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

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

## 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

#### Contact name

Mrs Diana Bzdúšková

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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

Bratislava Slovakia 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