produces the same sensation as active tDCS without having a measurable

effect on cortical excitability; it is a widely used technique to preserve subject blinding in investigations using tDCS (Gandiga, et al., 2006). For both groups, a 25 cm^2 anode was positioned over the cortical motor area controlling the leg; and a 35 cm^2 cathode was positioned supraorbitally. We used a larger cathode than anode in order to minimize potential unintended effects on cortical areas underlying the cathode. See Figure 1 for a depiction of the tDCS set-up.

2.2. LT-RGO

The Lokomat is an RGO that has been used with neurologically compromised individuals, including those with stroke (Figure 2) (Hesse, Schmidt, Werner, & Bardeleben, 2003; Mayr et al., 2007; Westlake & Patten, 2009; Winchester et al., 2005). The Lokomat exoskeleton facilitates a bilaterally symmetrical gait pattern as the subject attempts to walk on a treadmill (Hesse, et al., 2003; Hidler et al., 2009; Neckel, Wisman, & Hidler, 2006). This robotic mechanism can elicit a comparable-to-normal walking pattern with respect to gait cycle timing. Locomotor training with the use of the Lokomat has shown promise in small studies as a form of intensive, task-oriented, repetitive training for gait restoration in neurological populations (Hesse, et al., 2003; Husemann, Muller, Krewer, Heller, & Koenig, 2007; Mayr, et al., 2007; Westlake & Patten, 2009). However, recent, randomized controlled studies in stroke have shown that this intervention *in its conventional form* has no greater benefit than either intensive home health or standard physical therapy (Carda et al., 2012; Hidler, et al., 2009; Swinnen, Duerinck, Baeyens, Meeusen, & Kerckhofs, 2010; Vaney et al., 2012). Therefore, we developed a novel protocol that imposes progressive decrease of speed in conjunction with progressive decrease of guidance force to increase physical and mental demand as recovery progresses (Table 1). Additionally, this novel protocol requires attempted initiation of movement by the subject. The theoretical basis for our novel LT-RGO protocol is presented in the discussion section.

2.3 Outcome measures and analyses

Outcome measures were performed in a blinded fashion at baseline, at completion of the intervention, and at 1-month follow-up. The primary outcome measure was the 10 Meter Walk Test (10MWT) as walking speed is the best single variable to differentiate between household and community ambulatory function post-stroke (Mulroy et al., 2003; Perry, Garrett, Gronley, & Mulroy, 1995). It has excellent test-retest and intra-rater reliability for the chronic stroke population (Sullivan et al., 2011) and is considered more responsive than other functional scales to assess mobility changes post-stroke (Richards, Malouin, Dumas, & Tardif, 1995). Secondary outcome measures included the Timed Up and Go Test (TUG), the Berg Balance Scale (BBS), the Functional Ambulation Category (FAC), and the Stroke Impact Scale 16 (SIS-16). The TUG tests mobility, balance, and locomotor performance and has excellent test-retest reliability in stroke (Sullivan et al., 2011). The BBS assesses static balance and has excellent test-retest, inter-rater, and intra-rater reliability in chronic stroke (Sullivan et al., 2011). The FAC categorizes each subject using a 6-point scale from "0" (nonfunctional ambulatory) to "5" (ambulatory-independent), depending on how much assistance the subject requires from someone else when walking, regardless of assistive device (Sullivan et al., 2011; Teasell, Foley, & Salter, 2011). The FAC correlates significantly with temporal-distance measures (Sullivan et al., 2011). The SIS-16 is a self- or

proxy-report with 16 items capturing daily activities (Sullivan et al., 2011). It encompasses 4 domains of the Stroke Impact Scale 2.0 (strength, hand function, mobility, and activities of daily living) with the subject rating each item (Likert scale from 1 ("could not do at all") to 5 ("not difficult at all")) (Sullivan et al., 2011).

Motor performance and participation evaluations took place at baseline, upon completion of the intervention period, and at 1-month follow-up. We compared baseline measures for the 2 groups to assess group differences prior to the intervention. Analysis of variance (ANOVA) model was fitted to each dependent variable to evaluate group (changes, i.e., post intervention compared to baseline; 1-month compared to baseline) main effects (active versus sham). Significance was accepted at $\alpha < 0.05$. Statistics were calculated using StatView software.

2.4 Qualitative data collection and analyses

Semi-structured interviews were conducted with subjects and/or their caregivers regarding tDCS, LT-RGO, overall impressions of the study, and recommendations (see Appendix 1 for sample interview questions). Interviews took place in private settings at the study site at completion of the intervention period or at 1-month follow-up evaluation. The same researcher completed each interview. Interviews were recorded and transcribed verbatim. The interviewer checked transcriptions for accuracy and completed inductive thematic analysis (Braun & Clarke, 2006). The data were coded, and patterns of meaning were identified. For the qualitative results presented in this article, pseudonyms are used to conceal the identities of the participants.

3. Results

A total of 8 subjects (4 men) with chronic stroke, mean age of 67.8 years (range, 44–80 years), and average of 4 years since stroke onset (range, 1.1–11.6 years) completed the study (Table 2). Two subjects withdrew (1 after 2 sessions due to non-paretic arthritic knee pain unrelated to the study intervention; 1 prior to first attempt with LT-RGO due to contractures that developed between the initial screening and study onset). Six subjects lived with family, and 2 lived alone. All subjects completed every session of intervention with no adverse events. All subjects completed all evaluations except for 1 subject who did not complete 1-month follow-up due to Botox injections shortly after the completion evaluation. After the intervention period, all subjects and primary caregivers were questioned to determine interest in interviewing (qualitative portion of the study); and all consented except 2 study subjects who were unable to participate due to severe expressive aphasia. A total of 6 study participants and 4 caregivers completed interviews.

3.1 Quantitative results

Baseline data shows no significant differences between the 2 groups (active and sham, Table 3). Data analysis demonstrates trends towards improvement for both groups, with the active tDCS group showing marked improvements compared with the sham tDCS group in all measures except BBS (p=0.919); see Figure 3 for group comparisons. The FAC results showed statistical significance in favor of the active tDCS group (p=0.028). The TUG and

SIS-16 results favored the active tDCS group and approached significance (TUG p=0.066; SIS-16 p=0.062). The 10MWT results also favored the active tDCS group but were non-significant (p=0.19).

3.2 Qualitative findings

We identified 5 overarching themes that are labeled in the following subheadings and subsequently described.

3.2.1. Hope for recovery—Participants expressed a variety of reasons for joining the study, all of which indicated a hope for recovery. As one participant stated, "Cause, God, if I could just walk again... You don't know... how much it would mean to me" (Xavier). Participants also described a high level of motivation and belief in the concept of doing whatever it might take to support their recovery; they recognized the role of volunteering for research studies as one mechanism to support recovery.

3.2.2. Desire for innovation—This theme emerged from discussion about perceptions regarding the brain stimulation and the LT-RGO. Participants perceived these interventions as innovative means of facilitating a return of function. One participant described this by saying, "I'm always interested in things that are outside the box. To me, that's innovative thinking... I think it's better to find the root of the problem and try to fix it instead of takin' a pill to just decrease the symptoms" (Joanna).

3.2.3. Team support—Working with a hopeful, encouraging research team was important to participants. A sense of support and optimism from the team was valued and motivating. Trust in the researchers was also important to the subjects with stroke and their caregivers: "My mom does not work with you if she doesn't trust you" (Belinda, caregiver).

3.2.4. Improved participation—Participants expressed a sense of improved ability to participate in daily life within the home, community, or both, compared with how they felt before the study. Categories within this theme included better locomotor performance, improved balance and related confidence, and enhanced communication and cognition. Subjects in both groups contributed to all categories within this theme except that only subjects receiving the active tDCS contributed to "enhanced communication and cognition."

