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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
18/12/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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?
June 2024 to July 2027. The study is due to begin recruitment in early 2025. The last questionnaires are anticipated to be collected in July 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

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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)
submitted 18/10/2024, 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

Study design
Randomized controlled trial

Primary study design
Interventional

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
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Any of the following:-
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
17/02/2025

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Midlands Partnership University NHS Foundation Trust
Trust Headquarters
St Georges Hospital
Corporation Street
Stafford
United Kingdom
ST16 3SR

Study participating centre
University Hospital Southampton
Southampton University Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

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

Study participating centre
Dorset Healthcare University NHS Foundation Trust
Sentinel House
4-6 Nuffield Road
Nuffield Industrial Estate

Poole
United Kingdom
BH17 0RB

Study participating centre
Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
Torbay Hospital
Newton Road
Torquay
United Kingdom
TQ2 7AA

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

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

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

Study participating centre
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Clifford Bridge Road
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United Kingdom
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Study participating centre
Midlands Partnership University NHS Foundation Trust
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ST16 3SR

Study participating centre
Southampton General Hospital
Tremona Road
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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
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes