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Transcranial direct current stimulation with motor-learning based gait therapy post-stroke: A randomized controlled trial

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ABSTRACT

Background: Persistent gait deficits after stroke are prevalent and negatively impact function. Motor learning methods promote neuroplasticity and can produce significant clinical gains, however recovery is limited for many individuals in the chronic phase. Transcranial direct current stimulation(tDCS) can enhance neuroplastic effects of training and can be easily paired with neurorehabilitation.
Objective: We tested active vs. sham bihemispheric 2 mA tDCS targeting primary motor leg regions paired with gait therapy.
Methods: Individuals(n = 44) were randomized to 10 sessions of active tDCS/sham tDCS paired with motor training. Outcomes were collected at baseline, mid-treatment, post-treatment and 6-week follow-up. TDCS-induced electric field(e-field) and lesion load were calculated using each participant's magnetic resonance imaging (MRI). Statistical methods included longitudinal linear mixed-effects model with treatment group by time interaction effects, Wilcoxon signed rank test and correlation analyses.
Results: Thirty-nine individuals completed the study. No difference was observed between treatment groups. Total cohort analysis showed significant improvement ($p < 0.05$) in the following: Fugl-Meyer, fastest gait speed, preferred gait speed, Timed Up and Go, Functional Gait Assessment, and Gait Assessment and Intervention Tool across time, with maintenance or improvement at 6-week follow-up. E-field in targeted region ranged 0.10-0.29 V/m. Lesion load did not correlate with change in clinical outcomes.
Conclusions: Both groups improved across the clinical outcomes following short duration motor learning-based gait training with and without tDCS. Lesion load was not related to treatment response. E-field in targeted regions was variable across participants. Future studies employing optimized tDCS to ensure consistent dosing across subjects, paired with an effective gait training approach is needed.

1. Introduction

The effects of stroke are often severely debilitating with 46% of stroke survivors unable to walk at stroke onset [1]. Even after standard neurorehabilitation, 30% are unable to walk independently in their community [2]. Identification of adjuvant treatments that can be paired with and enhance established gait training methods may lead to greater gait recovery.

Motor learning-based gait training approaches [3–6] can produce statistically significant and clinically meaningful improvements in

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post-stroke gait performance, and notably are recommended as the therapeutic approach of choice by clinical practice guidelines [7]. However, even after treatment with motor learning-based approach, gait deficits often persist and a high number of sessions is required for improvement to occur [4,6,8]. Post-stroke gait deficits are due to disruption of structural and functional central nervous system (CNS) organization. Though gait training with motor learning-based approach has a neuroplastic effect on CNS [7], there is an opportunity to further amplify these effects through addition of neuromodulation.

Non-invasive brain stimulation methods that modulate CNS and can produce neuroplastic changes hold great promise for improving gait recovery and may serve as important adjuvants to a motor learning-based treatment approach. Transcranial direct current stimulation (tDCS) can modulate cortical activity [9], promote plasticity [10] and has been shown to improve upper limb motor function after stroke [11,12]. A few studies of chronic stroke reported tDCS had a neuromodulatory effect on cortical excitability, when paired with various gait training methods [13–15]. While these neuroplastic effects are promising, the effects of tDCS on recovery of gait are not yet clear, with some studies reporting favorable clinical effect on gait performance [15–18] and others reporting minimal to no tDCS effect [13,19–23]. This variability may be due to choice of therapeutic approach. TDCS has not yet been paired with an effective motor learning-based treatment approach in post-stroke gait training using a randomized controlled trial design (RCT).

Therefore, to test benefit of tDCS in improving gait performance, we conducted a RCT of active versus sham tDCS integrated within a short-duration (10 visits), motor learning-based stance phase training protocol [24].

2. Methods

2.1. Study design

We conducted a single-site, double-blind RCT, testing 2 mA bihemispheric tDCS of primary motor cortex (M1) versus sham within a motor-learning based gait training protocol targeting stance phase control [24]. This study was conducted using CONSORT 2025 guidelines.

2.2. Participants and study oversight

Participants were enrolled between 2018 and 2024 and gave written informed consent prior to participation. Inclusion criteria included: single unilateral stroke ≥6 months prior; endurance sufficient to complete 6-min walk test; lower limb Fugl-Meyer (FM) ≥15; medically stable; observable stance phase gait deficit; and ability to give informed consent. Exclusion criteria included: other neurological conditions; and contraindications to transcranial magnetic stimulation (TMS) or tDCS. Oversight was provided by the local Institutional Review Board (IRB). Adverse events were reviewed in weekly team meetings with serious events reported to the IRB.

2.3. Randomization

Individuals were stratified by gait speed (<0.4 m/s or ≥0.4 m/s) and randomized to group allocation from a random sequential list generated using a randomized block design with block sizes of 2 and 4 with random permutations. Only the study engineer who generated the list had access to it and assigned group allocation. A code for the stimulator specifically designed for clinical trials (Soterix 1x1 tES Clinical Trials) corresponding to either active or sham stimulation was assigned to each participant.

2.4. Intervention

Overview. Ten treatment sessions were delivered 2x/week, with each session comprised of 30 min of Virtual Reality (VR)-based treadmill training and 30 min of overground gait training [24]. This paradigm was selected as it approximates treatment frequency and session duration in clinical practice. Either active (2 mA) or sham tDCS was delivered concurrently during the first 15 min of VR-based treadmill training (Fig. 1). A home exercise program was individually assigned. After treatment, individuals were encouraged to live a healthy lifestyle, with no study specific activities assigned. They returned for 6-week follow-up testing.

