

Effectiveness of custom 3D-printed foot orthoses in improving foot symptoms: a pre-and post-intervention study

Submission date 23/02/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/03/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 07/03/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study aims to evaluate the effectiveness of custom 3D-printed foot orthoses in improving foot symptoms and functional status by comparing baseline and post-intervention outcomes. Custom 3D-printed foot orthoses are expected to effectively improve functional status and alleviate foot symptoms, supporting their use as a personalized treatment option in clinical practice. Future research should investigate their long-term efficacy and adaptability across diverse populations.

Who can participate?

Participants aged from 18 to 75 years old with and without foot pain

What does the study involve?

Baseline data included demographic and clinical characteristics (e.g., age, sex), physical function questionnaire scores, and pain intensity assessed using the numeric rating scale (NRS), and 3D-scanned foot morphology data. After three months of using custom 3D-printed foot orthoses, follow-up questionnaire scores were collected for comparison.

What are the possible benefits and risks of participating?

Possible Benefits: The custom insoles are designed based on the user’s foot morphology, providing active support to redistribute foot pressure, alleviate fatigue, and reduce pain. They offer excellent support and cushioning, protecting the feet, ankles, and knees from sports-related injuries. The insoles can also correct biomechanical misalignment caused by conditions such as high arches, flat feet, or foot deformities, helping to distribute foot pressure, enhance balance, improve athletic performance, and prevent injuries. They are particularly beneficial for older adults, as they support the arch of the foot, alleviate joint degeneration and fatigue, and improve overall quality of life. Additionally, the insoles can slow down or prevent the progression of hallux valgus and related foot conditions, promoting foot health.

Possible Risks: There is a possibility that foot pain symptoms may not improve, and foot function may not be enhanced.

Where is the study run from?
Affiliated Kunshan Hospital of Jiangsu University, China

When is the study starting and how long is it expected to run for?
November 2023 to May 2024

Who is funding the study?
Medical Innovation (Suzhou) Clinical Research Co., Ltd

Who is the main contact?
Dr Chong Li, lichong1705@163.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effectiveness of custom 3D-printed foot orthoses in improving FAAM scores among general populations: a pre-and post-intervention study

Study objectives

Custom 3D-printed foot orthoses have a positive effect on foot pain and foot function

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 05/07/2024, The First People's Hospital of Kunshan (No. 566 East of Qianjin Road, Suzhou, Jiangsu, 215300, China; +86-0512-57029736; sgu8434@sina.com), ref: 2024-03-029-H01-K00

Study design

Single-group pre-and post-intervention study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Quality of life, Efficacy

Participant information sheet

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

Health condition(s) or problem(s) studied

The improvement effect of custom 3D printed foot orthoses on foot pain and foot function

Interventions

A pre- and post-control study using Custom 3D printed foot orthoses

The study involves the use of custom 3D-printed foot orthoses tailored through 3D scanning technology, with participants from the general population using the orthoses for at least 24 days per month and 8 hours per day over a 3-month follow-up period. The intervention is location-independent, and data collection includes participant demographics, baseline and follow-up FAAM scores, baseline NRS scores, and 3D foot scan data.

Intervention Type

Device

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Custom 3D printed foot orthoses

Primary outcome measure

Physical function measured Foot and Ankle Ability Measure (FAAM) at baseline and three months after using Custom 3D printed foot orthoses

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

03/11/2023

Completion date

07/05/2024

Eligibility**Key inclusion criteria**

1. Age under 75 years, able to cooperate with the use of orthotic insoles independently
2. No medication treatment within the past three months
3. No other foot issues, such as skin ulcerations or diabetic foot
4. Participants agree to have no plans for pregnancy from the time of signing the informed consent until the end of the trial
5. Participants fully understand the purpose, nature, methods, and potential adverse reactions of the study, voluntarily consent to participate and sign the informed consent form before the initiation of any research procedures

Participant type(s)

Healthy volunteer, Patient

Age group

Mixed

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Both

Target number of participants

200

Total final enrolment

76

Key exclusion criteria

1. Individuals who use any medications or medical devices outside of the study-required trial products during the study period
2. Those with cognitive impairments who are unable to comply with treatment
3. Participants who have received topical treatments, physical therapy, or rehabilitation for foot conditions within one month prior to screening, or who are undergoing other treatments that may affect efficacy
4. Individuals with a history of foot surgery within the past 12 months or those planning surgery on the affected area during the trial
5. Participants who used anesthetics, opioid analgesics, antispasmodics, long-acting non-steroidal anti-inflammatory drugs (e.g., piroxicam, meloxicam, naproxen, etoricoxib) or other medications that could influence efficacy assessment within the last 7 days prior to screening; those who use analgesics during the 3-month trial period will be considered to have withdrawn voluntarily
6. Foot and ankle pain due to neurological disorders, autoimmune diseases, foot trauma, or referred pain unrelated to structural abnormalities
7. Individuals with severe organic primary diseases affecting the cardiovascular, hepatic, renal, or hematological systems, as well as those with mental illnesses
8. Other reasons deemed inappropriate for enrollment by the researchers or participants who withdraw from the trial for personal reasons
9. During the follow-up period, the worker was unable to complete the follow-up due to various reasons

Date of first enrolment

03/11/2023

Date of final enrolment

07/05/2024

Locations

Countries of recruitment

China

Study participating centre

The First People's Hospital of Kunshan

No. 566 East of Qianjin Road

Suzhou, Jiangsu

China

215300

Sponsor information

Organisation

First People's Hospital of Kunshan

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<https://www.ksrmyy.org/>

ROR

<https://ror.org/01kzs416>

Funder(s)

Funder type

Industry

Funder Name

Medical Innovation (Suzhou) Clinical Research Co., Ltd

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

07/05/2024

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication