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Customized 3D-printed foot orthoses improve foot function over time for flat feet

Submission date
24/07/2025

Recruitment status
No longer recruiting

Registration date
14/08/2025

Overall study status
Completed

Last Edited
07/08/2025

Condition category
Musculoskeletal Diseases

[ ] 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
Flatfoot is a condition that can cause pain and make walking difficult, affecting daily life. Many people use shoe inserts (called orthoses) to help, but it's not clear how well they work for adults with flexible flatfoot. This study looked at whether specially made 3D-printed insoles could improve movement and reduce discomfort when added to usual care.

Who can participate?
Adults aged 18 to 65 years who have been diagnosed with flatfoot by a doctor and haven't had any treatment for it yet can take part. They must not have other foot problems, must be able to use insoles, and must agree not to become pregnant during the study. Everyone must understand the study and give written consent before joining.

What does the study involve?
Participants are randomly placed into one of two groups. One group receives standard care, which includes exercises, advice on shoes, weight management, physical therapy if needed, and pain relief. The other group gets the same care plus custom-made 3D-printed insoles designed to support the foot and reduce impact. These insoles are worn daily for three months. Doctors check in regularly to make sure everything is going well.

What are the possible benefits and risks of participating?
Participants may benefit from reduced pain and better movement, especially if the 3D-printed insoles are effective. Risks are low but could include discomfort from wearing the insoles or not seeing any improvement. Any problems will be monitored by the study team.

Where is the study run from?
First People's Hospital of Kunshan (China)

When is the study starting and how long is it expected to run for?
July 2024 to January 2025

Who is funding the study?
The First People's Hospital of Kunshan (China)

Who is the main contact?
For more information, you can contact lichong1705@163.com or sgu8434@sina.com

Contact information

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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
Effect of customized 3D-printed foot orthoses on time-dependent improvement of foot function in patients with flatfoot: a randomized controlled trial

Study objectives
Flatfoot impairs function and quality of life through pain and gait limitations. Despite widespread use of foot orthoses, evidence for their efficacy in adult flexible flatfoot remains inconsistent, with traditional fabrication methods facing cost, comfort, and turnaround limitations. This randomized controlled trial (RCT) evaluated whether customized 3D-printed foot orthoses enhance functional outcomes when added to standard conservative care.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/07/2024, The First People’s Hospital of Kunshan (Room 309, Research Building, Jiangsu, 215300, China; +86 (0)512-57029732; lichong1705@163.com), ref: 2024-03-029-H01-K00

Study design
Single-center randomized parallel-group controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment, 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
Flat feet

Interventions

The study employed a parallel-group randomization design with a 1:1 allocation ratio. The randomization sequence was generated by an independent statistics unit using SAS software (version 9.4, SAS Institute, Cary, NC). Block randomization was utilized to ensure balanced group sizes. Upon screening, each participant was assigned a unique screening code and number (format SYYXXX, where “YY” denotes the center code and “XXX” the screening sequence at that center) for identification. After confirming eligibility, participants were formally enrolled and then randomly allocated to either the insole group or the control group according to the predefined randomization schedule. Each enrolled subject received a randomization identifier (format AYYXXX) corresponding to their inclusion order (with “A” indicating formal assignment and the same “YY” center code). Assignment to a group was thus concealed until the point of allocation. Due to the nature of the intervention, participants and treating clinicians could not be fully blinded to the group. However, outcome assessors were not involved in treatment and were kept unaware of each participant’s group whenever possible. The statisticians performing the data analysis were also blinded to group labels, analyzing group data as “Group 1” vs “Group 2” until final unblinding for interpretation.

Control Group (Standard Care): Participants in the control group received physician-prescribed basic treatment for flatfoot, serving as the standard conservative management. This regimen included a combination of: foot and lower leg exercises, advice on proper footwear, weight management guidance for those overweight, physical therapy modalities as needed, recommendations for rest and ice application in case of pain or after prolonged activity, short-term use of analgesic or anti-inflammatory medication if required, and general lifestyle modifications. These measures were individualized to each patient’s condition by the treating physician. Participants in the control group were instructed to adhere to this conservative management program consistently for three consecutive months.

Insole Group (Customized 3D-Printed Foot Orthoses + Standard Care): Participants in the insole group received standard care plus customized 3D-printed foot orthoses fabricated through a digital workflow: anatomical foot scanning captured precise geometry, coupled with intelligent morphology analysis to classify foot types and optimize design algorithms. The resulting multi-layer insoles featured biomechanical components—a core 3D-printed nylon arch support with Artificial Cartilage Foam (ACF) for impact energy dissipation via viscoelastic hysteresis; an intermediate OrthoLite foam cushioning layer for shock absorption; a breathable antimicrobial textile surface with silver-ion impregnation; and a high-density EVA base with micro-grooved anti-slip patterning for stability. After fitting, physicians instructed participants on proper use and break-in protocols, mandating daily wear (≥24 days/month) during the 3-month intervention by inserting customized 3D-printed foot orthoses into regular footwear. Compliance and adverse effects were monitored through scheduled follow-up calls.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Customized 3D-printed foot orthoses

Primary outcome measure
Overall foot function is measured using the Foot and Ankle Ability Measure (FAAM) score at baseline, 1, 2 and 3 months

Secondary outcome measures
1. Daily activity functions are measured using the Foot and Ankle Ability Measure (FAAM) - Activities of Daily Living (ADL) score at baseline, 1, 2 and 3 months
2. Sports function is measured using the Foot and Ankle Ability Measure (FAAM) - Sports score at baseline, 1, 2 and 3 months
3. Pain is measured using the Numerical Rating Scale (NRS) for pain at baseline, 1, 2 and 3 months

Overall study start date
05/07/2024

Completion date
31/01/2025

Eligibility

Key inclusion criteria
1. Age 18-65 years, male or female, capable of independent cooperation and orthotic insole usage.
2. Physician-confirmed diagnosis of flatfoot during screening.
3. No prior treatment received for the condition after symptom onset.
4. Absence of other foot disorders (e.g., foot ulcers, diabetic foot).
5. Agreement to avoid pregnancy from informed consent signing through trial completion.
6. Full understanding of trial objectives, procedures, and risks; voluntary participation with signed informed consent before any study procedures.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
200

Total final enrolment
200

Key exclusion criteria
1. Unauthorized use of non-protocol drugs/medical devices during the trial.
2. Cognitive impairment preventing treatment cooperation.
3. Flatfoot deemed by a physician to require surgical intervention (conservative treatment failure).
4. Foot-related topical agents, physical therapy, or rehabilitation within 1 month before screening, or concurrent treatments affecting efficacy.
5. History of foot surgery within 12 months before screening or planned surgery during the trial.
6. Use of anesthetics, opioids, antispasmodics, long-acting NSAIDs (e.g., piroxicam, meloxicam, nabumetone, etoricoxib), or other efficacy-impacting drugs within 7 days before screening.
7. Foot/ankle pain unrelated to structural abnormalities (e.g., neurological disorders, rheumatoid conditions, trauma, referred pain).
8. Severe primary diseases (cardiovascular, hepatic, renal, hematopoietic) or psychiatric disorders.
9. Other investigator-determined unsuitability or voluntary withdrawal.

Date of first enrolment
31/07/2024

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
China

Study participating centre
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Hospital/treatment centre

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ROR
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Funder(s)

Funder type
Hospital/treatment centre

Funder Name
First People’s Hospital of Kunshan

Results and Publications

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

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated and /or analysed during the current study will be published as a supplement to the result publication

IPD sharing plan summary
Published as a supplement to the results publication