For locomotor performance, participants described improvements in over-ground gait speed and pattern. As examples, 1 caregiver reported his wife's foot drag ceased. Another caregiver reported her husband traversed from the car to the house in 7 fewer steps and was more willing to wear shoes during household ambulation. Two participants reported they were able to walk without their cane at home for the first time since stroke: "I can walk further, faster, and I've even got so I can walk by myself... now that I took the Lokomat... I even walked 2 blocks the other day" (Xavier). One participant in the active tDCS group reported enhanced ability to participate in household activities of daily living (eg, cleaning, putting away dishes). This same participant also described the ability to descend a flight of stairs in his home for the first time since the stroke: "[Stairs are] easier... a long flight of stairs to get to the basement. And I made the steps the other day... this is the first time

coming down the stairs. I would go, before, up the stairs, no problem. But down the stairs was a problem until two weeks ago," (Jackson).

In describing improved balance ability and confidence, participants described feeling more steady with activities and having less fear of falling, which increased willingness to attempt activities. For example, 1 subject was previously fearful of falling and did not trust his wife to walk with him; but by the end of the study, his wife reported that this fear had profoundly diminished. Two participants noted improvements in steadiness with car transfers. Another participant reported increased confidence to negotiate challenging surfaces, specifically walking over snow and ice.

For enhanced communication and cognition, participants noted improvements in willingness to attempt communication, improved reading comprehension, word-finding ability, improved articulation, and/or improved voice quality (eg, loudness). Jackson commented on this, stating: "I recognized early on that speech came on stronger… I was talking louder."

3.2.5 Enhanced engagement with the locomotor training—Five subjects had previously participated in conventional LT-RGO with the Lokomat in standard outpatient physical therapy. This prior experience enabled them to compare conventional LT-RGO with the novel LT-RGO used in this study. While one subject was able to share feedback due to expressive aphasia, the other four subjects reported that compared with conventional LT-RGO, the novel LT-RGO required more concentration, focus, and facilitated more engagement with the activity. For example, carrying on a conversation during novel LT-RGO was difficult without the deterioration of their gait pattern, whereas subjects could converse easily while performing conventional LT-RGO. One subject described how the novel LT-RGO enhanced her engagement and ability to participate as an active learner:

> The goal of walking on the Lokomat 2 years ago was to be able to walk as quickly as possible and… move as much as I could, and this time, it was a matter of refinement, and really focused on perfecting the move rather than the sheer quantity of movement… I was able to concentrate. It was actually difficult… because as she [the therapist] slows the machine down more and more, and she uses the body support less and less, more of the self control has to come from me… so the walking and the refinement of my gait has to come more from me, from my concentration, from my mental and physical ability. –Joanna

4. Discussion

Our study was the first to evaluate the effects of non-invasive brain stimulation combined with motor training to promote gait recovery in chronic stroke subjects with low ambulatory status. Marked improvements were noted in locomotor function for both groups, however greater improvement was observed in the active tDCS group on all measures except BBS. While only FAC showed significant difference between the active and sham groups, it is conceivable that a larger sample size would have yielded significance on additional measures. These results show that active tDCS paired with our novel LT-RGO yields substantial improvement in gait in subjects with chronic stroke.

The BBS showed similar, remarkable improvements immediately after the training in both groups. The improvement, however, was not evident at the 1-month follow-up. This may suggest that tDCS has no enduring effect on balance as measured by the BBS. Investigating alternate balance outcome measures (eg, Activities-Specific Balance Confidence Scale; the Postural Assessment Scale for Stroke Patients) may be worthwhile in future trials.

