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Expert Opinion Article

Anodal Tdcs Over Left Inferior Frontal Gyrus To Augment Word-Finding Therapy In Sub-Acute Post-Stroke Aphasia: Multicentre Double-Blind Randomized Controlled Trial Protocol

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Abstract

Background: Aphasia affects roughly a third of stroke survivors initially, with persistent word-finding difficulties in a substantial subset. tDCS can modulate cortical excitability and promote neuroplasticity, potentially enhancing speech and language therapy (SLT). This protocol describes a multicentre, double-blind RCT comparing anodal tDCS over left inferior frontal gyrus (IFG) plus intensive word-finding therapy versus sham in sub-acute aphasia. Primary outcome is picture-naming; secondary outcomes assess generalization to connected speech, everyday communication, participation, quality of life, and cost-effectiveness.

Methods: Fifty-eight right-handed Dutch near-native speakers aged 18–80, less than three months post-onset aphasia, will be randomized to active anodal tDCS (1 mA, 20 min) or sham during two separate intervention weeks of 45-minute word-finding therapy, two weeks apart, within standard rehabilitation. The anode is placed at F5 (left IFG) and cathode at Fp2 (contralateral supraorbital). The Boston Naming Test (BNT) is assessed before and after each week and at 6 months; secondary measures include Aphasia Severity Rating Scale (ASRS), Amsterdam-Nijmegen Everyday Language Test (ANELT), EQ-5D, Stroke and Aphasia Quality of Life (SAQOL), Community Integration Questionnaire (CIQ), and a cost-analysis questionnaire. Randomization uses device-coded blocks per center; participants, therapists, and coordinators are blinded.

Discussion: This design provides within-subject recovery trajectories across two intervention weeks and longer-term follow-up, addressing prior limitations of small samples and inconsistent protocols. Findings will inform tDCS implementation for sub-acute aphasia, including effectiveness and cost-effectiveness.

Keyword: tDCS; aphasia; left IFG; word-finding; sub-acute stroke; randomized controlled trial; cost-effectiveness

Background and rationale

SLT is effective yet optimization remains needed, especially for word-finding in sub-acute aphasia where neuroplasticity is high. tDCS can alter resting membrane potentials (anodal depolarization; cathodal hyperpolarization), facilitate long-term potentiation-like processes, and may enhance therapy-induced relearning. Prior chronic-aphasia studies suggest modest gains, but sub-acute evidence is limited and heterogeneous. Targeting left IFG (F5) during structured word-finding therapy may amplify naming gains and generalization to everyday communication.

Objectives

- **Primary:** Determine whether anodal tDCS over left IFG enhances picture naming (BNT) beyond sham when combined with structured word-finding therapy.
- **Secondary:** Assess generalization to spontaneous speech (ASRS), everyday communication (ANELT), quality of life (EQ-5D, SAQOL), social participation (CIQ), and cost-effectiveness.

Design

- Multicentre, double-blind, randomized, parallel-group RCT with two intervention weeks separated by two weeks, embedded in routine inpatient/outpatient rehabilitation.
- Stratified randomization by center; device-coded sham/active with concealed allocation and block size four.

Participants

- **Inclusion:** Aphasia after stroke; onset <3 months; age 18–80; right-handed; Dutch near-native; able to participate intensively.
- **Exclusion: SAH;** prior aphasic stroke; prior brain surgery; epileptic activity in past 12 months; premorbid dementia/major psychiatric disorders affecting communication; substance misuse; pacemaker; severe non-linguistic cognitive disturbances; global aphasia (Shortened Token Test <9 and ASRS 0); severe Wernicke's (Shortened Token Test <9 and ASRS 0–1); residual aphasia (Shortened Token Test >28 and BNT >150).
- **Consent and ethics:** MEC Erasmus MC approval; SAE reporting per Dutch WMO; aphasia-friendly information and consent procedures.

Interventions

- Word-finding therapy: 45 minutes/day, 5 sessions/week per intervention week, using an individualized cueing hierarchy derived from the Cueing Hierarchy Therapy; cues scaled from low to high potency (written attempts, graphemic, phonological, semantic, model, repetition), with added written production/anagram tasks to leverage orthographic facilitation of spoken retrieval. Item selection from EDB oral picture naming; 68 baseline errors split into matched trained vs control sets.