Transcranial Direct Current Stimulation. TDCS was delivered using a 1X1 bihemispheric montage with anode over ipsilesional primary leg motor area (M1) and cathode over homologous contralesional M1. Electrode placement was determined by identifying the hotspot for paretic and non-paretic tibialis anterior (TA) using a Magstim 200 [2] transcranial magnetic stimulator (Magstim Company Ltd, Wales, UK). TMS target location was guided by frameless stereotactic neuronavigation (Brainsight2, Rogue Research, Inc., Montreal, QC). Using a custom batwing coil, optimal stimulation site for each TA in the respective contralateral M1 was identified as the 'hotspot' which is the location evoking the strongest motor evoked potential using the lowest stimulator output intensity [25]. Once identified, hotspot for paretic and non-paretic TA were used as targets for tDCS. The centers of 5 cm × 5 cm saline saturated sponge electrodes were positioned directly lateral to the TA hotspot at the level of C1 and C2 (International 10-20 system). In instances where paretic TA hotspot was unable to be identified, electrodes were placed symmetrically. To ensure consistent placement, the neuronavigation system was used to mark electrode placement at each treatment session, and electrodes were secured with an elastic head strap. Either sham or active tDCS (2 mA) was delivered during the first 15 min of VR treadmill training. To maintain blinding, stimulation ramped on/off for 30 s for sham. Participants, therapists, the principal investigator, and outcomes assessor were blinded.

VR Treadmill Stance Phase Training. Individuals walked at a self-selected pace on a treadmill synced with the visual flow of a virtual environment outdoor walking path displayed as a life-size movie on a large screen (D-Flow, Motek Medical, Amsterdam, Netherlands). As individuals walked, virtual objects appeared in the pathway of the uninvolved limb, and the individual was tasked with stepping over the obstacle by shifting weight onto the involved limb. To ensure practice of coordinated movement as well as adequate challenge, motor learning principles [7] guided therapists' decisions regarding application of training variables inherent in these technologies. Training variables included treadmill speed, virtual obstacle spacing (to encourage longer steps), and virtual object height and thickness (to increase paretic stance

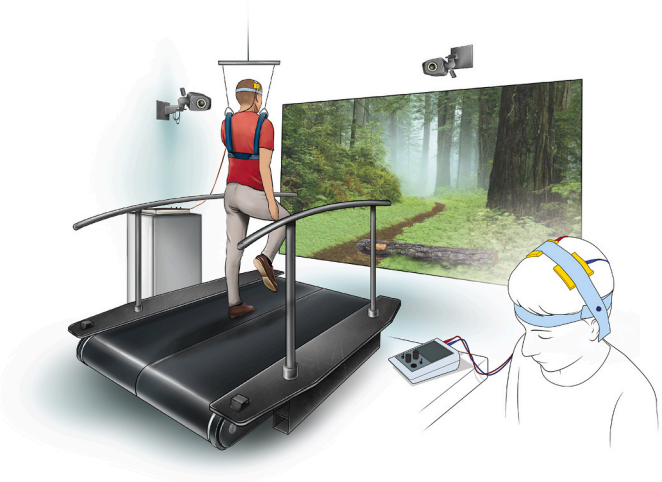

Fig. 1. Example of gait training with stepping over virtual objects while wearing tDCS system and an illustration of placement of tDCS electrodes.

control demand). A total of 34 virtual obstacles were provided in each training 'run'. Subjects completed as many 'runs' as able in each 30-min training period. Rest breaks were provided as requested, and training intensity was monitored with continuous heart rate monitoring and the rating of perceived exertion scale (targeting moderate or less exertion).

In-clinic Overground Stance Phase Training and Home Exercise Practice [5]. A motor learning-based approach was also used to administer stance phase coordination exercises [5]. Exercises included: lower limb, individual joint movement control; progression of lower limb multi-joint movement task difficulty; degree of weight-bearing (e.g., double limb, single limb weight bearing); weight shift task difficulty (e.g., side shift, forward shift); single step stance phase limb control; and, multiple-step, stance phase limb control [5]. A customized home exercise program reinforced in-clinic training.

Outcome measures. Data collection timepoints included pre-, mid- (after 5 training sessions), post-treatment (after 10 training sessions), and 6-week follow-up. The primary outcome was fastest gait speed using the *10-m walk test (fGS; m/s),* [26] assessed while walking as quickly as possible with the participant's customary device, averaged across three trials. We acquired several secondary outcomes. *Preferred gait speed (pGS; m/s)* was measured using the *2-min walk test* [27]. *Fugl-Meyer for Lower Limb (FM)* assessed lower limb motor control (0-34 points; higher score indicates less impairment) [28]. *Gait Assessment and Intervention Tool (GAIT; 0-62 points)* measured gait coordination [29], with lower scores indicating better performance. *Timed up and Go (TUG; seconds)* assessed rising from a chair, walking 3 m, then returning to sit, averaged across three trials [30]. *Functional Gait Assessment (FGA)* assessed postural stability and coordination during 10 functional walking task items (0-30 points; higher score indicative of better performance) [31]. Sensory function was assessed with a *proprioception test* which was collected with a custom-built device designed similar to a proprioception device for upper limb [32]. The foot is placed on a plate and passively moved by the assessor into predefined degrees of either plantarflexion or dorsiflexion from a neutral starting position. With their vision occluded, participants estimate degree of foot dorsi- or plantarflexion deflection. Scores are expressed as percent errors. Patient satisfaction with the VR environment was assessed using the *VR Presence Questionnaire* (Likert scale (1-7); score range, 22-154; Low (22) very dissatisfied, high (154) very satisfied) [33]. For each individual and each training session, we recorded treadmill training speed, number of obstacles presented, and the distance between obstacles.