We combined non-invasive brain stimulation with a novel form of LT-RGO that aligns more closely and comprehensively with basic principles of cortical plasticity than conventional LT-RGO. There was no scientific justification to pair cortical stimulation (tDCS) with locomotor training that did not specifically target cortical plasticity (i.e., conventional LT-RGO, which may target spinal excitability). Conventional LT-RGO uses progressively faster treadmill speeds over the course of intervention. This approach supports locomotion driven by or leading to activation of spinal mechanisms and other, non-cortical influences on gait function (eg, spinal reflexes, central pattern generators, lower extremity electromyographic activity, and cardiovascular conditioning) (Chen & Patten, 2006; Knikou, 2010; Koenig et al., 2009; Krewer et al., 2007). Although these non-cortical mechanisms do have influence on functional return, the importance of cortical mechanisms may supersede non-cortical influences on initial motor learning and enduring performance change after stroke. The conceptual basis for our novel approach to LT-RGO is to target cortical plasticity via use of progressively decreasing speed in conjunction with progressively decreasing guidance force. This novel approach increases physical and mental demand as time progresses. The increase in cortical demand results from a direct proportional decrease in momentum (a passive physical assist) as velocity is decreased (momentum = mass * velocity).

A recent study in subjects with stroke showed that tDCS paired with another form of locomotor training, Gait Trainer GT1 (Reha-Stim, Berlin, Germany) did not lead to more improved functional outcomes than control conditions (Geroin, et al., 2011). Investigators in this study applied 1.5 mA during locomotor training for 7 minutes. In our study we delivered 2.0 mA for 20 minutes before the training. It is possible that the intensity, duration and timing of their tDCS protocol were not optimal for gait rehabilitation in stroke.

Qualitative findings indicate participants in both groups experienced improved participation in the home and/or community (eg, ability to clean the kitchen, complete car transfers, ascend/descend stairs, walk, and maintain energy levels). This finding is consistent with the observed improvement in SIS-16 scores. Only participants who received active tDCS described enhanced communication and cognition. Finally, based on anecdotal observations and the qualitative data, the novel LT-RGO protocol in this study increased demands for attention and concentration. Subjects who had previously used the conventional LT-RGO during the outpatient physical therapy reported that our novel LT-RGO was physically and mentally more challenging.

The qualitative themes that emerged may aid the design of future studies. More specifically, the qualitative findings support the potential use of additional or alternate outcome measures pertaining to speech, communication, cognition, kinematic gait and balance assessments, clinical balance (eg, Activities-specific Balance Confidence (ABC) Scale; Falls Efficacy Scale) (Sullivan et al., 2011), stair navigation (eg, Functional Gait Assessment (Wrisley,

Marchetti, Kuharsky, & Whitney, 2004), and home/community participation (eg, Stroke Impact Scale 3.0 (Sullivan et al., 2011), Patient Specific Functional Scale (Horn, et al., 2012). Additional recommendations for future studies include investigation of the locomotor training approach in this study compared to conventional protocols and investigation of the optimal timing of tDCS application (eg, prior to versus simultaneous application with locomotor training).

The main limitation of this study is the small sample size. Also, while we attempted to initiate locomotor training as soon as possible following tDCS stimulation, we need to more closely monitor the time between stimulation and training. Given that increased corticospinal excitability exists for 60 minutes post-anodal stimulation (Jeffery, et al., 2007), we recommend initiating gait training as quickly as possible post-tDCS and recording the time between each. While we encouraged subjects to use the hand support rails as little as possible, we did not strictly control for upper extremity positioning. This may have been important as tibialis anterior and quadriceps muscles activation during swing phase increases with unsupported arm movements (Stephenson, De Serres, & Lamontagne, 2010). Transferability of the qualitative data to future subjects' experiences may also be construed as a limitation.

5. Conclusion

This study supports the feasibility of using tDCS in conjunction with our novel LT-RGO to optimize gait recovery in subjects with chronic stroke and low ambulatory status. The participants' insight gleaned from qualitative data provides guidance in designing future trials. Given the promising results even with a small sample size, a full-scale investigation based on this feasibility study is warranted with expanded outcome measures (eg, measures of neuroplasticity such as transcranial magnetic stimulation) and longer-term follow-ups.