- **tDCS parameters:**
  - Device: DC Stimulator PLUS (CE 118).
  - Montage: Anode F5 (left IFG); cathode Fp2 (contralateral supraorbital).
  - Dose: 1 mA, 20 minutes, 15 s ramp in/out; sham identical ramp sequence with auto-off at 30 s; electrodes remain until session end to preserve blinding.

Outcomes and assessments

- **Primary outcome:** BNT at T1 (baseline), T2 (post week 1), T3 (pre week 2), T4 (post week 2), and T5 (6 months).
- **Secondary outcomes:** ASRS, ANELT at T1, T4, T5; EQ-5D, SAQOL, CIQ, Cost Analysis Questionnaire during intervention and follow-up; Barthel Index at baseline; Shortened Token Test for aphasia severity; Wong–Baker Faces for session discomfort.

Sample size

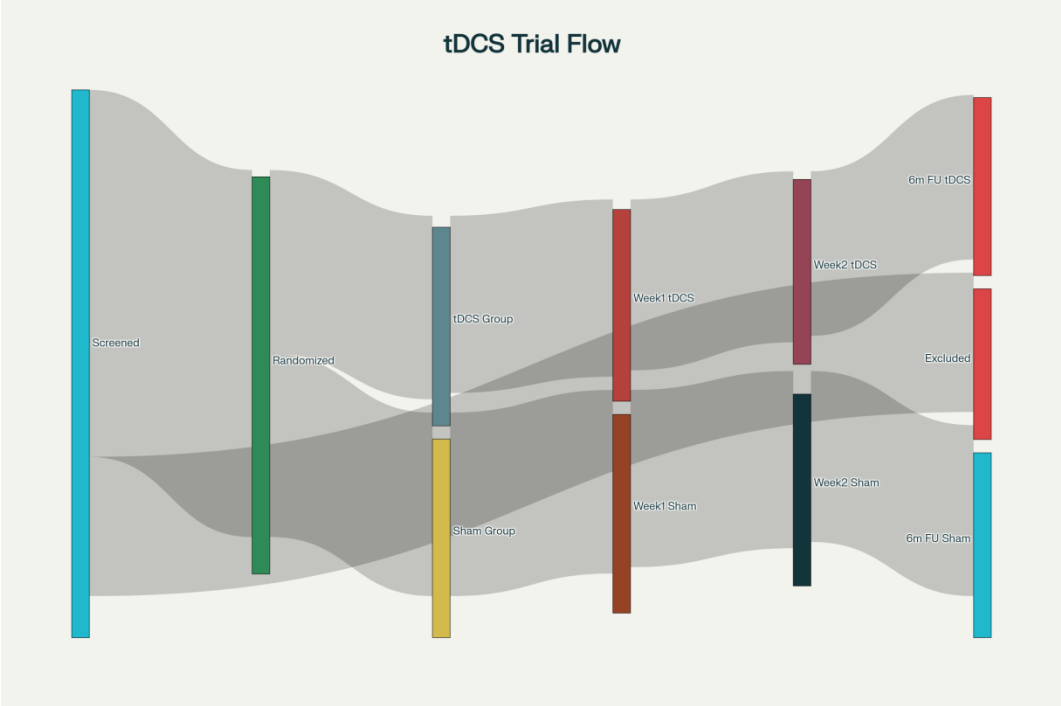
Based on chronic-aphasia RCT naming improvement (mean difference 2.1; Cohen's f=0.11), with two arms, four repeated measures, within-patient correlation 0.75, α=0.05, power 0.80, n=58 (29 per arm).