2.5. E-field modeling

For the active tDCS group, e-field was computed from a volume conduction model based on their structural MRI using established computational services (Soterix Medical, NJ) [34]. Mean e-field values were extracted for atlas-based [35,36] bilateral sensorimotor regions transformed from MNI space to subject space for each subject. Regions included premotor, postcentral gyrus (S1), posterior parietal cortex, and the leg region of M1 defined as the medial portion of the precentral gyrus.

2.6. Weighted corticospinal tract lesion load (wCST-LL)

For participants who underwent MRI, lesion volume and wCST-LL were computed from T1 images. Lesions were manually identified and outlined by a neurologist and translated into a common template space (Montreal Neurological Institute (MNI) template) where lesion volume and wCST-LL were computed for each participant. wCST-LL was computed as the overlap between the lesion and the cortical spinal tract (CST) from XTRACT [37]. The overlap between the CST and lesion at each axial slice was weighted by the ratio of the size of the CST at that slice relative to the largest CST slice [38]. This weighting accounts for the narrowing of the CST as it descends from the cortex to the brainstem.

2.7. Sample size and power analysis

The original sample size calculation was based on a previous study [39], and assuming 5% attrition, n = 40 would provide sufficient power for a two-sided Type I error of alpha = 0.05 to detect a significant treatment by time interaction effect in a longitudinal mixed model. We also conducted a post hoc power simulation to determine if the study was adequately powered for the studied population. The simulation used estimates from the study data with inflated values for the treatment by time interaction effects, and 38 subjects. In the inflated effects, the largest difference in fGS between treatment groups was set to 0.12 m/s (an MDC for this measure) at the post timepoint [40]. If there had been a difference in the trajectory of fGS between the treatment groups, there would have been 95% power to detect a treatment by time interaction at an alpha level of 0.05.

2.8. Statistical analysis

Group trajectories of change were compared through a longitudinal linear mixed-effects model and the analysis of treatment group by time interaction effects. The model included fixed effects for treatment group, time (as categorical variables of pre, mid, post and follow-up), and a treatment by time interaction. A random slope was added for subject. All available datapoints were included in the analysis, including those available for participants who did not complete the intervention or follow-up. To account for baseline differences between treatment groups, longitudinal mixed models were run with the addition of age, gender and wCST-LL as covariates. Active and sham tDCS groups were combined for analyses to determine whether the gait therapy itself produced improvement; for this, we used the Wilcoxon signed rank test. Holm-Bonferroni method was applied to adjust the p-value for multiple tests. Additionally, descriptive statistics (mean and standard deviation (SD)) for the clinical outcomes were calculated for each study group (active and sham) as well as the total cohort. Descriptive statistics (mean and SD) were generated for the practice parameters of treadmill speed, number of obstacles presented, and the distance between obstacles. Mean change from pre-to post-treatment for each practice parameter was calculated. Spearman correlation was used for wCST-LL and clinical measures. E-field across target ROIs was calculated as the mean.

3. Results

Table 1 provides subject characteristics. Forty-four individuals enrolled. Thirty-nine individuals completed the study (N = 20 sham tDCS, N = 19 active tDCS) (Fig. 2).

Table 1
Participant characteristics.

	Sham (n = 23)	Active (n = 21)	Total (n = 44)
Age, Mean ± SD	67.7 ± 8.3	62.5 ± 10.7	65.2 ± 10.0
Gender = Female, n (%)	4 (17.4%)	8 (38.1%)	12 (27.3%)
Years post stroke, mean ± SD	4.5 ± 4.9	4.5 ± 3.4	4.5 ± 4.2
Stroke Lesion Hemisphere = Right, n (%)	12 (52.2%)	12 (57.1%)	24 (54.5%)
Stroke location subcortical only (all other strokes were both cortical & subcortical), n (%)	19 (82.6%)	14 (66.7%)	33 (75%)
Stroke Type = Ischemic, n (%)	18 (78.3%)	16 (76.2%)	34 (77.3%)
Hypertension, n (%)	19 (82.6%)	14 (66.7%)	33 (75.0%)
Diabetes, n (%)	7 (30.4%)	10 (47.6%)	17 (38.6%)
Underwent MRI, n	21	18	39
Lesion volume (cm3), mean ± SD for those with MRI	24.3 ± 37.7	48.6 ± 84.8	35.5 ± 64.2
Weighted CST lesion load (%), mean ± SD for those with MRI	17.6 ± 17.8	24.2 ± 24.2	20.7 ± 21.0

Key: SD – standard deviation, MRI – Magnetic Resonance Imaging, CST – corticospinal tract.

