ISRCTN10672939 https://doi.org/10.1186/ISRCTN10672939

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

Submission date
29/01/2025

Recruitment status
Recruiting

Registration date
01/02/2025

Overall study status
Ongoing

Last Edited
31/01/2025

Condition category
Musculoskeletal Diseases

[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
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

Contact name
Mr Muhammad Ikhwan Zein

ORCID ID
http://orcid.org/0000-0003-3728-5065

Contact details
Faculty of Medicine, Universitas Negeri Yogyakarta (Jl. Colombo No.1 Karangmalang Yogyakarta)
Yogyakarta
Indonesia
55281
+62 8111286520
fk@uny.ac.id

Type(s)
Public, Scientific

Contact name
Mrs Laily Rahmawati

Contact details
Faculty of Medicine, Universitas Negeri Yogyakarta (Jl. Colombo No.1 Karangmalang Yogyakarta)
Yogyakarta
Indonesia
55281
+62 813-3316-0801
lailyrahmawati@uny.ac.id

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Community, Workplace, Other

Study type(s)
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
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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Bocorocco shoes with Pillow Concept technology

Primary outcome measure
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

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

Overall study start date
01/01/2025

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

Age group
Adult

Lower age limit
25 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
140 participants (70 in the intervention group and 70 in the control group).

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
Yogyakarta
Indonesia
55281

Sponsor information

Organisation
Universitas Negeri Yogyakarta

Sponsor details
Faculty of Medicine, Universitas Negeri Yogyakarta (Jl. Colombo No.1 Karangmalang Yogyakarta)
Yogyakarta
Indonesia
55281
+62 82137176969
fk@uny.ac.id

Sponsor type
University/education

Website
https://fk.uny.ac.id/

Funder(s)

Funder type
Industry

Funder Name
PT. Chosen Mitra Abadi (PT Bocorocco Entrepreneur Indonesia)

Results and Publications

Publication and dissemination plan
The results will be published in high-impact, peer-reviewed journals and presented at relevant academic conferences. Findings will also be shared with participants and stakeholders via institutional reports.

Intention to publish date
01/01/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upen request from : dr. Muhammad Ikhwan Zein, email : dr_ichwanz@uny.ac.id

IPD sharing plan summary
Available on request