Evaluation of the effectiveness and cost-effectiveness of lightweight fibreglass heel casts in the management of ulcers of the heel in diabetes: a randomised controlled trial

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Plain English summary

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U lcers of the heel in people with diabetes mellitus present a considerable risk of limb loss through amputation. However, one group has reported that a simple, moulded fibreglass heel cast may improve outcomes for such people. The purpose of this study was to formally evaluate this treatment. People with diabetes and heel ulcers attending specialist foot care centres in UK were allocated either to continue with usual care or to be provided with a fibreglass heel cast in addition to usual care, in order to assess whether or not the use of a cast increased the proportion of heel ulcers that healed within 24 weeks. The study was designed to see whether or not the number of ulcers healed could be increased by at least 15% (55% vs. 40%). A health economic analysis was also undertaken.

In total, 509 people were included in the study. The mean age of the participants was 67.5 years; 68% of the group were male and 15% of them had type 1 diabetes. Two hundred and fifty-six were allocated to the intervention group and 253 were allocated to the control (usual care) group. The percentage of ulcers that had healed by 24 weeks was 44% in the intervention group and 37% in the usual care group. However, this difference was not sufficient to prove that patients with diabetes mellitus and heel ulcers benefit from the use of fibreglass heel casts.

The health economic analysis found only very small differences between the groups, and we found no clear evidence that the heel cast device was good value for money for the NHS.

Although the provision of a lightweight heel cast may benefit some individuals, this study found no evidence to recommend that this be adopted in routine clinical practice.

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