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# BigTOE Trial

**Submission date**
14/11/2024

**Recruitment status**
Recruiting

**Registration date**
18/12/2024

**Overall study status**
Ongoing

**Last Edited**
17/11/2026

**Condition category**
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
Arthritis of the big toe joint, where the big toe joins the rest of the foot, is very common. It causes pain, swelling and stiffness in the joints, which can often get worse when walking. Living with big toe joint arthritis can affect people's day-to-day activities and impact whether they can work, what type of work they can do, and their enjoyment of other activities and hobbies. The best way of helping people living with painful big toe arthritis is not known. Some types of shoe inserts may help reduce pain which might make it easier to walk and do daily activities. This is a large research study (a clinical trial) to find out if shoe inserts can help people with big-toe arthritis. It is also unknown if one type of shoe insert is better than another for people with big-toe arthritis. This study will test two different types of shoe inserts to find out if they reduce pain, help people walk and have a better quality of life.

Who can participate?
People over 18 years old who have painful arthritis in their big toe joint

What does the study involve?
Participants will be asked to wear an insert in their shoes for their affected feet. They will also be asked to complete four more questionnaires over the next 12 months. These will ask about the pain in their toes and feet, their walking and daily activities, and if their health has changed over time. They will be asked how they are getting on with wearing your shoe inserts. They may also be asked to take part in a short interview with a researcher, but they do not have to do this if they do not want to.

What are the possible benefits and risks of participating?
Benefits:
The team cannot promise that this research study will help you directly. The information from this study will help the NHS decide if these shoe inserts could help other people with painful big-toe arthritis in the future.

Risks:
The shoe inserts are already used in NHS hospitals and clinics. There are no expected serious risks to participants. Some people may experience discomfort whilst getting used to their inserts, for example, skin irritation or blisters. If this continues, or foot symptoms become worse, participants should contact their healthcare practitioner or the clinical team who gave them to

them. One possible disadvantage of taking part is the inconvenience of having to complete questionnaires. The research team have worked with people with big-toe arthritis to make sure the questionnaires are as short as possible.

Where is the study run from?
The study is led by a research team at Warwick Clinical Trials Unit at the University of Warwick. The team includes experts in clinical trials, statistics, health economics and people with big-toe arthritis (patient representatives).

When is the study starting and how long is it expected to run for?
The study opened to recruitment in April 2025, and is due to complete recruitment in December 2026. The last questionnaires will be due in December 2027.

Who is funding the study?
National Institute for Health and Care Research Health Technology Assessment (NIHR HTA) Programme. The study is sponsored by the University of Warwick.

Who is the main contact?
Mrs Lauren Betteley, Clinical Trial Manager, bigtoetrial@warwick.ac.uk

# Contact information

### Type(s)
Principal investigator


### Contact name
Dr Michael Backhouse

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### Type(s)
Public, Scientific


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Mrs Lauren Betteley

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# Additional identifiers

### Integrated Research Application System (IRAS)
346977

### Central Portfolio Management System (CPMS)
56204

### National Institute for Health and Care Research (NIHR)
157097

### Protocol serial number
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC) Grant Codes:

# Study information

### Scientific Title
Big Toe OstEoarthritis (BigTOE) Trial: Inserts

### Acronym
BigTOE

### Study objectives
For people living with painful first metatarsophalangeal joint (MTPJ) osteoarthritis (OA), shoe inserts of different compositions may improve foot function, foot pain, health-related quality of life (HRQoL), and other health-related outcomes over three months and are cost-effective over one year.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 18/12/2024, Yorkshire & The Humber - Sheffield Research Ethics Committee (NHS Blood and Transplant Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)2071048139, (0)2071048135, (0)207 104 8210; sheffield.rec@hra.nhs.uk), ref: 24/YH/0240

### Primary study design
Interventional

### Study design
Randomized controlled trial

### Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Joint Disorders (Inflammatory); first metatarsophalangeal joint (MTPJ) osteoarthritis (OA)

## Interventions
Participants will be randomly allocated to receive one of two different types of insert. Each insert is made of different materials. Randomisation will take place after informed consent is given and baseline data collection is completed. Randomisation will be conducted by minimisation with a random factor in a 1:1 ratio and stratified by recruitment site, whether one or both feet have OA disease (unilateral/bilateral). This means neither the participant nor the clinical team can choose which group participants will be put in, ensuring the shoe inserts can be compared fairly.

