

# Plaster cast versus functional bracing for Achilles tendon rupture: the UKSTAR RCT

Matthew L Costa,<sup>1\*</sup> Juul Achten,<sup>1</sup>  
Susan Wagland,<sup>1</sup> Ioana R Marian,<sup>1</sup>  
Mandy Maredza,<sup>2</sup> Michael Maia Schlüssel,<sup>1</sup>  
Anna S Liew,<sup>1</sup> Nick R Parsons,<sup>3</sup>  
Susan J Dutton,<sup>1</sup> Rebecca S Kearney,<sup>2</sup>  
Sarah E Lamb,<sup>1,4</sup> Benjamin Ollivere<sup>5</sup>  
and Stavros Petrou<sup>2,6</sup> on behalf of the UKSTAR  
Trial Management Group

<sup>1</sup>Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK

<sup>2</sup>Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, Coventry, UK

<sup>3</sup>Statistics and Epidemiology Unit, Warwick Medical School, University of Warwick, Coventry, UK

<sup>4</sup>College of Medicine and Health, University of Exeter, Exeter, UK

<sup>5</sup>Division of Rheumatology, Orthopaedics and Dermatology, School of Medicine, Queen's Medical Centre Nottingham, University of Nottingham, Nottingham, UK

<sup>6</sup>Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, UK

\*Corresponding author [matthew.costa@ndorms.ox.ac.uk](mailto:matthew.costa@ndorms.ox.ac.uk)

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## Scientific summary

### The UKSTAR RCT

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# Scientific summary

## Background

Achilles tendon rupture affects > 11,000 people each year in the UK, leading to prolonged periods away from work, sports and social activities. Traditionally, after a ruptured tendon, the foot and ankle are immobilised in a plaster cast for  $\geq 8$  weeks. Functional bracing is an alternative treatment that allows patients to mobilise earlier, but there is little evidence about how it affects overall recovery.

## Objectives

To measure the Achilles Tendon Rupture Score, quality of life, complications, including re-rupture, and resource use of patients receiving non-operative treatment for acute Achilles tendon rupture, treated with plaster cast compared with functional brace.

## Design

This was a pragmatic, multicentre randomised controlled trial.

## Setting

The setting was 39 hospitals in the UK NHS.

## Participants

A total of 540 adult patients treated non-operatively for Achilles tendon rupture were randomised from July 2016 to May 2018 (266 patients in the plaster cast group and 274 patients in the functional brace group). Patients were excluded if they presented more 14 days after their injury, had suffered a previous rupture of the same Achilles tendon or were unable to complete questionnaires.

## Interventions

A total of 266 participants were randomised to receive a below-knee plaster cast applied in the 'gravity equinus' position (i.e. the position that the foot naturally adopts when unsupported). In this position, with the toes pointing down towards the floor, the ends of the ruptured tendon are roughly approximated. The participants were permitted to mobilise with crutches immediately using their toes for balance (toe-touch), but were not able to bear weight on the injured hindfoot. Over the first 8 weeks, as the tendon was healing, the participants returned to hospital and the position of the plaster cast was changed gradually until the foot achieved plantigrade (i.e. the foot was flat on the floor). At this point the patient was permitted to start to bear weight in the plaster cast. The number of changes of plaster cast and the time to weight-bearing were left to the discretion of the treating clinician, as per their usual practice. The cast was removed at 8 weeks. The plaster cast provided maximum protection for the healing tendon, specifically restricting upwards movement (dorsiflexion) of the ankle, which may stretch the healing tendon, but it did not allow the patient to bear weight on the foot immediately or to move their ankle.

A total of 274 patients were randomised to the functional brace group. Initially, two solid heel wedges (or equivalent) were inserted inside the brace to replicate the 'gravity equinus' position of the foot. However, because the bottom of the brace was flat to the floor, the participant was able to mobilise with immediate full weight-bearing within the functional brace. The brace also permitted some movement at the ankle joint. The number of wedges and the foot position were changed over 8 weeks until the patient reached plantigrade. Again, the timing of the removal of wedges and the change in foot position were left to the discretion of the treating clinician, as per their usual practice. The brace was removed at 8 weeks, as per routine clinical care.

## Outcome measures

The primary outcome measure was the Achilles Tendon Rupture Score. The Achilles Tendon Rupture Score is patient reported and consists of 10 items assessing symptoms and physical activity related to the Achilles tendon that give a score between 0 and 100 (100 being the best possible outcome). Secondary outcomes were health-related quality of life (EuroQol-5 Dimensions) and complications, including re-rupture. Outcomes were collected at 8 weeks and 3, 6 and 9 months post injury.

We also collected data on resource use from the perspective of the NHS and Personal Social Services. A societal perspective for costs was adopted for the sensitivity analysis and this included private costs incurred by trial participants and their families, as well as productivity losses and loss of earnings as a result of work absences.

## Results

Participants had a mean age of 48.7 years, were predominantly male (79%) and had ruptured their tendon during sports (70%). Over 93% of participants completed follow-up.

There was no statistically significant difference in Achilles Tendon Rupture Score at 9 months post injury (-1.38, 95% confidence interval -4.9 to 2.1). There was a statistically significant difference in the Achilles Tendon Rupture Score at 8 weeks post injury in favour of the functional brace group (5.53, 95% confidence interval 2.0 to 9.1), but not at 3 or 6 months post injury. Health-related quality of life showed the same pattern, with a statistically significant difference at 8 weeks post injury but not at later time points. Complication profiles were similar in both groups. There were 17 (6.4%) cases of re-rupture of the tendon in the plaster cast group and 13 (4.7%) cases in the functional brace group.

The mean direct intervention costs were £36 for the plaster cast group and £109 for the functional brace group; the mean difference of £73 was statistically significant. However, by 8 weeks this difference had reversed, such that the mean total NHS and Personal Social Services costs were significantly lower in the functional brace group. The difference at 8 weeks post injury was mostly driven by the cost of extra outpatient appointments in the plaster cast group.

The mean total NHS and Personal Social Services cost throughout the entire follow-up period was £1183 for the plaster cast group and £1018 for the functional brace group. Although functional bracing was marginally cheaper, the mean between-group cost difference of £164 was not statistically significant.

In terms of health-related quality of life, the mean quality-adjusted life-year value was, on average, marginally higher for the functional brace group among complete cases and in the sensitivity analyses, although this mean difference was not statistically significant.

Therefore, as the functional brace group incurred slightly lower costs and achieved slightly better quality of life over the course of the study, in health economic terms, functional bracing is the dominant intervention.

## Conclusions

This trial provides strong evidence that early weight-bearing in a functional brace provides similar outcomes to those from traditional plaster casting and is safe for patients having non-operative treatment of Achilles tendon rupture. On average, functional brace is associated with lower costs and higher quality-adjusted life-years, but this finding was not replicated in sensitivity analysis conducted from the societal perspective.

## Future work

Although the UK Study of Tendo Achilles Rehabilitation provides guidance with regard to the early management of patients, rehabilitation following Achilles tendon rupture is prolonged and further research is required to define the optimal mode of rehabilitation after the initial cast/brace is removed.

## Trial registration

This trial is registered as ISRCTN62639639.

## Funding

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## This report

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