[PO3] EVALUATION OF THE EFFECTIVENESS AND COST-EFFECTIVENESS OF LIGHTWEIGHT FIBREGLASS HEEL CASTS IN THE MANAGEMENT OF ULCERS THE HEEL IN DIABETES: A RANDOMISED CONTROLLED TRIAL

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Aim: Management of heel ulcers in diabetes is difficult: there is no specific treatment and the median time to healing exceeds 200 days. An uncontrolled pilot study presented to the DFSG in 2009 suggested that use of lightweight fibreglass heel casts might result acceleration of healing. The aim of this study was to undertake a formal evaluation by comparing outcome following the use of such heel casts in addition to usual standard care with standard care alone. The study was funded by the UK NIHR Health Technology Assessment programme.

Method: This was a randomised observer blind trial with patients randomised 1:1 to intervention or usual care, stratified by ulcer depth and cross-sectional area. The study was powered to detect a difference in healing of 15 percentage points (55% versus 40%). Participants were identified from 35 specialist diabetic foot services in UK. Soft tissue infection was not an exclusion criterion nor were peripheral artery disease of any severity or impaired renal function. Those in the intervention arm received usual care supplemented by the use of a lightweight fibreglass cast moulded from the participant's heel, applied over the primary dressing and held in place with tape/bandage. Participants were reviewed each two weeks when the ulcer was debrided (if necessary), cleaned and re-dressed. Dressing changes between clinic visits were undertaken by their usual clinical carer. The primary outcome was healing at or before 24 weeks. Secondary outcomes included time to healing, secondary infection, new ulceration, pain, incidence of minor and major amputation and health status. Health economic analysis was undertaken to assess the incremental cost per Quality Adjusted Life Year.

Results/Discussion: 509 participants (68% male; mean age 67.5±12.4 years) were recruited. Median ulcer area was 275 (25^{th}-75^{th} centile: 104-683) mm^2 and ulcer duration at baseline was at least 2 weeks. 256 and 253 participants were randomised to the intervention and control groups, respectively, and primary outcome data were available in 212 and 213. When analysed by intention to treat, 94 (44%) of the intervention group healed with 24 weeks of follow-up, compared with 80 (37%) in the control group (OR 1.42 (0.95, 2.14), p=0.088). Median adherence to the use of the intervention was 100%; findings were unaffected by *per protocol* analysis. There was no difference between groups in any other outcome measure or in adverse events. The costs in the two groups were not statistically different.

Conclusion: The study was conducted to a high standard. It was not possible to demonstrate clear benefit from the intervention.