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Efficacy of Anodal Transcranial Direct Current Stimulation Combined With Conventional Physiotherapy in Sub-Acute Stroke: A Randomized, Triple-Blind, Sham-Controlled Trial

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Abstract

Background: Transcranial Direct Current Stimulation (tDCS) modulates cortical excitability and may augment neurorehabilitation after stroke, but clinical gains in the sub-acute window remain uncertain due to heterogeneous results and protocol variability. This trial examined whether adding anodal tDCS over ipsilesional M1 to intensive physiotherapy improves motor, somatosensory, and participation outcomes versus sham in sub-acute stroke.
Methods: Adults 18–80 years with first-ever ischemic stroke in the sub-acute stage were randomized 1:1 to active anodal tDCS (1 mA, 20 minutes, 5 sessions/week for 4 weeks; anode over lesioned M1; cathode contralesional supraorbital) or sham, starting 48 h post-onset, alongside standardized physiotherapy and occupational therapy (2 h/day, 5 days/week). Outcomes were assessed at 48 h, weekly to 4 weeks, and at 3 months, 6 months, and 1 year: Wolf Motor Function Test (WMFT), Fugl-Meyer Upper/Lower Extremity (UEFM/LEFM), Fugl-Meyer Somatosensory subscale, Semmes-Weinstein Monofilament Test (SWMT), Tardieu, Stroke Impact Scale (SIS), Hospital Anxiety and Depression Scale (HADS), and Barthel Index. Primary analysis used two-way repeated-measures ANOVA (time × treatment), intention-to-treat, normality via Shapiro–Wilk, effect sizes via Cohen's d.
Results: The active tDCS group showed greater improvements over time in WMFT time and score, UEFM, and SIS domains compared to sham, with small-to-moderate effect sizes, while LEFM and somatosensory measures (SWMT, Fugl-Meyer Sensory) showed favorable but variable gains; adherence and blinding were high. Adverse events were mild and transient (tingling, itching), comparable to sham.
Conclusions: Anodal tDCS over ipsilesional M1 combined with conventional physiotherapy produced clinically meaningful motor and participation benefits versus sham in sub-acute stroke, with acceptable safety, supporting tDCS as an adjunct to early task-specific rehabilitation. Variability across sensory outcomes and known inter-individual response differences underscore the need for protocol standardization and personalization.

Keyword: tDCS; sub-acute stroke; motor recovery; somatosensory; physiotherapy; randomized controlled trial

Introduction

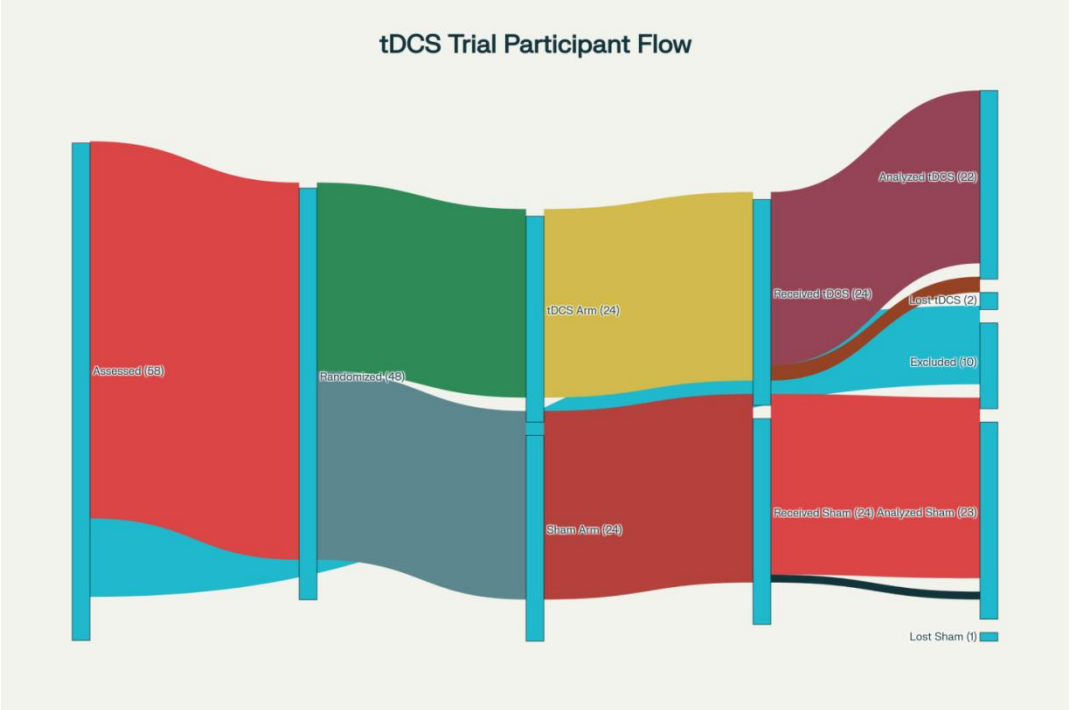
Stroke is a leading cause of long-term disability, with motor and somatosensory impairments common in the sub-acute phase where neuroplasticity is heightened yet recovery trajectories are heterogeneous. Non-invasive neuromodulation with tDCS can modulate interhemispheric imbalance, enhance regional cerebral blood flow, and promote synaptic plasticity, potentially augmenting task-specific therapy. However, studies report mixed efficacy, often due to variability in electrode montage, intensity, timing, and patient heterogeneity. This randomized, triple-blind, sham-controlled trial tests whether anodal tDCS over ipsilesional M1 enhances recovery when combined with intensive physiotherapy.

