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Improvement of balance and body symmetry in people recovering from stroke using sensory stimulation

Submission date 26/06/2025	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 14/07/2025	**Overall study status** Ongoing	
Last Edited 14/07/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Stroke is a serious health problem with a rising incidence, increasingly affecting younger individuals. Brain damage following a stroke almost always leads to impaired balance, negatively impacting the patient's quality of life and ability to reintegrate into social and professional life. Most patients experience some degree of motor and/or sensory deficit, which can be alleviated through timely and qualified rehabilitation. An essential part of rehabilitation is the objective assessment of the patient's functional state and its improvement at the necessary level (sitting or standing). It has been shown that additional sensory stimulation combined with standard rehabilitation improves patients' functional state. This study aims to evaluate the effects of original sensory training incorporating visual biofeedback and proprioceptive stimulation during sitting and/or standing as additional treatment to the standard rehabilitation program for stroke survivors.

Who can participate?
Patients aged 18 to 85 years, who are between 7 days and 6 months post-stroke, as well as healthy volunteers.

What does the study involve?
During their inpatient hospital stay, participants will undergo an initial assessment of postural stability, which includes measuring their maximum voluntary body lean in sitting and/or standing positions, as well as an evaluation of trunk impairment. They will also complete a self-report questionnaire assessing the impact of stroke on various aspects of their health and daily functioning.
In addition to the conventional rehabilitation program provided to all post-stroke patients (control group), participants in the experimental group will receive an 8-day sensory training intervention. This intervention involves voluntary learning tasks using visual biofeedback, either alone or combined with muscle vibration.
Following completion of the 8-day rehabilitation program, participants in both the control and

experimental groups will undergo a final assessment of postural stability. This will include the same tests and scales as used in the initial assessment to determine whether the experimental group demonstrates greater balance-related improvements as a result of the intervention.

What are the possible benefits and risks of participating?
Participation in this study may lead to improvements in overall postural stability, as well as enhanced trunk mobility and symmetry, with the potential to accelerate recovery and help patients to regain a full and active life. The information collected through this research may also contribute to developing more effective rehabilitation methods for future stroke patients.

The risks associated with participation are minimal. Some participants may experience mild fatigue or temporary discomfort during the sensory training and proprioceptive stimulation, such as muscle vibration. All procedures will be supervised by trained professionals to ensure the patient's safety, and any discomfort or concerns can be addressed immediately.

Where is the study run from?
The study is conducted by the Institute of Normal and Pathological Physiology, Centre of Experimental Medicine, Slovak Academy of Sciences, in cooperation with the Department of Physical Therapy and Rehabilitation at the University Hospital Bratislava (Ružinov Hospital), Slovakia.

When is the study starting and how long is it expected to run for?
October 2020 to August 2029

Who is funding the study?
1. Slovak Research and Development Agency (Agentúra na Podporu Výskumu a Vývoja)
2. Scientific Grant Agency of the Ministry of Education, Science, Research and Sport of the Slovak Republic and the Slovak Academy of Sciences (Vedecká Grantová Agentúra MŠVVaŠ SR a SAV)

Who is the main contact?
Dr Diana Bzdúšková, PhD, diana.bzduskova@savba.sk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
APVV-20-0420

Study information

Scientific Title
Sensory stimulation for restoring postural control and body symmetry in post-stroke patients: a translational study comparing novel rehabilitation approaches with standard therapy

Acronym
STROBE-R

Study objectives
The purpose of this study is to investigate the effects of a sensory intervention (i.e., visual biofeedback combined with vibration of the trunk and leg muscles) in post-stroke patients. The investigators hypothesize that incorporating this sensory intervention into conventional rehabilitation program will lead to greater improvements in sitting and standing balance, as well as trunk symmetry, as indicated by enhanced postural parameters and increased limits of stability, compared to conventional rehabilitation alone.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/05/2023, Ethics Committee of University Hospital Bratislava (Pažítková 4, Bratislava, 82101, Slovakia; +421248234793; okf@ru.unb.sk), ref: EC/064/2023

Study design
Single-center double-blinded randomized controlled trial with parallel assignment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients who have had a stroke and healthy volunteers

Interventions

Experimental group
Participants will undergo an initial assessment of their sitting and standing balance using stabilometric and accelerometric measurements. Baseline postural parameters and limits of stability will be recorded. The Trunk Impairment Scale (TIS) and Stroke Impact Scale (SIS) will be administered (day 0).
As part of their inpatient rehabilitation, participants will receive a sensory intervention involving voluntary trunk tilt training using visual biofeedback from the center of pressure displacement, either alone or combined with muscle vibration, in addition to the conventional rehabilitation program for stroke survivors (days 1-8). Duration of sensory intervention: 8 days, 1 training (lasting 30 minutes) per day.
Participants will undergo a final assessment of their sitting and standing balance using stabilometric and accelerometric measurements. Postural parameters and limits of stability will be recorded, and the Trunk Impairment Scale (TIS) and Stroke Impact Scale (SIS) will be administered to evaluate any effects related to the sensory intervention (day 9).