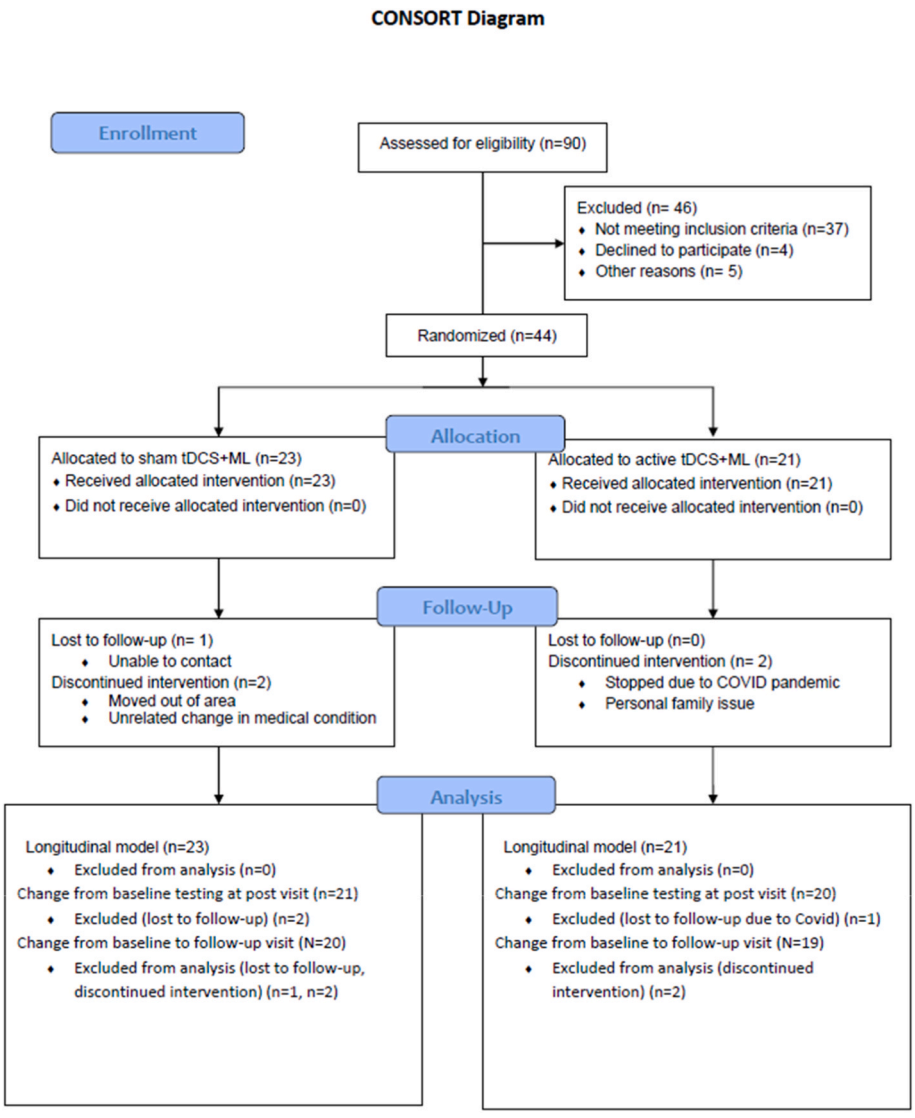

Fig. 2. CONSORT diagram.

3.1. Comparison of active tDCS versus sham tDCS groups

3.1.1. Primary measure

No significant treatment by time interaction effect was detected in the longitudinal mixed model for fastest gait speed (fGS). Since no significant interaction effect was detected, no post-hoc testing was done to compare differences between treatments across specific time points. Fig. 3 provides longitudinal mean (SD) values of outcomes and Table 2 includes mean (SD) for changes in outcomes from baseline. The trajectories of treatment response were similar for active tDCS and sham groups. Further mixed models to account for baseline differences of age, gender and wCST-LL did not detect either a significant treatment by time interaction effect or significant main effects for the additional covariates included.

3.1.2. Secondary measures

No significant treatment by time interaction effect was detected in the longitudinal mixed model for any of the secondary measures; FM, GAIT, pGS, TUG, FGA, and proprioception. Since no significant interaction effects were detected, no post-hoc testing was done to compare differences in secondary measures between treatments across specific time points (Fig. 3 and Table 2).

3.2. Total cohort response to treatment: primary and secondary measure analysis

Given no group difference, we combined active tDCS and sham tDCS groups to further study treatment response. There was statistically significant improvement for the primary and most secondary measures except for the proprioception test (Table 2). A statistically significant improvement at all time points was exhibited for the following: fGS, FM, FGA and GAIT (Table 2). TUG and pGS showed statistically significant improvement at post and follow-up (Table 2).

For functional gait and mobility measures, there were also clinically detectable improvements. For example, mean fGS improved 0.14 m/s. Minimal detectable change (MDC) for fGS has been reported as 0.12 m/s for moderate speed walkers [40]. Additionally, the mean TUG score improved by 6.28 s at post-treatment and maintained a mean improved score by 5.6 s at follow-up; these gains surpass the MDC value of 2.9 s for TUG [41]. Statistically significant improvement in pGS was observed and the gain (0.06 m/s) met the criterion for MDC value (0.05 m/s) [42].

3.2.1. Therapy progress parameters during VR training

Individuals were progressed across the 10 VR training sessions, according to treadmill speed, number of obstacles, and placement of obstacles. We computed the group descriptive statistics of mean change

