

Study on the effects of footwear on pain and fatigue in the lower extremities

Submission date 29/01/2025	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/02/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 31/01/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Lower extremity pain and fatigue are common issues affecting mobility and quality of life. This study aims to evaluate the efficacy of health shoes with Pillow Concept technology in reducing pain and fatigue and improving balance and satisfaction among adults with lower limb discomfort.

Who can participate?

Adults aged 25-60 years who have experienced foot or lower limb pain or fatigue for more than one month and able to walk independently.

What does the study involve?

Participants will be randomly assigned to two groups:

1. An intervention group using health shoes with Pillow Concept technology.
2. A control group using their regular footwear.

Participants will wear the assigned shoes for 4 weeks, walking approximately 3000 steps (or 30 minutes) daily. Pain, fatigue, balance, and satisfaction will be assessed at baseline, week 2, and week 4.

What are the possible benefits and risks of participating?

Participants may experience a reduction in pain and fatigue, improved balance, and increased satisfaction with footwear. Risks are minimal but may include mild discomfort or adjustment issues when using the new shoes (in the intervention group).

Where is the study run from?

The study will be conducted at the Faculty of Medicine, Universitas Negeri Yogyakarta, Indonesia.

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

January 2025 to January 2026

Who is funding the study?

PT. Chosen Mitra Abadi (Indonesia)

Who is the main contact?

Dr Muhammad Ikhwan Zein, dr_ichwanz@uny.ac.id

Contact information

Type(s)

Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

T/3/UN34.20/PT.01.03/2024

Study information

Scientific Title

Randomised controlled trial of health shoes with pillow concept technology to reduce pain and fatigue in the lower extremities

Acronym

STEPFIT

Study objectives

We hypothesize that a four-week use of shoes featuring Pillow Concept technology will significantly reduce pain and fatigue in the feet and lower limbs compared to regular shoes. Our secondary hypothesis is that participants in the intervention group will report greater user satisfaction and comfort during daily activities.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 01/01/2025, Ethics committee at Directorate of Research and Community Service, Universitas Negeri Yogyakarta (Universitas Negeri Yogyakarta, Jl. Colombo No.1 Karang Malang, Sleman, Yogyakarta, 55281, Indonesia; +62 274586168, ext. 262, 550839; komisi.etik@uny.ac.id), ref: T/6.96/UN34.9/KP.06.07/2024

Study design

Randomised controlled trial with a parallel-group design

Primary study design

Interventional

Study type(s)

Efficacy

Health condition(s) or problem(s) studied

Lower extremity pain and fatigue

Interventions

Group 1 (Intervention): Shoes with Pillow Concept Technology, designed to reduce vibrations during walking to alleviate discomfort, pain, and fatigue in the lower extremities. The intervention period lasts for 4 weeks, with participants walking 3000 steps (or 30 minutes) daily.

Group 2 (Control): Regular shoes used by participants in their daily activities, also worn for the same duration.

The subjects will be randomized with a 1:1 allocation ratio using an online software application (Sealed Envelope™) and assigned to either the intervention group (shoes with pillow technology) or the control group (using their daily shoes). The coordinating researcher (MIZ) will manage the allocation process and remain blinded to the assigned intervention. An unblinded research assistant who is not part of the research team will deliver the randomization results and inform the subjects of their assigned intervention. The researchers conducting and interpreting the analysis will remain blinded to group allocation until all outcome analyses have been completed. No changes will be made to the interpretation after the analysis results are unblinded.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Bocorocco shoes with Pillow Concept technology

Primary outcome(s)

1. Foot health is measured using the Foot Health Assessment Questionnaire at baseline, 2-week follow-up, and 4-week follow-up
2. Pain intensity is measured using the Numerical Rating Scale (NRS) at baseline, 2-week follow-up, and 4-week follow-up
3. Pressure pain threshold is measured using a dolorimeter at baseline, 2-week follow-up, and 4-week follow-up
4. Balance is measured using the Single Leg Stance Test at baseline, 2-week follow-up, and 4-week follow-up
5. Functional reach is measured using the Functional Reach Test at baseline, 2-week follow-up, and 4-week follow-up

Key secondary outcome(s)

User satisfaction for shoes will be assessed using Likert scale at 4 weeks

Completion date

01/01/2026

Eligibility**Key inclusion criteria**

1. Adults aged between 25-60 years.
2. Pain or fatigue in the feet or lower extremities lasting more than one month.
3. Able to walk independently without assistance.

Participant type(s)

Patient, Other

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

25 years

Upper age limit

60 years

Sex

All

Key exclusion criteria

1. History of foot or lower limb surgery within the past 6 months.
2. Neurological disorders affecting walking ability.
3. Use of medications that influence pain perception.

Date of first enrolment

14/02/2025

Date of final enrolment

30/10/2025

Locations**Countries of recruitment**

Indonesia

Study participating centre**Universitas Negeri Yogyakarta**

Jl. Colombo No.1, Karang Malang, Caturtunggal, Kec. Depok, Kabupaten Sleman, Daerah Istimewa Yogyakarta
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Sponsor information**Organisation**

Universitas Negeri Yogyakarta

Funder(s)**Funder type**

Industry

Funder Name

PT. Chosen Mitra Abadi (PT Bocorocco Entrepreneur Indonesia)

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 from : dr. Muhammad Ikhwan Zein, email : dr_ichwanz@uny.ac.id

IPD sharing plan summary

Available on request