



The BigTOE Trial: A Multicentre Randomised Controlled Trial Testing Carbon-Fibre Shoe-Stiffening Inserts for 1st MTPJ Osteoarthritis



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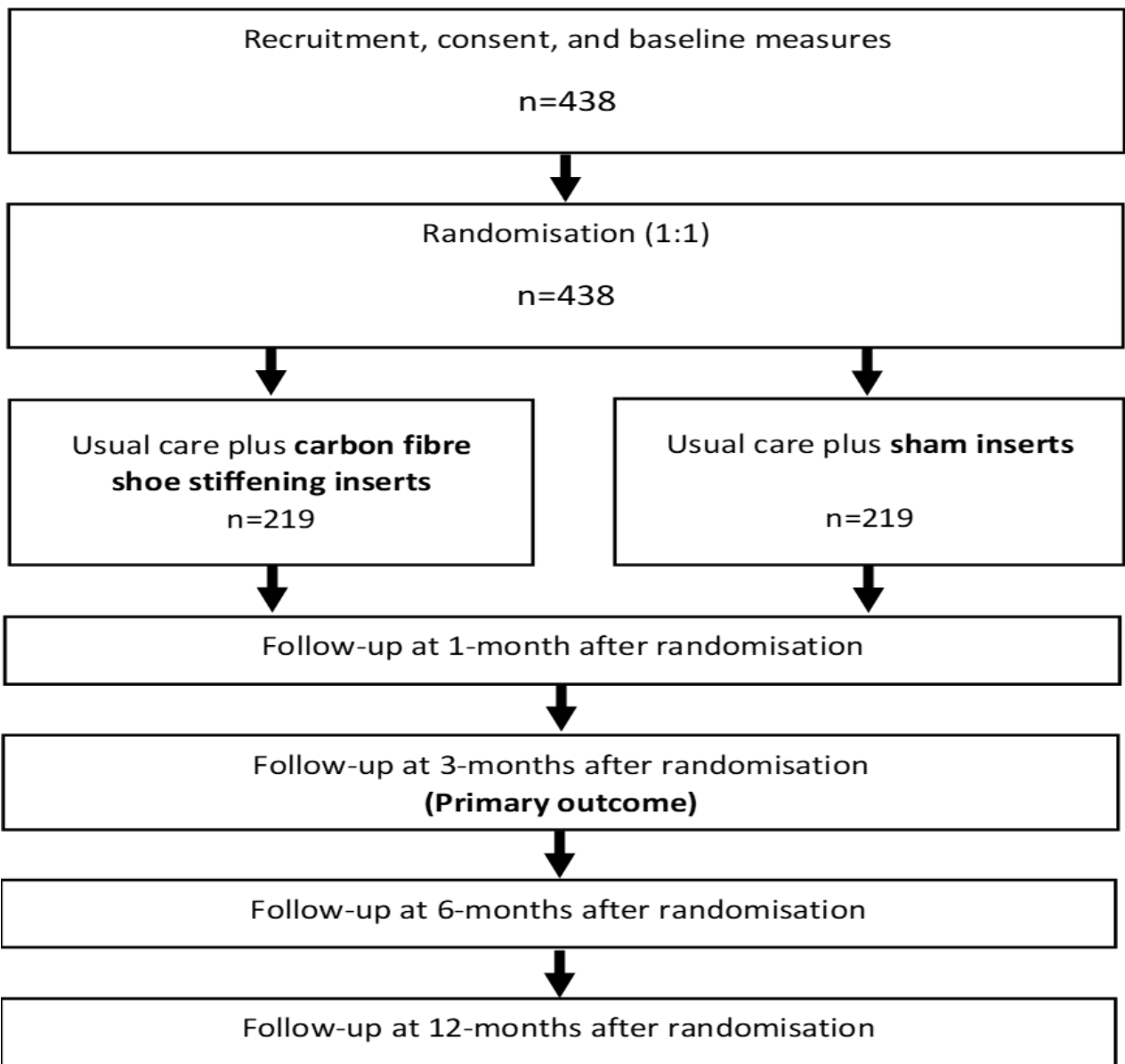
Background

- Painful big toe joint (1st MTPJ) OA is common and disabling; NHS care varies and current guidelines lack foot-specific advice
- Evidence for management mostly from other joints
- Trials of carbon-fibre inserts suggest may reduce dorsiflexion, improve pain & function, but these are small and poor quality

Aim: To compare carbon-fibre vs sham inserts on pain, function, HRQoL and healthcare costs

Method

Trial Design: Pragmatic, multicentre, participant blinded, sham controlled RCT



Inclusion criteria

- ✓ Activity-related pain ≥ 4/10 in 1st MTPJ for 3 or more months
- ✓ Aged ≥18 years with a diagnosis of 1st MTPJ OA (as per NICE NG226)

Exclusion criteria

- ✗ Pain on the plantar surface suggestive of sesamoid pathology
- ✗ Morning stiffness >30 mins
- ✗ Connective tissue disease
- ✗ Septic, inflammatory, or crystal arthritis
- ✗ Recent or planned foot/ankle surgery
- ✗ Steroid injection or insole use within last 3 months
- ✗ Moderate or Severe hallux valgus
- ✗ Previously enrolled in trial

Interventions



Layers	Sham	Carbon Fibre
Top	0.8mm lining material	0.8mm lining material
Foam	3mm green urethane polymer	3mm green urethane polymer
Carbon Fibre	none	1.6mm carbon fibre
Bottom	0.8mm lining material	0.8mm lining material

Study Outcomes

Primary outcome at 3 months

Manchester Oxford Foot Questionnaire (MOxFAQ) walking/standing subscale at three months

Secondary outcomes

- MOxFAQ (pain & social interaction scales & summary index)
- Pain whilst walking (NRS)
- EQ-5D-5L
- Healthcare resource use
- Adverse Events & Serious Adverse Events

Key Dates and Study Progress

- Recruitment started: May 2025
- Pilot phase ends: January 2026
- Recruitment ends: July 2026
- Trial completes: November 2027

As of October 2025
18 NHS sites opened
76 patients randomised

Discussion

- Trial codesigned with patients & clinicians, with a low burden on NHS sites
- Trial is testing a simple, scalable orthotic intervention in a national UK trial
- Trial results are due end 2027 – if effective & cost-effective, carbon-fibre inserts could be rapidly implemented across services

This trial is recruiting. Please contact the team if your site would like to be involved. The BigTOE trial will provide evidence for treatment of symptomatic 1st MTPJ OA.

Acknowledgments

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References

- Roddy E, et al. 2015. Ann Rheum Dis 74(1):156–163.
- Bannuru RR, et al. 2019. Osteoarthritis Cartilage 27(11):1578–1589.
- NICE. 2022. NG226: Osteoarthritis in over 16s.
- Paterson KL, et al. 2020. J Foot Ankle Res 13(1):14.