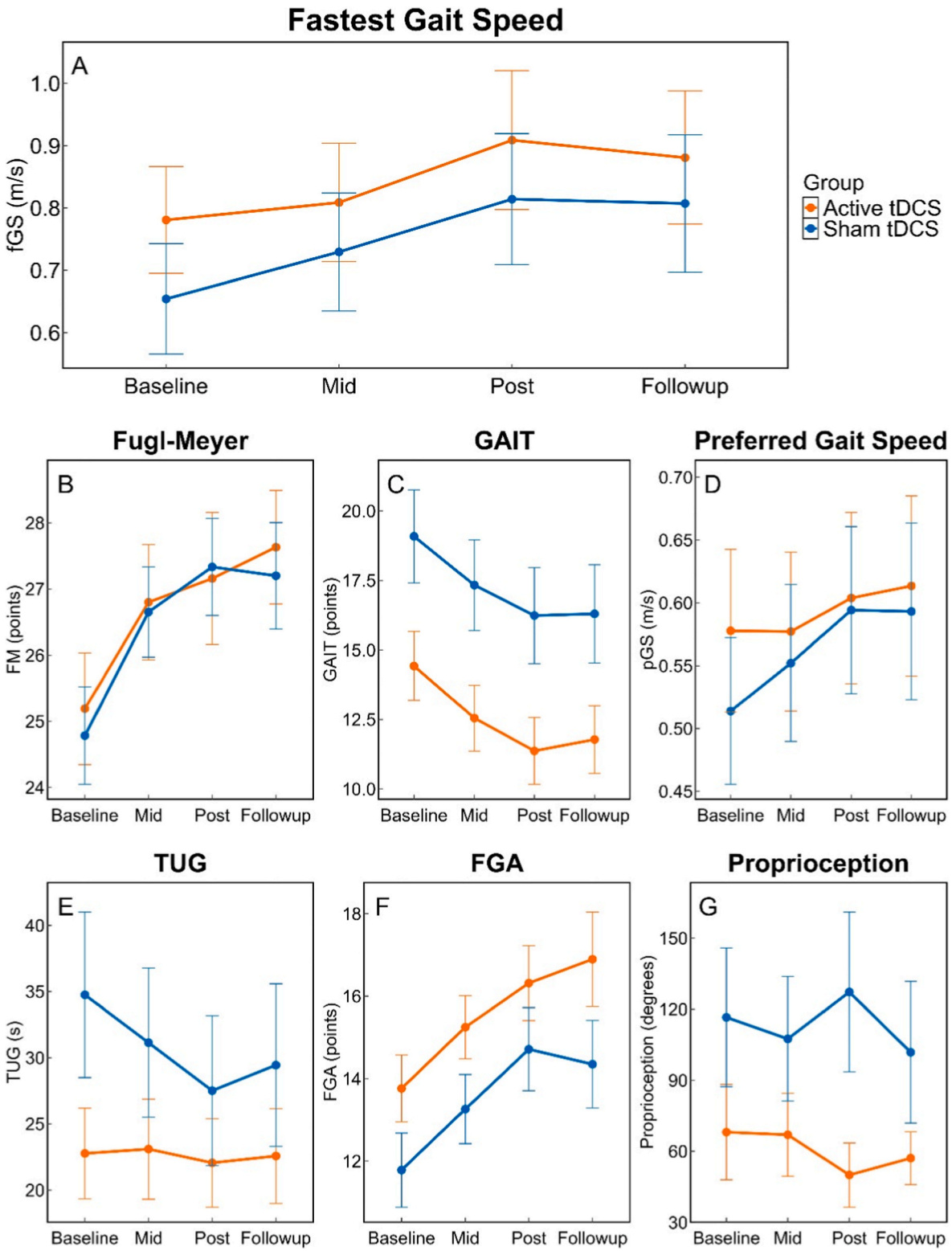

Fig. 3. Mean(SD) trajectories for primary (fastest gait speed, Panel A) and secondary (Fugl-Meyer (B), GAIT (C), preferred gait speed (D), TUG (E), FGA (F) and proprioception (G)) outcome measures for active and sham tDCS groups.
Abbreviations: SD – standard deviation, GAIT - gait assessment and intervention tool, TUG – timed up and go, FGA – functional gait assessment, tDCS – transcranial Direct Current Stimulation.

across the sessions (e.g., mean of the change between session 1 and 2; session 2 and 3, etc., averaged). The final value and the mean change per session are as follows (mean ± SD): final session speed 0.19 ± 0.062 m/s, speed was increased by 0.007 ± 0.002 m/s per session; final number of obstacles presented 145 ± 58, increased by 4 ± 8 obstacles per session; and, obstacle spread, 1.5 ± 0.04 VR system units, increased by 0.05 ± 0.02 VR system units. There were no differences in these statistics between groups.

Table 2
Descriptive statistics and Wilcoxon Signed rank test for primary and secondary clinical outcomes across the study data collection timepoints.

