

# NEUROlogic rehabilitation with GAIT training using body weight support and music-based feedback

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<b>Registration date</b> 03/02/2026	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/02/2026	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Many people who have had a stroke, spinal cord injury, or multiple sclerosis have difficulties with walking. Rehabilitation usually includes physiotherapy exercises to improve strength, balance, and movement. This study aims to find out if using a treadmill with body weight support, together with rhythmic music therapy (neurologic music therapy), can help patients improve their walking ability more than standard rehabilitation alone.

### Who can participate?

Patients aged 18 to 80 years will be invited to take part while staying in a neurological rehabilitation ward.

### What does the study involve?

Every patient will receive standard physiotherapy. In addition, one group will also train on a treadmill (BIODEX Gait Trainer 3) with partial body weight support and music therapy. The other group will continue with standard therapy only, without treadmill training or music. The training will last for 4 weeks, with 3–5 sessions each week, each lasting around 20–30 minutes.

The study will measure walking ability before therapy (T0), after 4 weeks of therapy (T1), and again after 4 weeks of follow-up (T2, optional). Assessments will include step length, walking speed, gait cycle, gait symmetry, independence in daily activities, use of walking aids, and quality of life questionnaires.

### What are the possible benefits and risks of participating?

By comparing the results, it is hoped to confirm whether adding treadmill training with music therapy is more effective in improving gait, mobility, and quality of life in people with neurological conditions.

The risks of participating in this study are minimal. Some patients may feel temporary fatigue, muscle soreness, or balance difficulties during treadmill training. There is also a small risk of falls, but all sessions will be supervised by trained physiotherapists and conducted with safety.

harnesses and body weight support. Music therapy does not involve medical risk, though some participants may find rhythmic stimulation uncomfortable. Participation is voluntary, and patients may withdraw at any time without affecting their medical care.

Where is the study run from?

Wroclaw Medical University, Poland

When is the study starting and how long is it expected to run for?

May 2025 to May 2026

Who is funding the study?

Wroclaw Medical University, Poland

Who is the main contact?

Dr Wojciech T Laber, Wroclaw Medical University, wojciech.t.laber@umw.edu.pl.

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

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## Additional identifiers

## Study information

### Scientific Title

NEUROGAIT Study – the effect of body weight supported treadmill training combined with neurologic music therapy on gait parameters and locomotor symmetry in neurological patients: a prospective randomized controlled trial

### Acronym

NEUROGAIT

### Study objectives

Evaluation of the effectiveness of body weight–supported treadmill training combined with neurologic music therapy (NMT) as a component of neurological rehabilitation in patients with locomotor deficits, with particular emphasis on post-stroke individuals, focusing on the improvement of gait parameters, locomotor symmetry, and motor functionality.

#### Primary Specific Objectives:

To assess the effect of the intervention on spatiotemporal gait parameters, such as step length, gait speed, and gait cycle, measured before and after the intervention.

To examine changes in gait symmetry by analyzing stance time and step length for the right and left limb, as well as the coefficient of variation within the gait cycle.

To compare the effectiveness of treadmill training with and without neurologic music therapy in improving locomotor para

#### Hypotheses:

H1.1: Treadmill training with neurologic music therapy and body weight support leads to a significant improvement in step length, walking speed, and gait cycle compared with conventional therapy.

H1.2: Neurologic music therapy enhances gait symmetry (stance time and step length of the right /left limb) to a greater extent than training without auditory stimulation.

H1.3: The combination of neurologic music therapy with treadmill training produces superior outcomes compared to treadmill training with body weight support alone (without music) in improving spatiotemporal gait parameters

#### **Ethics approval required**

Ethics approval required

#### **Ethics approval(s)**

approved 23/05/2025, Bioethics Committee at the Medical University of Wrocław (J. Mikulicza-Radeckiego 4a, Wrocław, 50-367, Poland; +48 71 784 10 14; bioetyka@umw.edu.pl), ref: KB 221 /2025

#### **Study design**

Prospective randomized controlled trial

#### **Primary study design**

Interventional

#### **Study type(s)**

Treatment

#### **Health condition(s) or problem(s) studied**

The effectiveness of a therapeutic intervention consisting of body weight–supported treadmill training combined with neurologic music therapy in neurological patients (post-stroke, spinal cord injury, multiple sclerosis) undergoing inpatient rehabilitation.

## **Interventions**

The study is designed as a prospective, randomized controlled trial with assessments at baseline (T0), after completion of therapy (T1), and with an optional follow-up assessment (T2) at 4 weeks.

### **Recruitment and Patient Eligibility**

Participants will be recruited from the Neurological Rehabilitation Department.

Eligibility will be determined according to predefined inclusion and exclusion criteria.

All participants will receive detailed information about the study and provide written informed consent before enrollment.

### **Allocation to Study Groups**

Participants in the NEUROGAIT Study will be randomly assigned to one of two study groups:

#### **Experimental Group**

Patients will receive standard neurological physiotherapy in accordance with National Health Fund (NFZ) procedures, including individual exercises, gait re-education, balance training, activities of daily living training, stretching, and at least one neurophysiological method (PNF, Bobath, Vojta).