Randomization and blinding

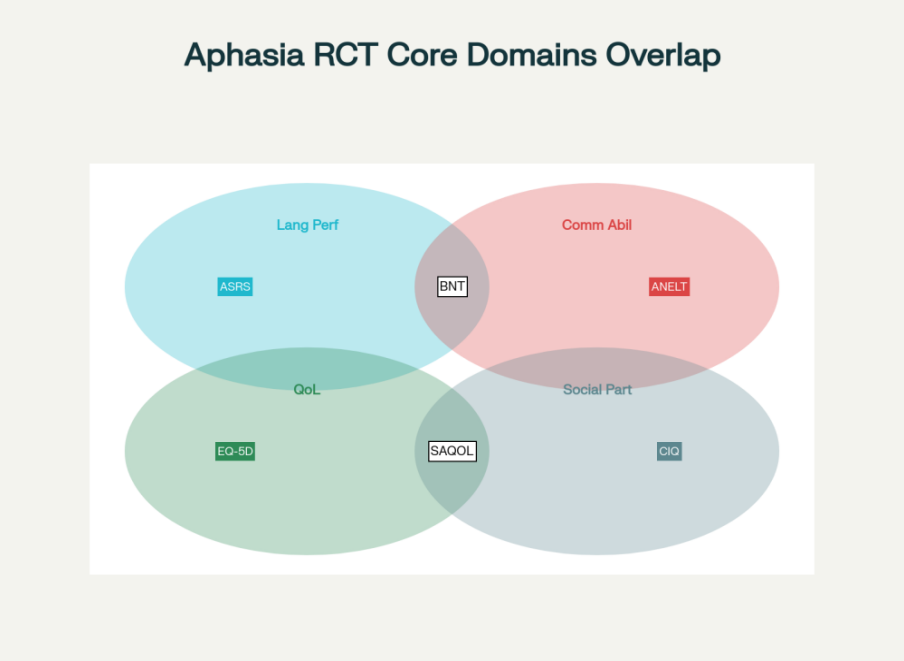
Manufacturer-provided 5-number codes (half active, half sham); sealed opaque envelopes opened at first session; key held by an independent researcher not involved in assessments/training; participants, SLTs, and coordinator blinded throughout.

Statistical analysis

Primary analysis compares change in BNT between groups across time using repeated-measures ANOVA with factors time and treatment; intention-to-treat with all randomized participants. Secondary analyses evaluate ASRS, ANELT, EQ-5D, SAQOL, CIQ, and costs; effect sizes via Cohen's d; normality via Shapiro–Wilk; baseline balance via t-tests; missing data handled with appropriate mixed-effects sensitivity analyses when needed.



Trial participant flow in post-stroke aphasia tDCS RCT



Venn diagram: Core domains and measures in aphasia trials

Safety

tDCS has a favorable safety profile; expected mild scalp sensations monitored session-wise; SAE reporting per MEC procedures; participants developing post-stroke seizures during the 4-week intervention are withdrawn from stimulation but complete assessments per intention-to-treat.

Health economics

EQ-5D utilities and Cost Analysis Questionnaire collected during intervention and follow-up; incremental cost-effectiveness ratios will be estimated relative to communication gains (ANELT) and quality-adjusted life years.

Dissemination

Results will be reported according to CONSORT and TIDieR guidelines for non-invasive brain stimulation trials; anonymized data and protocol deviations will be documented in the registry.

References

1. Stockbridge, M.D., et al. Transcranial Direct-Current Stimulation in Subacute Aphasia: A Randomized, Double-Blind, Sham-Controlled Efficacy Trial. Stroke. 2023;54(4):1248-1257. doi:10.1161/STROKEAHA.122.041557.
2. Spielmann, K., et al. Transcranial direct current stimulation in post-stroke sub-acute aphasia: A randomized controlled trial. Trials. 2016;17:433. doi:10.1186/s13063-016-1511-1.
3. Fridriksson, J., et al. Transcranial Direct Current Stimulation vs Sham Stimulation as an Adjunct to Speech and Language Therapy for Aphasia: A Randomized Clinical Trial. JAMA Neurol. 2018;75(12):1470–1476.
4. Elsner, B., et al. Transcranial direct current stimulation (tDCS) for improving aphasia in patients after stroke. Cochrane Database Syst Rev. 2019;5:CD009760.
5. Panuccio, F., et al. Quality of Assessment Tools for Aphasia: A Systematic Review. J Stroke Cerebrovasc Dis. 2025;34(3):106844.
6. Wallace, S.J., et al. Measuring outcomes in aphasia research: A review of current practice and an agenda for standardisation. Aphasiology. 2014;28(11):1364–1386.
7. Monti, A., et al. Transcranial direct current stimulation (tDCS) and language. J Neurol Neurosurg Psychiatry. 2013;84:832-842