

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

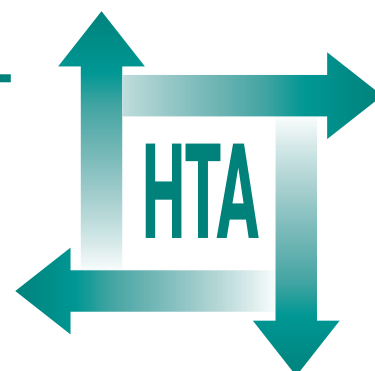
² Department of Health Sciences, University of York, UK

*  responding author

Executive summary

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Executive summary

Objectives

The primary objective of the PRESSURE (Pressure Relieving Support SURfaces: 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%) than mattress replacement patients (18.9%, $p = 0.02$) 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

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NHS R&D HTA Programme

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