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

Submission date
03/10/2025

Recruitment status
Recruiting

Registration date
03/02/2026

Overall study status
Ongoing

Last Edited
03/02/2026

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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
Mr Wojciech T. Laber

ORCID ID
https://orcid.org/0000-0002-3876-5581

Contact details
University Center of Physiotherapy and Rehabilitation, Wroclaw Medical University, 3 T. Chałubińskiego Street, 50-368 Wrocław, Poland
Wrocław
Poland
50-368
+4871/784 28 15
wojciech.t.laber@umw.edu.pl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

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: ≥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 music6

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
Poland
51-317

Study participating centre
University Center of Physiotherapy and Rehabilitation, Wroclaw Medical University
3 T. Chałubińskiego Street, 50-368 Wrocław, Poland
Wroclaw
Poland
50-368

Sponsor information

Organisation
Wroclaw Medical University

ROR
https://ror.org/01qpw1b93

Funder(s)

Funder type
University/education

Funder Name
Uniwersytet Medyczny im. Piastów Slaskich we Wroclawiu

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

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