Measure	Group	Baseline	Change from Baseline					
			Mid	Mid p-value	Post	Post p-value	Follow-Up	Follow-Up p-value
Primary Measure								
fGS (m/s)	Total, Median (95% CI)		0.06 (0.02, 0.1)	0.014	0.12 (0.08, 0.16)	$p < 0.001$	0.11 (0.07, 0.16)	$p < 0.001$
	Total, Mean ± SD	0.71 ± 0.410	0.07 ± 0.121		0.14 ± 0.161		0.14 ± 0.159	
	Active, Mean ± SD	0.78 ± 0.393	0.06 ± 0.128		0.16 ± 0.183		0.13 ± 0.179	
	Sham, Mean ± SD	0.65 ± 0.425	0.08 ± 0.117		0.12 ± 0.141		0.14 ± 0.142	
Secondary Measures								
FM (points)	Total, Median (95% CI)		2.0 (1.0, 2.5)	$p < 0.001$	2.5 (2.0, 3.0)	$p < 0.001$	3.0 (2.5, 3.5)	$p < 0.001$
	Total, Mean ± SD	25.0 ± 3.67	1.7 ± 2.11		2.5 ± 2.16		2.7 ± 2.32	
	Active, Mean ± SD	25.2 ± 3.88	1.6 ± 1.96		2.3 ± 2.00		2.7 ± 1.76	
	Sham, Mean ± SD	24.8 ± 3.54	1.9 ± 2.26		2.6 ± 2.33		2.7 ± 2.80	
GAIT (points)	Total, Median (95% CI)		−2.0 (−2.5, −1.5)	$p < 0.001$	−2.5 (−3.5, −2.0)	$p < 0.001$	−3.0 (−4.0, −2.0)	$p < 0.001$
	Total, Mean ± SD	16.9 ± 7.32	−1.7 ± 2.03		−2.7 ± 2.51		−2.8 ± 2.52	
	Active, Mean ± SD	14.4 ± 5.67	−1.4 ± 1.66		−2.4 ± 2.22		−2.4 ± 2.03	
	Sham, Mean ± SD	19.1 ± 8.04	−2.1 ± 2.31		−2.9 ± 2.78		−3.2 ± 2.90	
pGS (m/s)	Total, Median (95% CI)		0.03 (0.01, 0.05)	ns	0.05 (0.03, 0.07)	0.008	0.05 (0.02, 0.09)	0.011
	Total, Mean ± SD	0.55 ± 0.284	0.03 ± 0.067		0.05 ± 0.082		0.06 ± 0.093	
	Active, Mean ± SD	0.58 ± 0.297	0.02 ± 0.067		0.05 ± 0.090		0.06 ± 0.098	
	Sham, Mean ± SD	0.51 ± 0.274	0.04 ± 0.068		0.05 ± 0.077		0.06 ± 0.089	
TUG (s)	Total, Median (95% CI)		−1.5 (−2.9, −0.3)	ns	−3.9 (−5.7, −2.5)	$p < 0.001$	−3.3 (−5.2, −2.0)	$p < 0.001$
	Total, Mean ± SD	33.2 ± 30.59	−2.0 ± 4.86		−6.3 ± 12.98		−5.6 ± 13.08	
	Active, Mean ± SD	27.5 ± 26.16	−0.4 ± 3.17		−6.9 ± 16.96		−6.4 ± 17.93	
	Sham, Mean ± SD	38.5 ± 33.85	−3.5 ± 5.65		−5.7 ± 8.31		−4.8 ± 6.03	
FGA (points)	Total, Median (95% CI)		2.0 (1.0, 2.5)	$p < 0.001$	3.0 (2.5, 3.5)	$p < 0.001$	3.0 (2.0, 3.5)	$p < 0.001$
	Total, Mean ± SD	12.7 ± 4.11	1.6 ± 2.32		2.6 ± 2.42		2.7 ± 2.66	
	Active, Mean ± SD	13.8 ± 3.71	1.8 ± 2.92		2.8 ± 3.05		3.4 ± 3.35	
	Sham, Mean ± SD	11.8 ± 4.31	1.5 ± 1.70		2.4 ± 1.72		2.2 ± 1.66	
Proprioception (degrees)	Total, Median (95% CI)		−2.5 (−20, 12.5)	ns	−2.5 (−20, 17.5)	ns	2.5 (−12.5, 15)	ns
	Total, Mean ± SD	92.9 ± 118.78	−6.9 ± 48.65		5.1 ± 63.63		−6.3 ± 65.01	
	Active, Mean ± SD	68.1 ± 92.30	−4.5 ± 44.10		−2.1 ± 52.66		5.0 ± 45.61	
	Sham, Mean ± SD	116.6 ± 137.47	−9.1 ± 53.40		12 ± 73.28		−17.6 ± 79.61	

The Wilcoxon signed rank test was used to test the median change from baseline.
P-values were adjusted for multiple comparisons using the Holm-Bonferroni method.

3.2.2. Participant self-reported change in response to the training protocol and satisfaction

Individuals self-reported a variety of changes in impairment, gait function and quality of life. Reported gains included: range of motion and strength; everyday functional gait tasks (e.g. walking on uneven terrain, walking on steps); and quality of life (e.g. standing on a moving boat while fishing).

Subject-reported satisfaction with training in the VR environment for subjects who completed all sessions ($n = 39$) was as follows (mean ± SD): 140.9 ± 14.8 points; equivalent to average Likert score of 6.4 ± 0.67 out of 7 points.

3.2.3. Safety/feasibility; blinding as to treatment group

No participants terminated any sessions (0/421 sessions), and no clinical indicators of exercise intolerance (RPE, HR, SpO2) prompted cessation of a session. No serious, related adverse events occurred. The study intervention was well tolerated (Table 3). Both therapists and participants were successfully blinded to group assignment (Supplemental Table 1).

Table 3
Tolerability and safety of tDCS.

Symptoms reported	Active tDCS	Sham tDCS
	% Experienced symptoms	% Experienced Symptoms
Tingling	73.7%	71.4%
Itching	36.8%	19.0%
Burning	5.3%	9.5%
Headache	5.3%	4.8%
Nervousness	0.0%	9.5%

3.3. E-field strength across active tDCS participants

The mean e-field in both ipsilesional and contralesional leg M1 (medial portion of precentral gyrus) ranged from 0.10 to 0.29 V/m (Fig. 4). There was no correlation between change in clinical measures and e-field in the bilateral leg M1 regions.

3.4. Correlation of wCST-LL and change in clinical measures

Exploratory Spearman correlations were calculated between wCST-LL and change in clinical measures. Correlations were weak for both active ($r \leq 0.39$) and sham groups ($r \leq 0.32$) indicating lesion load did not have a strong influence on response to therapy.

