Pressure relieving support surfaces: a randomised evaluation

J Nixon,¹ EA Nelson,² G Cranny,¹ CP Iglesias,² K Hawkins,¹ NA Cullum,²* A Phillips,¹ K Spilsbury,² DJ Torgerson² and S Mason¹ on behalf of the PRESSURE Trial Group

¹ Clinical Trials Research Unit, University of Leeds, UK
² Department of Health Sciences, University of York, UK

* Corresponding author

Executive summary

Health Technology Assessment 2006; Vol. 10: No. 22
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Objectives
The primary objective of the PRESSURE (Pressure RElieving Support SUpfaces: a Randomised Evaluation) Trial was to determine whether there are differences between alternating pressure overlays and alternating pressure replacement mattresses with respect to the development of new pressure ulcers, healing of existing pressure ulcers, patient acceptability and cost-effectiveness of the different pressure-relieving surfaces. The secondary objective was to investigate the specific additional impact of pressure ulcers on patients’ well-being.

Methods

Design
A multicentre, randomised, controlled, open, fixed sample, parallel-group trial with equal randomisation was undertaken. The trial used remote, concealed allocation and intention-to-treat analysis. The main trial design was supplemented with a qualitative study involving a purposive sample of 20–30 patients who developed pressure ulcers, to assess the impact of the pressure ulcers on their well-being. In addition, a focus group interview was carried out with clinical research nurses, who participated in the PRESSURE Trial, to explore the experiences of their role and observations of pressure area care.

Setting
The study took place in 11 hospital-based research centres within six NHS trusts in the UK.

Participants
Acute and elective patients aged 55 years or older and admitted to vascular, orthopaedic, medical or care of the elderly wards in the previous 24 hours were investigated. Additional inclusion criteria were: (1) acute and elective patients with activity limitation/existing pressure ulcer on admission, who had an expected length of stay of 7 or more days; were bedfast or chairfast and completely immobile or had very limited mobility and/or had a pre-existing grade 2 pressure ulcer on admission; and gave their written informed consent to participate (or in unconscious or confused patients, the next of kin gave informed written relative assent); and (2) elective surgical patients with no activity limitation/existing pressure ulcer on admission, who were undergoing a surgical procedure with an average length of hospital stay of 7 or more days and/or expected to be bedfast or chairfast and immobile or to have very limited mobility for at least 3 days postoperatively; and gave their written informed consent to participate.

Patients were excluded from the study where they had participated in this trial during a previous admission; had a pre-existing grade 3, 4 or 5 pressure ulcer on admission; were an elective surgical patient with a planned postoperative admission to the intensive care unit; were an elective surgical patient admitted more than 4 days before surgery; slept at night in a chair; or weighed over 140 kg (upper weight limit for overlay mattress) or less than 45 kg (lower weight limit for replacement mattresses with automatic sensor mats).

Interventions
Patients were randomised to either an alternating pressure overlay or an alternating pressure mattress replacement, with mattress specifications clearly defined to enable the inclusion of centres using products from different manufacturers, and to exclude hybrid mattress systems (which either combine foam or constant low pressure with alternating pressure in one mattress, or can be used as either an overlay or a replacement mattress).

Main outcome measures
The primary end-point for the PRESSURE Trial was defined as the development of a new pressure ulcer (grade ≥ 2, i.e. partial-thickness wound involving epidermis/dermis only) on any skin site. Secondary end-points were healing of existing pressures ulcers, patient acceptability and cost-effectiveness.

