Study Protocol

«Efficacy of Combined Use of Dynamic Stabilometry and Transcranial Electrical Stimulation in the Early Recovery Period of Ischemic Stroke in Patients with Hemiparesis: a Single-Center Randomized Study»

Version 1.0 · Last updated: April 15, 2026

Relevance of the Study

Stroke remains one of the leading causes of permanent disability worldwide. Motor impairments, primarily hemiparesis, are found in 60–80% of patients who have suffered an acute cerebrovascular accident (ACVA) and substantially limit their functional independence and quality of life. Restoration of voluntary movement, postural control and functional mobility is a key goal of neurorehabilitation.

Modern principles of neurorehabilitation are based on the mechanisms of neuroplasticity — the brain's capacity for structural and functional reorganization in response to goal-directed training. The early recovery period (7–30 days after ACVA onset) is characterized by maximal neuroplasticity and is the optimal «window» for intensive intervention.

Dynamic stabilometry with biofeedback (BFB) is a method of active postural control training in which the patient receives real-time information on the position of the center of pressure and balance parameters. Unlike static stabilometry, the dynamic mode of the platform creates a controlled sensory load on the postural system, activating adaptive cerebellar-cortical mechanisms.

Transcranial electrical stimulation (TES), in particular anodal transcranial direct current stimulation (tDCS), is a non-invasive method of modulating the excitability of cortical neurons. Anodal tDCS over the primary motor cortex (M1) of the contralateral hemisphere increases its excitability and potentiates the formation of new motor engrams. The combination of TES with active motor training has demonstrated a synergistic effect in a number of studies; however, its combination with dynamic stabilometry has not been studied previously.

Thus, this study fills an existing gap by investigating the efficacy of synchronized use of dynamic stabilometry and TES in the early period of stroke with hemiparesis.

Aim of the Study

To evaluate the efficacy of combined use of dynamic stabilometry and transcranial electrical stimulation in restoring motor function in patients in the early recovery period of ischemic stroke with hemiparesis.

Objectives of the Study

- To evaluate the effect of the intervention on patients' postural balance using the Berg Balance Scale (BBS).
- To evaluate the effect of the intervention on patients' functional mobility: the FIM scale, the Morse Fall Scale, and the Hauser Ambulation Index.
- To evaluate the effect of combined use of dynamic stabilometry and TES on clinical indicators of neurological manifestations of stroke: the Rankin Scale, the Rivermead Mobility Index, the NIHSS scale, the MRC scale and the Ashworth Scale.
- To compare the efficacy of four variants of rehabilitation intervention (2×2 factorial design).
- To evaluate the safety of combined use of dynamic stabilometry and TES in the early period of stroke.

Study Population

The study will include 120 patients with ischemic stroke and hemiparesis aged 30 to 85 years, divided into 4 groups of 25 people (randomized controlled trial, 2×2 factorial design).

Inclusion criteria:

- Diagnosis of ischemic stroke verified by neuroimaging (CT/MRI)
- Hemiparesis of mild or moderate severity
- Time since stroke onset: 7 days to 6 months
- Ability to stand with support for at least 30 seconds
- Patient age: 30–85 years
- Cognitive status: MMSE ⩾ 20 points
- Medical stability: absence of acute somatic complications
- Signed informed voluntary consent

Exclusion criteria:

- Hemorrhagic stroke
- History of epilepsy or seizures
- Metal implants in the cranial cavity or a cardiac pacemaker
- Severe aphasia preventing understanding of instructions
- Marked vestibular dysfunction (Meniere's disease, BPPV in exacerbation)
- Severe visual impairment preventing the use of visual BFB
- Severe lower limb spasticity (MAS ⩾ 3 points)

- Severe concomitant orthopedic diseases preventing verticalization
- Unstable somatic condition (HF NYHA III–IV, unstable angina, BP > 180/110 mm Hg)
- Recurrent stroke within the last 3 months
- MMSE < 20 points
- Scalp diseases in the electrode placement areas

Study Design

Prospective pilot randomized controlled trial with parallel groups (4-arm RCT), 2×2 factorial design. Double blinding: the patient and the outcome assessor are unaware of group allocation. The study complies with the CONSORT 2010 reporting standard.