Acknowledgments

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Appendix 1

Examples of interview guide questions[*]

Tell me your thoughts and impressions of participating in this study. (probes: experience with the brain stimulation, experience with the walking intervention, experiences with the research team)

Why did you want to participate in this study?

What changes have you noticed in yourself or your abilities, if any, either during or after the study ended?

How does a difficulty with moving or walking impact life at home and in the community?

What would it mean for you to be able to move better?

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[*] Questions were adjusted as needed to address either the person with stroke or his/her caregiver. Interviews conducted either immediately post-intervention or at one-month follow-up based on subject availability.

Fig. 1.
This is a mock depiction of the tDCS delivery. The salmon-colored electrode is the anode, or excitatory electrode; it was placed over the cortical motor area controlling the lower extremity. The blue electrode is the cathode, or inhibitory electrode; it was placed supraorbitally.

Fig. 2.
LT-RGO (Lokomat, Hocoma Inc, Switzerland). The harness system provides body weight support. The robotic exoskeleton facilitates a bilaterally symmetrical gait pattern as the user attempts to walk on the treadmill.
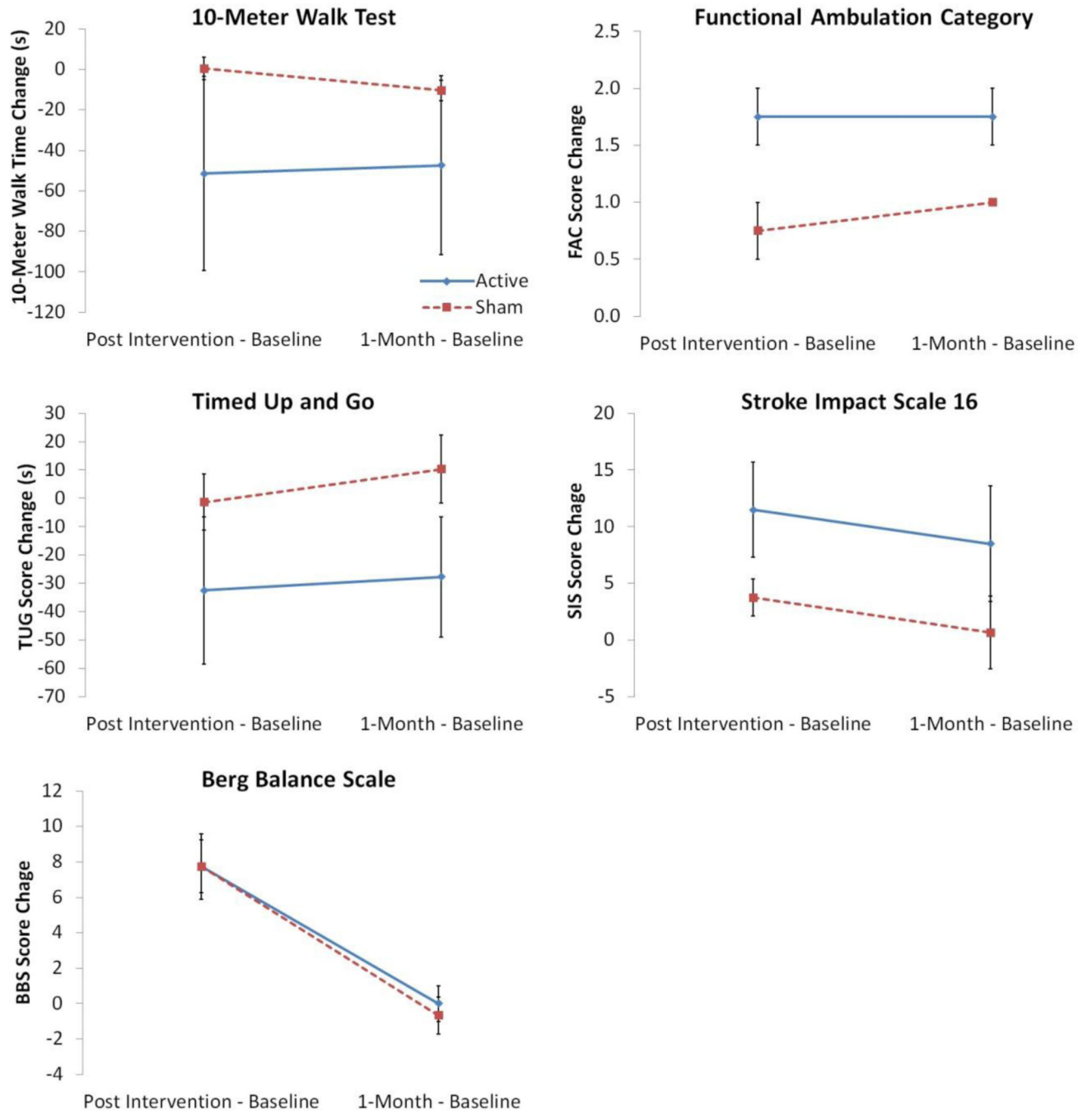
Fig. 3.
Results comparing group data (active versus sham tDCS) for the 10 Meter Walk Test, Timed Up and Go, Functional Ambulation Category, and Berg Balance Score including change from baseline to post-intervention (4 weeks) and change from baseline to 1-month follow-up.