Results
In total, 6155 patients were assessed for eligibility to the trial and 1972 were randomised: 990 to the
alternating pressure overlay (989 after one postrandomisation exclusion) and 982 to the alternating pressure mattress replacement. Intention-to-treat analysis found no statistically significant difference in the proportions of patients developing a new pressure ulcer of grade 2 or above [10.7% overlay patients, 10.3% mattress replacement patients, a difference of 0.4%, 95% confidence interval (CI) –2.3 to 3.1%, \( p = 0.75 \)]. When logistic regression analysis was used to adjust for minimisation factors and prespecified baseline covariates, there was no difference between the mattresses with respect to the odds of ulceration (odds ratio 0.94, 95% CI 0.68 to 1.29). There was no evidence of a difference between the mattress groups with respect to time to healing (\( p = 0.86 \)). The Kaplan–Meier estimate of the median time to healing was 20 days for each intervention. More patients allocated overlays requested mattress changes due to dissatisfaction (23.3%, \( p = 0.02 \)) and more than one-third of patients reporting difficulties associated with movement in bed and getting into or out of bed. There is a higher probability (64%) that alternating mattress replacements are cost-saving; they were associated with lower overall costs (£74.50 per patient on average, mainly due to reduced length of stay) and greater benefits (a delay in time to ulceration of 10.64 days on average). Patients' accounts highlighted that the development of a pressure ulcer could be pivotal in the trajectory from illness to recovery, by preventing full recovery or causing varied impacts on their quality of life.

Conclusions

There is no difference between alternating pressure mattress replacements and overlays in terms of the proportion of patients developing new pressure ulcers; however, alternating pressure mattress replacements are more likely to be cost-saving.

**Implications for healthcare**

The results suggest that when renewing alternating pressure surfaces or ordering equipment within a rental contract, mattress replacements should be specified; however, overlays are acceptable if no replacement mattress is available. Similarly, patient preferences can be supported, without any great increase in risk, if individual patients request an overlay rather than a replacement mattress.

**Recommendations for research**

The following areas are recommended for further investigation.

- A randomised controlled trial could compare alternating pressure mattress replacements and high-specification foam mattresses in patients at moderate to high risk (it may not be possible to answer this question in the UK, where alternating pressure surfaces have become the standard for at-risk patients).
- An accurate costing study should be undertaken to understand better how much pressure ulcers cost health and social services in the UK.
- Trials are needed in higher risk groups of patients, in whom serious pressure ulcers are more common and the consequences greater (e.g. people with spinal cord injuries).
- Future trials should measure time to ulceration as the primary end-point, since this is more informative economically and possibly also from a patient and clinical perspective.

**Publication**

The research findings from the NHS R&D Health Technology Assessment (HTA) Programme directly influence key decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC) who rely on HTA outputs to help raise standards of care. HTA findings also help to improve the quality of the service in the NHS indirectly in that they form a key component of the ‘National Knowledge Service’ that is being developed to improve the evidence of clinical practice throughout the NHS.

The HTA Programme was set up in 1993. Its role is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS. ‘Health technologies’ are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care, rather than settings of care.

The HTA Programme commissions research only on topics where it has identified key gaps in the evidence needed by the NHS. Suggestions for topics are actively sought from people working in the NHS, the public, service-users groups and professional bodies such as Royal Colleges and NHS Trusts.

Research suggestions are carefully considered by panels of independent experts (including service users) whose advice results in a ranked list of recommended research priorities. The HTA Programme then commissions the research team best suited to undertake the work, in the manner most appropriate to find the relevant answers. Some projects may take only months, others need several years to answer the research questions adequately. They may involve synthesising existing evidence or conducting a trial to produce new evidence where none currently exists.

Additionally, through its Technology Assessment Report (TAR) call-off contract, the HTA Programme is able to commission bespoke reports, principally for NICE, but also for other policy customers, such as a National Clinical Director. TARs bring together evidence on key aspects of the use of specific technologies and usually have to be completed within a short time period.

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Reports are published in the HTA monograph series if (1) they have resulted from work commissioned for the HTA Programme, and (2) they are of a sufficiently high scientific quality as assessed by the referees 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.

The research reported in this monograph was commissioned by the HTA Programme as project number 97/06/14. The contractual start date was in May 2000. The draft report began editorial review in February 2005 and was accepted for publication in September 2005. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. 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 referees 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.

The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme or the Department of Health.

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