

The effectiveness of at-home foot temperature monitoring in reducing the incidence of ulcer recurrence in people with diabetes: a multicentre randomized controlled trial (DIATEMP)

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Background: The skin of people with diabetic foot disease is suggested to heat up before it breaks down into ulceration. This allows for monitoring and early intervention to prevent ulcers. We assessed whether at-home plantar foot skin temperature monitoring can help prevent ulcer recurrence in people with diabetes

Methods: In this multicentre outcome-assessor blinded randomized controlled trial we assigned 304 people with diabetes, neuropathy and a healed foot ulcer (<4 years) or Charcot's neuro-arthropathy to usual care (i.e. podiatric care, education, and therapeutic footwear) or usual care plus measuring temperatures at 6-8 predefined plantar foot locations each day (enhanced therapy). With $\Delta T > 2.2^\circ\text{C}$ between left-to-right-foot corresponding regions for two consecutive days, participants were instructed to reduce ambulatory activity until this hotspot disappeared. Primary outcome was ulcer recurrence in 18 months on the plantar foot, interdigital, toe apical or medial/lateral forefoot surfaces (i.e. at or adjacent to the measurement sites). Secondary outcomes were ulcer recurrence in adherent participants and at any foot site.

Results: On the basis of intention-to-treat, 44 of 151 (29.1%) participants in enhanced therapy and 57 of 153 (37.3%) in usual care had ulcer recurrence (RR 0.782 [95%CI 0.566–1.080], $P=0.133$). Ulcer recurrence survival curves showed no significant group differences ($P=0.167$). Participants measuring foot temperature and reducing activity when finding a hotspot had fewer recurrences than those in usual care (RR 0.336 [95%CI 0.114-0.986], $P=0.017$). Enhanced therapy was effective over usual care for recurrence at any foot site (RR 0.760 [95%CI 0.579–0.997], $P=0.046$).

Discussion/Conclusion: At-home daily foot temperature monitoring does not significantly reduce incidence of diabetic foot ulcer recurrence at or adjacent to measurement sites over usual care, unless participants reduce their activity with hotspots found or when ulcers can occur at any foot site.