Additionally, as part of gait re-education, patients will undergo treadmill training using the BIODEX Gait Trainer 3 with body weight support combined with neurologic music therapy (NMT). Treadmill sessions will be tailored to the patient's functional abilities and delivered as part of the five contracted therapeutic procedures, integrated into the individual rehabilitation plan.

#### **Control Group**

Patients will receive standard neurological physiotherapy in accordance with NFZ-contracted procedures, without treadmill training or music therapy. Therapy may include overground gait training, general individual physiotherapy, training with orthopedic aids (e.g., walker, crutches), active verticalization, balance training, stretching, and selected neurophysiological methods. Therapy will be adapted to the patient's current clinical status, with dynamic modification of procedures as appropriate (e.g., transition from passive to active verticalization, progressive introduction of assisted gait).

Duration: 4 weeks

Frequency: 3–5 sessions per week (minimum of 12 sessions)

Session length: Approximately 20–30 minutes each

Delivery: The intervention will be administered by physiotherapists with appropriate training

## **Intervention Type**

Behavioural

### **Primary outcome(s)**

1. Change in spatiotemporal gait parameters (step length, gait speed, gait cycle) measured using the Biodex Gait Trainer 3 from baseline (T0) to post-intervention (T1)
2. Change in gait symmetry, assessed by stance time and step length (right vs. left limb) and coefficient of variation within the gait cycle, measured with the Biodex Gait Trainer 3 from T0 to T1
3. Comparison of locomotor outcomes between groups (treadmill training with vs. without neurologic music therapy), including patients using orthopedic aids (cane, crutch, walker), measured with Biodex Gait Trainer 3 from baseline (T0) to post-intervention (T1)

## **Key secondary outcome(s)**

The following functional independence and mobility secondary outcomes will be assessed from T0 to T1 (and T2, optional) using:

1. Barthel Index
2. Timed Up and Go (TUG)
3. 10-Meter Walk Test (10MWT)
4. Rivermead Motor Assessment – Gross Function
5. Patient Locomotion Ability Form (classification of mobility with/without aids)
6. Modified Ashworth Scale (muscle tone)
7. Medical Research Council (MRC) Scale (muscle strength)
8. ICF Short Assessment
9. Change in the use of orthopedic aids (walker, cane, crutches), documented at T0, T1, and T2
10. Health-related quality of life using the WHOQOL-BREF (or EQ-5D, depending on availability), from T0 to T1 (and T2)

## **Completion date**

30/05/2026

## **Eligibility**

### **Key inclusion criteria**

1. Age: 18–80 years
2. Sex/Gender: Women and men; no sex-based recruitment preferences
3. Neurological diagnosis (e.g., ischemic or hemorrhagic stroke, spinal cord injury, multiple sclerosis)
4. Time since neurological event:  $\geq 3$  weeks; up to several years (stable subacute or chronic phase)
5. Mobility status: Able to ambulate with an orthopedic aid and/or therapist assistance
6. Medical fitness: Clinical status permitting participation in gait training (as assessed by the attending physician and physiotherapist)
7. Cognitive capacity: Sufficient to understand instructions and provide written informed consent

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

18 years

### **Upper age limit**

80 years

### **Sex**

All

### **Total final enrolment**

0

### **Key exclusion criteria**

1. Unstable cardiac or pulmonary disease
2. Severe cognitive impairment (MMSE < 24 or AMTS < 9)
3. Severe lower limb spasticity (Modified Ashworth Scale > 3)
4. History of orthopedic surgery, preventing gait training
5. Hypersensitivity or significant discomfort related to sounds or music<sup>6</sup>

### **Date of first enrolment**

01/07/2025

### **Date of final enrolment**

30/04/2026

## **Locations**

### **Countries of recruitment**

Poland

### **Study participating centre**

**Bonifraterskie Medical Center Ltd., Neurological Rehabilitation Department, Provita Unit – Wrocław**

63 Bierutowska Street, 51-317 Wrocław, Poland

Wrocław

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### **Study participating centre**

**University Center of Physiotherapy and Rehabilitation, Wrocław Medical University**

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Wrocław

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50-368

## **Sponsor information**

### **Organisation**

Wrocław Medical University

### **ROR**

<https://ror.org/01qpw1b93>

# Funder(s)

## Funder type

University/education

## Funder Name

Uniwersytet Medyczny im. Piastów Śląskich we Wrocławiu

## Alternative Name(s)

Wroclaw Medical University

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Universities (academic only)

## Location

Poland

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request from Dr Wojciech T Laber, Wroclaw Medical University, wojciech.t.laber@umw.edu.pl.

- o Type of data to be shared: De-identified individual participant data (IPD) including baseline demographics, gait parameters, functional assessment scores, and quality-of-life measures.
- o Timing of availability: Data will be available beginning 12 months after study completion and for at least 5 years thereafter.
- o Consent: Written informed consent for participation has been obtained from all participants. Additional consent for data sharing is included in the patient information sheet.
- o Data anonymization: All data will be fully de-identified prior to sharing; no names, dates of birth, or identifying information will be included.
- o Ethical or legal restrictions: Data will only be shared in anonymized form and in accordance with applicable data protection regulations (GDPR).
- o Additional comments: Access to data will be provided upon reasonable request to the corresponding author and after approval of a data-sharing agreement.

## IPD sharing plan summary

Available on request