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

William Jeffcoate,[1]* Frances Game,[1,2] Vivienne Turtle-Savage,[1] Alison Musgrove,[1] Patricia Price,[3] Wei Tan,[4] Lucy Bradshaw,[4] Alan Montgomery,[4] Deborah Fitzsimmons,[5] Angela Farr,[5] Thomas Winfield[5] and Ceri Phillips[5]

[1]Foot Ulcer Trials Unit, Nottingham University Hospitals Trust, Nottingham, UK
[2]Diabetes and Endocrinology, Derby Teaching Hospitals NHS Foundation Trust, Derby, UK
[3]Vice-Chancellor's Office, Cardiff University, Cardiff, UK
[4]Nottingham Clinical Trials Unit, University of Nottingham, Nottingham, UK
[5]Swansea Centre for Health Economics, College of Human and Health Science, Swansea University, Swansea, UK

*Corresponding author william.jeffcoate@gmail.com

Declared competing interests of authors: none

Published May 2017
DOI: 10.3310/hta21340

Plain English summary

Heel casts in the management of ulcers of the heel in diabetes

Health Technology Assessment 2017; Vol. 21: No. 34
DOI: 10.3310/hta21340

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Plain English summary

Ulcers 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.

Health Technology Assessment

HTA/HTA TAR

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.058

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: http://www.nets.nihr.ac.uk/programmes/hta

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 09/01/53. The contractual start date was in February 2012. The draft report began editorial review in March 2016 and was accepted for publication in December 2016. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).