4. Discussion

This study contributes to the literature in a number of ways. First, we are providing the results of a well-controlled and conducted post-stroke rehabilitation study testing the effect of 2 mA tDCS. In this study no additive effect of tDCS was observed, with both cohorts demonstrating statistically and/or clinically detectable improvement in an array of measures at post-treatment that were maintained at follow-up. Second,

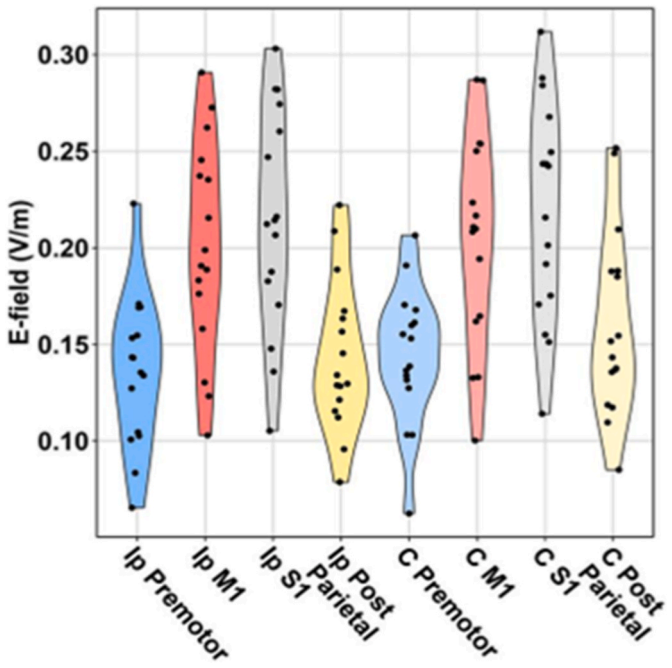

Fig. 4. Variability of mean e-field in the target regions. Ip-ipsilesional, C-contralesional, M1, S1(primary sensory).

we demonstrate high variability of e-field in the targeted cortical regions across participants which may be contributing to the lack of tDCS effect, suggesting the need to consider dosing of tDCS based on the estimates of tissue e-field rather than a current applied at the skin. Third, we contribute findings that evaluate the relationship between the underlying extent of CST damage and clinical gait performance in response to therapy.

4.1. No additive effect of active 2 mA tDCS to the treadmill-based virtual reality and overground gait therapy

For motor behavior measures, we found that there was no differential response of active 2 mA tDCS versus sham tDCS, with both groups demonstrating statistically significant gains in impairment and gait performance measures. Safety, tolerability, and participant satisfaction measures supported the safety and feasibility of the protocol.

The motor behavior results from our study are consistent with those of others that compared active vs. sham 1 – 2 mA tDCS in studies of robotics [19], task oriented training [22], treadmill training [23], and high intensity treadmill training [13]. Furthermore, gait speed was measured in several other studies, with no additive effect of tDCS reported for gait speed improvement [13,15–17,20–22].

There is unevenness in the field regarding the description of methods and results reported, with further information needed in some studies for clear interpretation of meaning. For example, one study reported a benefit of tDCS for improvement of dual task walking speed measured with the GAITRite walkway system [15]. However, it appears the active tDCS group showed greater baseline speed versus the control group, which could have affected the result. Another study reported promising findings with better response in the tDCS group on the Functional Ambulation Category, however the sample size was considerably small (n = 4 active; n = 4 sham) [17]. In one RCT of 2 mA tDCS, there was a differential improvement for the 6 Minute Walk Test, based on the percent of subjects improved, suggesting the statistics may have been based on percent of subjects rather than the actual values of the measure itself [16]. Also, in this study, baseline Fugl-Meyer for sham (17 points) was 6 points less than the active tDCS group (23 points), which would provide the active group with a large baseline advantage [16]. Therefore, there are limitations preventing strong conclusions from some "positive" studies.

At the same time, encouraging information in prior studies supports the continued investigation of tDCS as a neuromodulating intervention to combine with other gait training methods. For example, studies have reported a modest but favorable tDCS group differential in measures such as gait kinematics [20], the Berg Balance Scale [43], as well as the Fugl-Meyer and TUG [21]. Two intriguing studies of narrowly focused motor training showed a beneficial tDCS effect. First, a visuomotor 'stepping-over' training showed a benefit of anodal tDCS according to a measure of ground reaction force [18]. Second, ankle therapy and balance training showed a differential anodal tDCS effect according to the Motor Assessment Scale and the Berg Balance Scale [44]. While both of these studies report a tDCS effect, the trainings were narrowly targeting a specific movement pattern such as weight shift [18] or ankle movement [44] both of which are less complex motor tasks than the gait training methods we employed. Nonetheless, these results support application of tDCS in training of gait components and suggest the need to further understand how to pair tDCS in comprehensive gait therapy.

4.2. Unoptimized tDCS delivery is a potential source of neutral results

tDCS montage, duration, and intensity can all be varied, with no set-up considered the gold standard. In most gait studies, tDCS was applied using either bihemispheric M1 or anodal on ipsilesional M1 montages with no accounting for polarization achieved at the tissue level [13,15–23]. Similarly in our study, tDCS delivery may not have been optimal to modulate brain activity to achieve improvement on global gait function. Importantly, while our tDCS montage did achieve expected focality with M1 e-field higher than surrounding frontal and parietal regions, we found approximately three-fold difference in M1 e-field across active tDCS group participants. This inconsistency is caused by variabilities in brain anatomy especially due to stroke lesion [45,46]. It is possible that e-field achieved in the targeted region for some participants was too low to have an effect. Yet, it is known that neuroplasticity is dependent on the e-field strength [47]. When there is high variability of e-field strength and some individuals are not achieving sufficient tissue level dose, it is not surprising that no tDCS effect has been found. The lack of uniformity of e-field at the targeted regions needs to be considered in tDCS application. In future studies, it is important to ensure precise and consistent e-field "dose" among study participants for more uniform brain stimulation across individuals.