Group	n	Dynamic stabilometry	TES	Sham
A (main)	30	Dynamic (active)	Active tDCS	–
B (control 1)	30	Dynamic (active)	Sham tDCS	+
C (control 2)	30	Static (platform locked)	Active tDCS	–
D (control 3)	30	Static (platform locked)	Sham tDCS	+

All four groups receive standard rehabilitation of the same volume (exercise therapy, physiotherapy). The volume of standard rehabilitation is monitored by a session log.

Intervention Protocol

Dynamic stabilometry (groups A, B):

The ReviStabix stabilometric trainer (FSBEI HE SamSMU of the Ministry of Health of Russia) is used («ReviStabix», medical device registration number No. G004-00110-00/03075665 of 29.08.2025, https://revi.life/products/revistabix/) in dynamic operating mode with biofeedback (visual + auditory). The platform is in dynamic mode (active balancing); the standard angle is fixed and does not vary. Session duration: 20 minutes. Course: 10 sessions over 12 days (weekdays, 5 sessions per week, 2 days off).

Transcranial electrical stimulation — tDCS (transcranial Direct Current Stimulation) (groups A, C):

The «Neurostim» device by Neurosoft, intended for transcranial micropolarization (TCMP), is used (Medical device registration certificate No. RZN 2021/13529 of 20 February 2021, https://neurosoft.com/ru/catalog/tms/1969#delivery). Method: anodal tDCS. Stimulation area: M1 contralateral to the lesion. Intensity: 2 mA. Electrode area: 35

cm². Duration: 20 minutes. Placement: anode — M1 of the contralateral hemisphere, cathode — supraorbital, ipsilateral. The start of stimulation coincides with the start of the stabilometry session (synchronization).

Sham stimulation (groups B, D):

Electrodes are applied at the same points. Stimulation is delivered for the first 30 seconds (to imitate tactile sensations) and is then switched off automatically. The patient is not informed of the nature of the stimulation.

Session Schedule (12 days)

Day	Session	Stabilometry	Note
1	1	Dynamic / Static	Adaptation
2	2	Dynamic / Static	Main load
3	3	Dynamic / Static	Main load
4	4	Dynamic / Static	Main load
5	5	Dynamic / Static	Main load
6	6	Dynamic / Static	Main load
7	7	Dynamic / Static	Main load
8	8	Dynamic / Static	Main load
9	9	Dynamic / Static	Main load
10	10	Dynamic / Static	Main load
11	11	Dynamic / Static	Main load

Clinical Testing

Procedures	Visit 1 (Day 0)	Interim (Day 6)	Visit 2 (Day 12)
Hauser Ambulation Index	X	X	X
Berg Balance Scale (BBS)	X	X	X
Rankin Scale	X	X	X
Rivermead Index	X	X	X

Procedures	Visit 1 (Day 0)	Interim (Day 6)	Visit 2 (Day 12)
FIM Scale	X	X	X
NIHSS Scale	X	X	X
MRC Scale	X	X	X
Morse Fall Scale	X	X	X
Ashworth Scale	X	X	X

Hauser Ambulation Index (HAI)

A scale for assessing the ability to ambulate, mainly in multiple sclerosis. It reflects the level of mobility from free walking to being confined to a wheelchair. Easy to use, but less sensitive to small changes.

Berg Balance Scale (BBS)

A clinical functional test for assessing static and dynamic balance. It is a secondary endpoint. It assesses postural control and predicts the risk of falls.

Rankin Scale (RS)

A global functional outcome scale widely used in stroke. It assesses the degree of disability and dependence on assistance from others. The modified version (mRS) is the gold standard in clinical trials.

