



BigTOE Inserts Trial: Initial Study Summary Information

Study Title	Big Toe Osteoarthritis Trial: Inserts
Study Acronym:	BigTOE Inserts
CPMS ID:	56204
IRAS:	328691
CIs/Sponsor:	Dr Michael Backhouse & Prof Julie Bruce, University of Warwick
Specialty:	MSK (Podiatry, Orthotics)
Contact Details:	Trial Manager: Lauren Betteley: bigtoetrial@warwick.ac.uk

Expression of Interest Opportunity

This is an exciting, new clinical trial that will test shoe stiffening insoles for people with painful big toe osteoarthritis. We are looking for clinical sites who treat adults with big toe osteoarthritis. Please see the below information including the scientific summary of the study. Please do get in contact if you have any questions, would like further information or would like to attend one of our online information sessions.

What's involved for sites?

We've designed the trial so that it has minimal impact on your service. Once open to recruitment following study setup, mainly identifying eligible patients, taking consent and providing the inserts with advice about their use. All other research outcomes collected up to 1 year will be organised by the University of Warwick team, so no additional clinic visits are required.

Intervention: – People will be given either carbon fibre shoe stiffening insoles or asked to wear other (sham) inserts and then everyone will continue with usual care. People will be randomised equally to either treatment group.

Advantages for your team:

- We are keen to support research and advanced practice.
- We are very keen to work with sites who are new to research and to support you through this process.
- The study is registered to the NIHR associate principal investigator training scheme.

Scientific Summary

<p>Design:</p>	<p><u>Background</u> Osteoarthritis (OA) of the first metatarsophalangeal joint (1st MTPJ) is a progressive, lifelong condition that becomes more prevalent with age. Few studies have investigated whether carbon fibre shoe inserts can help reduce pain, improve function and quality of life. This will be the first UK study to investigate these inserts for people with painful 1st MTPJ OA.</p> <p><u>Research question</u> What is the clinical and cost-effectiveness of carbon fibre inserts compared to sham inserts, for people with painful 1st MTPJ OA?</p> <p><u>Design</u> Multicentre, parallel group, participant-blinded sham-controlled randomised controlled trial (RCT) with internal pilot, embedded process evaluation and cost-effectiveness evaluation. A UK randomised controlled clinical trial.</p> <p><u>Setting</u> We want to work with any NHS sites providing treatment for people with painful 1st MTPJ OA. This includes podiatry, orthotics, physiotherapy, and orthopaedic/foot and ankle surgery units based in secondary and community care.</p> <p><u>Participants</u> People (n=438) with painful 1st MTPJ OA seeking treatment through the NHS.</p> <p><u>Outcomes</u> Collected at baseline, then at 1, 3, 6 and 12 months via questionnaires organised by the University of Warwick team, so no additional clinic visits required.</p> <p>Primary Outcome: function at 3 months post-randomisation, measured using the Manchester Oxford Foot Questionnaire (MOxFAQ) standing/walking subscale.</p>
<p>Inclusion Criteria:</p>	<ul style="list-style-type: none"> • People aged 18 ≥ years and over with the diagnosis of 1st MTPJ OA in one or both feet as per NICE NG226 • Pain score >4 (numerical rating scale (NRS) 0-10) in the index joint present for at least 12 weeks <p><i>People with bilateral disease will be included but only one toe joint, the most painful, will be randomised</i></p>
<p>Exclusion Criteria:</p>	<ul style="list-style-type: none"> • Pain predominantly on the plantar aspect of the 1st MTPJ, suggestive of sesamoid pathology. • Clinical suspicion or previous diagnosis of inflammatory arthritis, connective tissue disease, septic arthritis, or crystal arthropathy • History of surgery or clinically important trauma to the foot and ankle in either foot in the last 12 months, or planned foot and ankle surgery in either foot within the next 12 months. • Corticosteroid injection therapy on the index foot within last three months. • Used an insole, prescribed by a health professional, within the last three months. • Have moderate or severe grade 3 or 4 hallux valgus using the Manchester Scale.
<p>Funding:</p>	<p>The Trial is funded by the NIHR Health Technology Assessment Programme.</p>
<p>Expected site target:</p>	<p>We want at least 25 sites based either in community or secondary care recruiting at any point, so are keen to hear from as many sites as possible.</p>
<p>Planned recruitment start & end date:</p>	<p>Start Date: December 2024.</p> <p>End Date: End of July 2026.</p>

Response and queries to:	<p>Trial Manager: Lauren Betteley: bigtoetrial@warwick.ac.uk</p> <p>Chief Investigator: Dr Mike Backhouse: michael.backhouse@warwick.ac.uk</p>
Target response date:	June 1 st 2024
Additional information:	<p>Site Requirements</p> <p>The attached Feasibility Questions Sheet contains questions that we hope will help determine suitability to take part.</p> <p>We are very keen to work with sites who are not as experienced in conducting research, and would work with you to provide the support needed to enable your participation. We will be able to work with sites to aid in operationalising the research to your local processes.</p> <p>Site recruitment targets will vary determined on site capacity and patient population, but we would be looking for a minimum of 1 patient a month.</p> <p>Registered Associate PI Scheme Study</p> <p>Please be aware that this study is registered onto the Associate PI Scheme. There are many benefits of becoming a recruiting site for a study registered onto the scheme, such as providing opportunities to upskill your workforce and raise awareness of clinical research, as well as there being an extra pair of hands for study delivery, etc.) Data suggests that sites with an Associate PI recruit up to three times more participants than other sites. To find out more about the Scheme and its opportunities please visit our website linked here. https://www.nihr.ac.uk/health-and-care-professionals/training/associate-principal-investigator-scheme.htm Alternatively please contact us at associatepiscHEME@nihr.ac.uk</p>