

# The Ankle Injury Management (AIM) trial: a pragmatic, multicentre, equivalence randomised controlled trial and economic evaluation comparing close contact casting with open surgical reduction and internal fixation in the treatment of unstable ankle fractures in patients aged over 60 years

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## Plain English summary

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## Plain English summary

An ankle fracture is an injury to bones of the ankle joint. If severe, the ankle joint may become unstable. Unstable ankle injuries are usually treated with surgery. The operation aligns and holds the bones in position with metal screws and/or plates during healing. In older adults surgery outcomes are uncertain because of bone and skin frailty. We developed a lower-leg cast called close contact casting (CCC) with the aim of offering an alternative to surgery.

We randomly allocated 620 participants from 24 NHS hospitals to either surgery or CCC. A researcher assessed participants before treatment and at 6 weeks and 6 months after randomisation. The assessments collected information on ankle function, quality of life, pain, joint flexibility, mobility, complications, patient satisfaction and NHS and personal health-care use. We also interviewed 36 participants.

Participants with CCC had very similar outcomes to surgical patients, but at reduced NHS and society costs. Wound problems or infections occurred in around 1 in 10 participants in the surgery group. Within 6 months, around 1 in 20 participants who initially received surgery required an additional surgical procedure. One in five participants who initially had CCC later had surgery because the cast could not always maintain good ankle alignment. Both groups struggled to live with the fracture and with the uncertainty about further treatment.

We are conducting follow-up of participants for at least 2 years to see if higher rates of poor ankle alignment and bone healing observed in the CCC group affect the overall outcome in the longer term.



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