After getting a shoe insert fitted, the research team at the University of Warwick will get in touch with the participants to ask them to fill out follow-up questionnaires. These will be due after one, three, six and 12 months. Participants will be sent a text message to let them know these are due and sent an email link so they can complete them online. Paper questionnaires which can be completed and returned to the study team by freepost will also be available. Additional texts will be sent to check if the questionnaire has been received and also to remind them to complete it if not yet been returned.

Qualitative interviews
Interviews will be conducted with participants and healthcare practitioners who consent to interview to explore experiences of taking part in the trial.

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Shoe inserts

## Primary outcome(s)
Foot function is measured using the Manchester Oxford Foot Questionnaire (MOxFQ) standing /walking subscale at 3 months

## Key secondary outcome(s)
The following secondary outcome measures are assessed at baseline, 1, 3, 6 and 12 months:
1. Foot-related quality of life (QoL) is measured using the Manchester Oxford Foot Questionnaire (MOxFQ) standing/walking subscale
2. Pain is measured using average pain intensity in the index 1st MTPJ & index foot recalled over the last week using a Numerical Rating Scale (NRS)
3. Health-related quality of life is measured using the EQ-5D-5L
4. Insert adherence is measured using participant-reported adherence
5. Analgesic use is measured using participant-reported analgesic use
6. Healthcare resource use is measured using participant-reported healthcare resource use
7. Global rating of change is measured using a Global Rating of Change (GROC) NRS

8. Adverse events are measured using Adverse Event and Serious Adverse Event forms
9. Normal shoe insert outcomes are measured using participant-reported problems with shoe inserts

### Completion date
31/07/2027

## Eligibility

### Key inclusion criteria
To be eligible to be included in the BigTOE Trial, patients must meet all of the following criteria:
1. Diagnosis of 1st MTPJ OA in one or both feet
2. Activity-related joint pain ≥4 on a 0-10 (NRS) in 1st MTPJ present for at least three months
3. Aged ≥18 years at the time of randomisation
4. Willing to provide written informed consent

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 Years

### Upper age limit
120 Years

### Sex
All

### Total final enrolment
0

### Key exclusion criteria
Current key exclusion criteria as of 14/10/2026:

1. Pain primarily on the plantar (underside) aspect of the index 1st MTPJ, suggestive of sesamoid pathology
2. Morning joint-related stiffness or morning stiffness in any joint throughout the body that lasts longer than 30 minutes.
3. Clinical suspicion or previous diagnosis of:
3.1. Inflammatory arthritis: rheumatoid, psoriatic, reactive, enteropathic, or axial spondyloarthritis,
3.2. Connective tissue disease: Systemic Lupus Erythematosus, systemic sclerosis, Sjorgren’s, polymyositis, or dermatomyositis
3.3. Septic arthritis in index joint

3.4. Crystal arthropathy (gout, or calcium pyrophosphate crystal deposition (pseudogout))
4. History of surgery or clinically important trauma to the foot or ankle in either foot/ankle in the last 12 months
5. Planned foot or ankle surgery in either foot/ankle within the next 12 months
6. Corticosteroid injection therapy in the index foot or ankle within last three months
7. Used an insole for either foot, prescribed by a health professional, within the last three months
8. Have moderate or severe grade 3 or 4 hallux valgus in the index foot using the Manchester Scale
9. Previous randomisation in the present trial (i.e. for contralateral 1st MTPJ)

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Previous key exclusion criteria:

