

The acute effect of percutaneous tibial nerve stimulation on postural control

Submission date 30/11/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/12/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/08/2025	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

This study aims to explore how stimulating a specific nerve in the leg (the posterior tibial nerve) affects balance in healthy young men. The goal is to see if this technique can improve postural control, which is important for maintaining stability and preventing falls.

Who can participate?

Healthy young men aged 18 to 35 years who are physically active and do not have any neurological, musculoskeletal, or cardiovascular disorders that could affect their balance.

What does the study involve?

Participants will be divided into three groups:

PTNS intervention group: This group will receive electrical stimulation to the posterior tibial nerve using a small needle and a certified medical device.

SHAM group: This group will have a needle inserted, but no electrical stimulation will be applied.

Control group: This group will only undergo balance tests without any needle insertion or stimulation.

Balance will be tested by having participants stand on one leg with their hands on their hips, both with their eyes open and closed. These tests will be repeated immediately after the intervention, and then at 2 hours, 24 hours, and 48 hours later.

What are the possible benefits and risks of participating?

The main benefit is contributing to research that could improve treatments for balance disorders. Risks are minimal but may include mild numbness or small bruises at the needle site, which should go away in a few days.

Where is the study run from?

Fundación Universitaria San Pablo CEU (Spain)

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

September 2024 to January 2025

Who is funding the study?
Fundación Universitaria San Pablo CEU (Spain)

Who is the main contact?
Miguel Rodríguez Rosal, mrodriguezr@ceu.es

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

The acute effect of percutaneous tibial nerve stimulation on postural control: a randomized controlled trial

Study objectives

We hypothesize that percutaneous neuromodulation of the posterior tibial nerve will have an acute effect on postural control in healthy subjects. Specifically, we expect that this intervention will lead to improvements in postural control compared to baseline measures.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 02/09/2024, Universidad San Pablo-CEU, CEU Universities (Glorieta Ángel Herrera Oria, s/n, Bormujos/ Sevilla, 41930, Spain; +34 954 48 80 00; investigacion@ceuandalucia.es), ref: -

Study design

Prospective randomized controlled trial

Primary study design

Interventional

Study type(s)

Prevention, Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied

Postural control

Interventions

Participants were randomly and equally assigned to each group using a 1:1:1 design via the Random.org program. The therapist was informed only through sealed envelopes.

Group Percutaneous tibial nerve stimulation (PTNS)

Participants in the PTNS group will receive the PTNS intervention, which will involve the application of a biphasic electrical current (10 Hz frequency, 250 μ s pulse width) at the maximum tolerable intensity for 1.5 minutes, sufficient to induce a visible muscle contraction. A certified medical device (Physio Invasiva; PRIM Physio®, Madrid, Spain) will be used for this procedure.

Participants will be positioned prone with their feet hanging off the edge of the treatment table. The posterior tibial nerve will be located using an ultrasound machine (Logic; GE Healthcare, Chicago, IL, USA) for the insertion of a needle (0.30 mm x 40 mm). Prior to insertion, the skin surface will be cleaned with alcohol. The procedure will be performed by a physiotherapist with 8 years of experience in invasive physiotherapy.

Group SHAM

In the SHAM group, a puncture will be performed with a needle (0.30 mm x 40 mm) following the same methodology as in the PTNS group. A "nonacupoint deep puncture" technique will be employed to create the sensation of needle insertion without applying electrical current. The same timing and procedural techniques described for the PTNS group will be maintained.

Group CON

In the control group, no intervention will be performed

For the intervention groups, a single session was conducted, and the acute effect was followed up. All measurements were repeated before and immediately after the intervention, as well as at 2, 24, and 48 hours.

Intervention Type

Other

Primary outcome(s)

Postural control will be measured using a force platform (Accupower; AMTI, Watertown, MA, USA) with a sampling frequency of 1000 Hz. Participants will stand on one leg, with their hands

on their hips and their gaze fixed on a point 2 meters away. The tests will be conducted with eyes open and closed. For each condition, three attempts will be made. Each test will last 30 seconds, followed by a 1-minute rest period.

The displacement of the center of pressure will be analyzed using linear variables: total center of pressure displacement (DOT) and the total length of its path; total displacement area (Area); mediolateral displacement (Displ_ML) and anteroposterior displacement (Displ_AP); and the amplitude of the center of pressure in the mediolateral (Ampl_ML) and anteroposterior (Ampl_AP) directions, defined as the distance between the minimum and maximum values.

1. Variable DOT measured using force platform at baseline, 0, 2, 24 and 48 h
2. Variable Area measured using force platform at baseline, 0, 2, 24 and 48 h
3. Variable Displ_ML measured using force platform at baseline, 0, 2, 24 and 48 h
4. Variable Displ_AP measured using force platform at baseline, 0, 2, 24 and 48 h
5. Variable Ampl_ML measured using force platform at baseline, 0, 2, 24 and 48 h
5. Variable Ampl_AP measured using force platform at baseline, 0, 2, 24 and 48 h

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

15/01/2025

Eligibility

Key inclusion criteria

1. Healthy young adults
2. Engage in at least 150 minutes of moderate aerobic activity per week (or the equivalent in vigorous activity), or at least 20 minutes per week of vigorous physical activity

Participant type(s)

Healthy volunteer, Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

35 years

Sex

Male

Key exclusion criteria

1. An injury affecting balance in one limb within the past year that prevented participation in sports for at least 1 day
2. A Personal Psychological Apprehension Scale (EPPAS) score >37.5

3. Commonly accepted contraindications for invasive physiotherapy techniques, including chronic joint disease, surgery, prosthetics, or osteosynthesis in the intervention area, as well as cardiac diseases, neoplasms, coagulopathies, and the use of certain medications
4. Any contraindication to the puncture itself
5. Epilepsy

Date of first enrolment

16/12/2024

Date of final enrolment

12/02/2025

Locations

Countries of recruitment

Spain

Study participating centre

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Sponsor information

Organisation

Fundación Universitaria San Pablo CEU

ROR

<https://ror.org/04a0dbe36>

Funder(s)

Funder type

University/education

Funder Name

Fundación Universitaria San Pablo CEU

Alternative Name(s)

San Pablo CEU University Foundation, CEU San Pablo University Foundation, Centro de Estudios Universitarios, FUSP-CEU, CEU

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Spain

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request

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IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/08/2025	22/08/2025	Yes	No
Other files			11/12/2024	No	No