Table 1

Novel protocol for LT-RGO with the Lokomat

Weeks	Body Weight Support	Time	Speed	Guidance Force[*]
1 (sessions 1–3)	40–50%	Targeted goal: 20–40 minutes per session	Initially at most comfortable speed, followed by progressive, rapid decrease to a speed slow enough to allow subject to initiate movement, thereby increasing engagement with the task and appropriate attentional demands.	Maximal decrease in percentage (so robotic exoskeleton provides least assistance possible) while maintaining a gait pattern within normal limits
2 (sessions 4–6)	40%			
3 (sessions 7–9)	30%			
4 (sessions 10–12)	20%			

[*] Guidance force is defined as the torque produced by the hip and knee actuators of the Lokomat. The ability to adjust this torque allows the robotic assist legs to provide varied amounts of assistance, measured in percentages from 0–100% (from no assist to stiff servo system (high amount of holding torque to maintain positions accurately), respectively).

Table 2

Participant Demographics

Subject	Age	Group	Sex	Affected Hemisphere	Stroke Type	Years Post-Stroke	Baseline Walking Ability
1	76	Active	M	Left	Ischemic	3	Primarily wheelchair user; required assistive device, ankle-foot orthosis, and moderate physical assistance to walk
2	64	Active	M	Left	Hemorrhagic	3	Required walker, no physical assistance
3	77	Sham	F	Left	Ischemic	1.9	Primarily wheelchair user; required assistive device and moderate to maximal physical assistance to walk
4	55	Sham	F	Left	Ischemic	2.7	Required walker and supervision assistance
5	44	Active	M	Left	Hemorrhagic	1.5	Required cane and supervision assistance
6	75	Active	F	Left	Ischemic	11.6	Primarily wheelchair user; required a walker and supervision assistance to walk
7	71	Sham	F	Left	Ischemic	1.1	Primarily wheelchair user; required a quadricane and supervision assistance to walk
8	80	Sham	M	Left	Ischemic	7.2	Required a quadricane and supervision assistance

Abbreviations: F, Female; M, Male

Table 3

Group Baseline Data and Differences

Outcome Measure	Active Group (mean±SE)	Sham Group (mean±SE)	P value
10 Meter Walk Test (seconds)	117.43 ± 83.89	65.55 ± 21.00	0.57
Timed Up and Go (seconds)	99.16 ± 60.27	59.81 ±19.99	0.56
Stroke Impact Scale 16	54.25 ± 4.59	53.50 ± 4.98	0.92
Functional Ambulation Category	2.25 ± 0.48	2.75 ± 0.75	0.59
Berg Balance Scale	32.50 ± 4.63	32.25 ± 6.89	0.98

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