1. Pain primarily on the plantar (underside) aspect of the 1st MTPJ, suggestive of sesamoid pathology
2. Morning joint-related stiffness or morning stiffness that lasts longer than 30 minutes
3. Clinical suspicion or previous diagnosis of:
3.1. Inflammatory arthritis: rheumatoid, psoriatic, reactive, enteropathic, or axial spondyloarthritis
3.2. Connective tissue disease: Systemic Lupus Erythematosus, systemic sclerosis, Sjogren's, polymyositis, or dermatomyositis
3.3. Septic arthritis in index joint
3.4. Crystal arthropathy (gout, or calcium pyrophosphate crystal deposition (pseudogout))
4. History of surgery or clinically important trauma to the foot and ankle in either foot in the last 12 months
5. Planned foot and ankle surgery in either foot within the next 12 months
6. Corticosteroid injection therapy in the index foot within the last three months
7. Used an insole, prescribed by a health professional, within the last three months
8. Have moderate or severe grade 3 or 4 hallux valgus (bunions) using the Manchester Scale
9. Previous randomisation in the present trial (i.e. for contralateral 1st MTPJ)

### Date of first enrolment
17/04/2025

### Date of final enrolment
31/12/2026

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Midlands Partnership University NHS Foundation Trust**
Trust Headquarters

St Georges Hospital
Corporation Street
Stafford
England
ST16 3SR

**Study participating centre**
**University Hospital Southampton**
Southampton University Hospital
Tremona Road
Southampton
England
SO16 6YD

**Study participating centre**
**East Sussex Healthcare NHS Trust Hq**
St. Annes House
729 the Ridge
St. Leonards-on-sea
England
TN37 7PT

**Study participating centre**
**Dorset Healthcare University NHS Foundation Trust**
Sentinel House
4-6 Nuffield Road
Nuffield Industrial Estate
Poole
England
BH17 0RB

**Study participating centre**
**Salisbury District Hospital**
Odstock Road
Salisbury
England
SP2 8BJ

**Study participating centre**
**Torbay Hospital**
Newton Road

Torquay
England
TQ2 7AA

**Study participating centre**
**Freeman Hospital**
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

**Study participating centre**
**John Radcliffe Hospital**
Headley Way
Headington
Oxford
England
OX3 9DU

**Study participating centre**
**Hounslow and Richmond Community Healthcare NHS Trust**
Thames House
180-194 High Street
Teddington
England
TW11 8HU

**Study participating centre**
**Leeds Community Healthcare NHS Trust**
3 White Rose Office Park
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LS11 0DL

**Study participating centre**
**Walsgrave General Hospital**
Clifford Bridge Road

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**Study participating centre**
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**Study participating centre**
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# Sponsor information

**Organisation**
University of Warwick

**ROR**
https://ror.org/01a77tt86

# Funder(s)

**Funder type**
Government

**Funder Name**
Health Technology Assessment Programme

**Alternative Name(s)**
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

**Funding Body Type**

Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan
Individual participant data-sharing plan: De-identified individual participant-level data will be available following publication of the primary trial results. The data-sharing pack will include de-identified participant data and a data dictionary. Researchers may request access by contacting Warwick Clinical Trials Unit at WCTUDataAccess@warwick.ac.uk. Data will be available upon reasonable request, in accordance with participant consent and applicable ethical and legal requirements. Requests will be reviewed through WCTU's data-sharing procedures. Approved access will be subject to completion of a signed data-sharing agreement. Data will be provided only for an approved research purpose, and no identifiable participant information will be shared. The full trial protocol and Statistical Analysis Plan will be made publicly available as supplementary materials linked to the published trial report. Data will be available following publication of the primary trial results and for a minimum of 10 years. Any changes to this data-sharing plan will be updated in the ISRCTN registry record and reported in the Data Availability Statement of the relevant trial report.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | V3.0 | | 17/11/2026 | No | No |
| Protocol (other) | | 04/04/2025 | 17/11/2026 | No | No |
| Study website | | 11/11/2025 | 11/11/2025 | No | Yes |