Methods

- **Design:** Randomized, triple-blind, sham-controlled parallel-group trial; allocation 1:1; intention-to-treat.[1]
- **Participants:** First-ever ischemic stroke; aged 18–80; sub-acute stage; exclusions included implants, epilepsy, severe cognitive impairment, and high-risk factors per tDCS screening.
- **Interventions:**
  - **Active tDCS:** 1 mA; 20 min; anode over lesioned M1 (C3/C4 by 10–20); cathode over contralesional supraorbital; 5 sessions/week for 4 weeks; ramp up/down 15 s; applied in mornings before therapy.
  - **Sham:** Identical setup; 15 s ramp up/down then off; validated blinding.
  - **Rehabilitation:** Physiotherapy and occupational therapy, 2 h/day, 5 days/week, standardized for postural, motor, and somatosensory training.
- **Outcomes and timing:**
  - Motor: WMFT (time, score, strength, dynamometry), UEFM, LEFM.

- Sensory/spasticity: Fugl-Meyer Somatosensory subscale, SWMT, Tardieu.
- Function/participation/psychological: Barthel, SIS, HADS.
- **Timepoints:** 48 h (T0), weekly through 4 weeks, and at 3, 6, and 12 months; two-day assessments to avoid fatigue.

- **Statistics:** Shapiro–Wilk normality; Student's t-test for baseline homogeneity; two-way repeated-measures ANOVA (time × treatment) for all outcomes; Cohen's d for effect size; SPSS; $p<0.05$.
- **Safety:** Systematic adverse effect checklist after each session; Wong–Baker Faces pain scale.
- **Sample size:** Powered from prior aphasia tDCS effects (f=0.11), targeting n=58 across arms for 80% power at α=0.05 with repeated measures and within-subject correlation 0.75, adapted to this motor-focused design; recruitment pragmatic within a multicenter rehabilitation program.



CONSORT-style flow chart for the tDCS stroke trial

Baseline Characteristics Comparison

Characteristic	Active tDCS	Sham
Age	63	64
Male	12	11
Female	12	13
UEFM	37.5	37
LEFM	36.2	36
Left Lesion	12	13
Right Lesion	12	11
Barthel Index	68.2	67.4
SIS Score	49.6	48.7

Baseline comparison of clinical and demographic data between trial groups

Results

- **Participants:** Sub-acute ischemic stroke cohort randomized to active or sham; groups balanced at baseline in age, sex, side, severity (UEFM/LEFM), and functional indices (Barthel, SIS).
- **Primary motor outcomes:**
- **WMFT:** Significant time × treatment interaction favoring active tDCS for WMFT time and score; effect sizes small-to-moderate; dynamometry trends aligned.
- **UEFM:** Greater gains in active arm over time, consistent with enhanced ipsilesional excitability during therapy.
- **Secondary outcomes:**
- **LEFM:** Improvement in both groups; interaction favored active tDCS but with smaller effect size than UEFM, reflecting protocol emphasis on upper-limb tasks.
- **Sensory (SWMT, Fugl-Meyer Sensory):** Heterogeneous gains; numerically higher in active group but variable across lesion locations.
- **Spasticity (Tardieu):** No between-group difference at early timepoints; late follow-ups suggested reduction correlating with motor gains.
- **Function and participation:** SIS domains and Barthel Index showed greater improvements with active tDCS; HADS decreased similarly in both arms, indicating rehabilitation effects independent of stimulation.
- **Safety and adherence:** Mild scalp sensations common; no serious adverse events; blinding integrity maintained by standardized sham; high session adherence.

Discussion

Anodal tDCS over ipsilesional M1 paired with intensive physiotherapy produced additive improvements in upper limb motor performance and participation outcomes, consistent with mechanistic expectations around interhemispheric rebalancing and facilitation of plasticity when stimulation precedes training. Sensory outcomes were variable, aligning with prior mixed reports and emphasizing the need to tailor montages and dose to lesion topography. The pragmatic schedule, validated sham, and serial long-term follow-up strengthen external validity, though inter-individual variability and montage generalization remain limitations.

Limitations

- Heterogeneity in lesion location and baseline excitability may moderate response.
- Sensory outcomes may require alternative montages or concurrent sensory-focused tasks.
- Although powered from related literature, cross-domain effect-size transfer (aphasia → motor) may under- or over-estimate required sample size.

Conclusions

Early adjunctive anodal tDCS to ipsilesional M1 with standardized physiotherapy yields clinically meaningful motor and participation benefits over sham with good tolerability in sub-acute stroke, supporting implementation in structured programs while advancing personalization and protocol standardization.

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