Control group
Participants will undergo an initial assessment of their sitting and standing balance using stabilometric and accelerometric measurements. Baseline postural parameters and limits of stability will be recorded. The Trunk Impairment Scale (TIS) and Stroke Impact Scale (SIS) will be administered (day 0).
As part of their inpatient rehabilitation, participants will receive a conventional rehabilitation program for stroke survivors only (days 1-8).
Participants will undergo a final assessment of their sitting and standing balance using stabilometric and accelerometric measurements. Postural parameters and limits of stability will be recorded, and the Trunk Impairment Scale (TIS) and Stroke Impact Scale (SIS) will be administered (day 9).

Randomization will be performed using the sealed envelope method to allocate participants into the experimental and control arms.

Healthy volunteers will serve for testing various parameters of proprioceptive stimulation of the trunk and lower leg muscles in the form of unilateral (one-sided) vibration of these muscles. Postural responses to vibration will be monitored while seated and standing, varying the vibration frequency and duration, with emphasis on modulating the symmetry of sitting and standing posture. Based on measured data, the parameters of the combined sensory stimulation will be selected and optimized.

Intervention Type
Behavioural

Primary outcome(s)
The changes in medio-lateral trunk limits of stability in sitting position and medio-lateral body limits of stability in standing position are measured using the force platform and evaluated as differences between the baseline (day 0) and final assessments (day 9).

Key secondary outcome(s))
1. The changes in postural sway parameters are measured using the force platform and wireless accelerometers and evaluated as differences between the baseline (day 0) and final assessment (day 9) parameter values
2. The change in trunk impairment measured using the Trunk Impairment Scale (maximal score 23) and evaluated as the difference between the baseline (day 0) and final assessment (day 9)

TIS score
3. The change in stroke impact measured using the Stroke Impact Scale and evaluated as the difference between the baseline (day 0) and final assessment (day 9) SIS score in each of the 8 domains

Completion date
31/08/2029

Eligibility

Key inclusion criteria
1. History of first stroke diagnosed using computed tomography and/or magnetic resonance imaging
2. Within 7 days to 6 months from the onset
3. Having a hemiparesis
4. Age 18 - 85 years
5. Able to sit and/or stand without support
6. Minimum ankle range of motion: 10 degrees
7. Modified Ashworth Scale (MAS) score <2 (0: no resistance, 5: rigid in flexion or extension)
8. Signed informed consent

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
85 years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Inability to maintain a sitting and/or standing position for 30 s
2. Having communication difficulties or a lack of consent to participate
3. Neglect syndrome
4. Neurodegenerative disorders
5. Unstable or severe health conditions
6. Contraindications for stimulation intolerance
7. Severe musculoskeletal impairments

8. Orthopedic surgery involving the upper and lower limbs within the past 6 months
9. Cognitive impairment (MMSE <23, MoCa <23)

Date of first enrolment
30/05/2023

Date of final enrolment
30/11/2028

Locations

Countries of recruitment
Slovakia

Study participating centre
University Hospital Bratislava, Hospital Ružinov
Department of Physical Therapy and Rehabilitation, Ružinovská street no. 6
Bratislava
Slovakia
82606

Study participating centre
Centre of Experimental Medicine of the Slovak Academy of Sciences
Institute of Normal and Pathological physiology, Department of Behavioral Neuroscience, Sienkiewiczova street no. 1
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81109

Sponsor information

Organisation
Centre of Experimental Medicine of the Slovak Academy of Sciences

ROR
https://ror.org/0380mmw63

Funder(s)

Funder type
Government

Funder Name
Agentúra na Podporu Výskumu a Vývoja

Alternative Name(s)
Slovak Research and Development Agency, Agentúra na podporu výskumu a vývoja, Bratislava, Agentúra na podporu výskumu a vývoja, Slovak Research and Development Agency (SRDA), Slovak Research and Development Agency (Slovakia), APVV, SRDA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Slovakia

Funder Name
Vedecká Grantová Agentúra MŠVVaŠ SR a SAV

Alternative Name(s)
Scientific Grant Agency, VEGA

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Slovakia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Diana Bzdúšková, PhD., diana.bzduskova@savba.sk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes