



Title	Pressure Relieving Support Surfaces: A Randomized Evaluation
Agency	NCCHTA, National Coordinating Centre for Health Technology Assessment Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom; Tel: +44 2380 595586, Fax: +44 2380 595639
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Aim

To determine any differences between alternating pressure overlays and alternating pressure replacement mattresses with respect to development of new pressure ulcers, healing of existing pressure ulcers, patient acceptability, and cost effectiveness of different pressure relieving surfaces; and to investigate the specific additional impact of pressure ulcers on patients' wellbeing.

Conclusions and results

We assessed 6155 patients for eligibility to the trial, and randomized 1972 (990 to alternating pressure overlay and 982 to alternating pressure mattress replacement). Intention-to-treat analysis found no statistically significant difference in the proportions of patients developing a new pressure ulcer of \geq Grade 2 (10.7% overlay patients, 10.3% mattress replacement patients, a difference of 0.4%, 95% CI: -2.3%, 3.1%, $p=0.75$). Logistic regression analysis, used to adjust for minimization factors and prespecified baseline covariates, showed no difference between mattresses with respect to the odds of ulceration (odds ratio 0.94, 95% CI: 0.68, 1.29). There was no evidence of a difference between the mattress groups as regards 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 did mattress replacement patients (18.9%, $p=0.02$), with more than a third of patients reporting difficulties moving in bed and getting in/out of bed. There is a higher probability (64%) that alternating mattress replacements save cost; they were associated with lower overall costs (GBP 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.

Recommendations

No difference was found 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 save cost.

Methods

A multicenter, randomized, controlled, open, fixed-sample, parallel group trial with equal randomization. The main trial design was supplemented with a qualitative study involving a purposive sample of 20 to 30 patients who developed pressure ulcers, to assess the impact of pressure ulcers on well-being. A focus group was carried out with Clinical Research Nurses (CRNs), who participated in the PRESSURE trial to explore their role and observations of pressure area care.

Further research/reviews required

1. RCT comparing 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).
2. Trials to measure the time to ulceration as the primary endpoint since this is more informative economically and possibly from a patient and clinical perspective.
3. An accurate costing study to better understand the cost of pressure ulcers to health and social services in the UK.
4. Trials in higher risk groups of patients in whom serious pressure ulcers are more common and the consequences greater (eg, spinal cord injuries).
5. Epidemiological studies to determine whether people with diabetes are at higher risk of heel ulceration.