4.3. Uniform improvement in an array of gait measures in response to our short duration motor learning-based protocol suggests it can serve as a viable testbed for future studies with optimized and personalized tDCS paradigms

Using an effective therapy to pair with tDCS is an important element in neuromodulation research. Our short duration motor learning-based protocol produced statistically and/or clinically detectable gains in total cohort analysis. Our results are consistent with others who found statistically significant gains in gait speed [13,15–17,19,22,43] and mobility function measures [13,22,23] in response to other gait training methods with and without tDCS. However, not all of these prior studies utilized and/or reported gains across a broad array of measures. Our statistically significant gains extend across all study measures of impairment (joint movement coordination, gait coordination) and functional balance and mobility (gait speed, TUG, FGA). This uniform improvement across measures supports efficacy of our gait training protocol. As described in Methods, we incorporated technologies within the framework of motor learning principles, as well as training specificity for stance phase. Additionally, we customized the gait training ('precision medicine') to the specific impairments exhibited by a given participant. Thus, the gait therapy protocol provided in this otherwise neutral study can serve as a testbed for future tDCS paradigms as it

produces improvement in clinical performance in a treatment resistant chronic stroke population. Given the expectation that tDCS serves to amplify therapeutic effect of motor therapy, it is likely that our unoptimized, "one-size-fits-all" tDCS montage was not effective. Future studies focused on consistent and sufficient e-field dosing (that is, delivery of a consistent tissue level dose across all participants) through application of personalized approach may overcome this issue.

4.4. Relationship of motor behavior response to underlying extent of CST damage

CST lesion load has consistently shown accurate prediction of upper limb motor function recovery in stroke [48,49], particularly in individuals with severe arm impairment [48]. However, little is known about how CST damage relates to gait performance after stroke. In one prior study of acute/subacute stroke, CST lesion load independently predicted response to therapy for Functional Ambulation Category and Modified Rivermead Mobility Index but did not predict gait speed recovery [50]. In the same study through voxel-based lesion symptom mapping, gait speed was predicted by damage to putamen, insula, external capsule, and nearby white matter, not CST, suggesting alternative neurologic structures may be more critical to gait speed performance [50]. In our study, CST damage was not correlated with gait improvement after therapy, nor was CST lesion load a significant covariate when included in the longitudinal mixed model. It is not surprising that findings in gait performance differ from those of the upper limb, particularly given that gait requires bilateral coordination and movement of the entire body through space. Better understanding of neurophysiologic mechanisms driving gait recovery will help guide development of future brain stimulation paradigms.

4.5. Limitations

First, there was a gender and lesion volume imbalance. Second, individuals across a range of gait impairment levels were included which may have influenced response on clinical outcomes. Third, the study employed a short duration of therapy focused only on stance phase. Longer duration treatment with addition of swing phase training may be needed to maximize the gait training plus brain stimulation effect. Finally, high e-field variability may have influenced response to tDCS.

5. Conclusions

No added benefit was observed in favor of active tDCS. However, both groups had statistically significant improvements in gait performance in response to our short duration motor learning therapy to target stance phase control in ambulatory chronic stroke survivors. Treatment was well tolerated and individuals reported high satisfaction with the approach. E-field in targeted regions was highly variable among participants and probably too low in some. Optimization of tDCS delivery to achieve consistent e-field should considered in future post-stroke therapy studies.

Consent to participate

All participants provided written informed consent prior to enrollment in the study.

Ethical considerations

This study was approved by the VA Northeast Ohio Institutional Review Board (Approval no. 1583896). This research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki.

Consent for publication

Not applicable.

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CRediT authorship contribution statement

Svetlana Pundik: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Margaret Skelly:** Data curation, Formal analysis, Methodology, Resources, Software, Validation, Visualization, Writing – original draft, Writing – review & editing. **Ahlam Salameh:** Data curation, Investigation, Writing – review & editing. **Lisa Leonhardt:** Data curation, Project administration, Writing – review & editing. **Elizabeth C. Hardin:** Data curation, Investigation, Writing – review & editing. **Terri Hisel:** Data curation, Investigation, Writing – review & editing. **Kelsey R. Duncan:** Data curation, Formal analysis, Project administration, Writing – review & editing. **Elizabeth Zink:** Data curation, Formal analysis. **Sarah J. Carr:** Data curation, Writing – review & editing. **Luke Mosca:** Project administration, Writing – review & editing. **Bassam Yaghmoor:** Data curation, Writing – review & editing. **Marom Bikson:** Conceptualization, Data curation, Writing – review & editing. **Janis J. Daly:** Conceptualization, Supervision, Writing – review & editing. **Jessica McCabe:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Project administration, Supervision, Visualization, Writing – original draft, Writing – review & editing.

Declaration of competing interest

The City University of New York holds patents on brain stimulation with MB as inventor. MB has equity in Soterix Medical Inc.

Acknowledgments

Fig. 1 was created by the medical illustrator of the Cleveland FES Center.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.brs.2026.103132.

Data availability

Data supporting the study results will be made available upon reasonable request to the corresponding author.

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