Rivermead Mobility Index (RMI)

An instrument for assessing mobility in patients with neurological disorders, most often after stroke. It consists of 15 items (from turning over in bed to running). It reflects functional changes during rehabilitation.

Functional Independence Measure (FIM)

A comprehensive scale of functional independence for patients with various diseases. It assesses the level of assistance needed in daily life (movement, self-care, communication, cognitive functions). It is sensitive to changes during rehabilitation.

National Institutes of Health Stroke Scale (NIHSS)

A standardized scale for assessing stroke severity. It consists of 11 items, including level of consciousness, movement, speech and vision. Widely used for decisions on thrombolytic therapy and outcome prognosis.

Medical Research Council Scale (MRC)

A classic scale for assessing muscle strength (from 0 to 5 points). It is used for each muscle segment separately. Simple and reproducible, but subjective at borderline values.

Morse Fall Scale (MFS)

A prognostic tool for identifying fall risk in hospitalized elderly patients. It takes into account history of falls, secondary diagnosis, ambulation, intravenous infusions, gait and mental status. Recommended for routine screening.

Modified Ashworth Scale (MAS)

The most common clinical scale for assessing spasticity. It measures resistance to passive movement of a limb (from 0 to 4 points). Widely used in neurology and rehabilitation, although it has limited inter-rater reliability.

Randomization and Blinding

Block randomization (blocks of 8), stratified by age (<65 / ≥65 years) and side of the lesion (left / right hemisphere). Allocation concealment: sealed opaque envelopes or centralized web-based randomization. The outcome assessor is unaware of the patient's group. The patient is blinded to the type of stimulation (active / sham).

Statistical Analysis

Primary analysis: ANCOVA adjusted for the baseline FMA. Additionally: mixed analysis of variance (Mixed ANOVA) for changes in parameters at time points 0–6–12 days; 2×2 factorial ANOVA to assess the synergistic interaction effect (dynamic stabilometry × TES). Effect size: Cohen's d. The main analysis follows the intention-to-treat (ITT) principle. Significance level: $\alpha = 0.05$. Study power: 80%. Sample size calculation: expected ΔBBS = 6 points, SD = 10, d = 0.6; n = 36 per group; with a 15% dropout adjustment — n ≥ 30 per group.

Scientific Novelty

For the first time, the combined synchronized use of dynamic stabilometry with biofeedback and transcranial electrical stimulation (tDCS) is studied in the early recovery period of ischemic stroke (the first). Previously, both methods were used in isolation; their synergistic interaction has not been investigated. The use of a 2×2 factorial design makes it possible to isolate the independent contribution of each method and to assess the interaction effect. For the first time, a two-component motor matrix (BBS + FIM) is used to assess efficacy, covering the postural and functional domains of recovery.

Practical Significance

The results of the study will make it possible to develop a scientifically substantiated protocol for the combined use of dynamic stabilometry and TES in the system of early neurorehabilitation of patients after stroke. If efficacy is confirmed, the method may be recommended for inclusion in clinical guidelines for the rehabilitation of post-stroke patients.

Study Site

Research Institute of Neurosciences, FSBEI HE SamSMU of the Ministry of Health of Russia, at the address: 18 Gagarina St., Samara; SBHI SR Samara City Clinical Hospital No. 2 named after N.A. Semashko.

Signatures of the Study Participants and Date

Head of Research, Director of the Research Institute of Neurosciences, FSBEI HE SamSMU of the Ministry of Health of Russia, Candidate of Medical Sciences (PhD), Associate Professor

21.04.2026 _____ /signature/ _____ **A.V. Zakharov**

(signature, date)

Investigator, Assistant Professor, Department of Medical Rehabilitation, Sports Medicine, Physiotherapy and Balneology, FSBEI HE SamSMU of the Ministry of Health of Russia, Candidate of Medical Sciences (PhD)

21.04.2026 _____ /signature/ _____ **Yu.D. Minina**

(signature, date)