ISRCTN17765352 https://doi.org/10.1186/ISRCTN17765352

# The acute effect of percutaneous tibial nerve stimulation on postural control

**Submission date**
30/11/2024

**Recruitment status**
No longer recruiting

**Registration date**
13/12/2024

**Overall study status**
Completed

**Last Edited**
19/03/2025

**Condition category**
Other

[X] 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
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

### Contact name
Mr Miguel Rodriguez Rosal

### ORCID ID
http://orcid.org/0000-0001-7816-1654

### Contact details
Glorieta Ángel Herrera Oria, s/n,
Bormujos/ Sevilla
Spain
41930
+34 954 48 80 00
mrodriguezr@ceu.es

# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
University/medical school/dental school

## Study type(s)
Prevention, Quality of life, Treatment, Efficacy

## Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

## 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 µs 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 × 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 measure
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

### Secondary outcome measures
There are no secondary outcome measures

### Overall study start date
02/09/2024

### 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

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
35 Years

### Sex
Male

### Target number of participants
The required sample size to detect a medium effect was calculated to be at least 39 participants for inclusion in a multifactorial ANOVA with repeated measures and three intervention groups

### 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
**Universidad CEU Fernando III, CEU U**
Glorieta Ángel Herrera Oria, s/n,
Bormujos/Sevilla
Spain
41930

## Sponsor information

### Organisation
Fundación Universitaria San Pablo CEU

### Sponsor details
Glorieta Ángel Herrera Oria, s/n
Bormujos/ Sevilla
Spain
41930
+34 954 48 80 00
investigacion@ceuandalucia.es

### Sponsor type
University/education

### Website
https://www.uspceu.com

### 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

### Publication and dissemination plan
Planned publication in a peer-reviewed journal

### Intention to publish date
31/01/2025

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request
mrodriguezr@ceu.es

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Other files | | | 11/12/2024 | No | No |