

Pressure ulcers

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ABSTRACT




INTRODUCTION: Unrelieved pressure or friction of the skin, particularly over bony prominences, can lead to pressure ulcers in up to one third of people in hospitals or community care, and one fifth of nursing home residents. Pressure ulcers are more likely in people with reduced mobility and poor skin condition, such as older people or those with vascular disease. **METHODS AND OUTCOMES:** We conducted a systematic review and aimed to answer the following clinical questions: What are the effects of preventive interventions in people at risk of developing pressure ulcers? What are the effects of treatments in people with pressure ulcers? We searched: Medline, Embase, The Cochrane Library, and other important databases up to June 2010 (Clinical Evidence reviews are updated periodically, please check our website for the most up-to-date version of this review). We included harms alerts from relevant organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA). **RESULTS:** We found 64 systematic reviews, RCTs, or observational studies that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions. **CONCLUSIONS:** In this systematic review we present information relating to the effectiveness and safety of the following interventions: air-filled vinyl boots, air-fluidised supports, alternating-pressure surfaces (including mattresses), alternative foam mattresses, constant low-pressure supports, debridement, electric profiling beds, electrotherapy, hydrocellular heel supports, low-air-loss beds (including hydrotherapy beds), low-level laser therapy, low-tech constant-low-pressure supports, medical sheepskin overlays, nutritional supplements, orthopaedic wool padding, pressure-relieving overlays on operating tables, pressure-relieving surfaces, repositioning (regular "turning"), seat cushions, standard beds, standard care, standard foam mattresses, standard tables, surgery, therapeutic ultrasound, topical lotions and dressings, topical negative pressure, and topical phenytoin.

QUESTIONS

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What are the effects of treatments in people with pressure ulcers?	20

INTERVENTIONS



PREVENTIVE INTERVENTIONS FOR PRESSURE ULCERS

 Beneficial	
Foam alternatives (compared with standard foam mattresses)	3
 Likely to be beneficial	
Pressure-relieving overlays on operating tables (compared with standard tables)	5
Low-air-loss beds in intensive care (more effective than standard beds; effects relative to alternating-pressure mattresses unclear)	6
Medical sheepskin overlays (compared with standard care)	7
 Unknown effectiveness	
Alternating-pressure surfaces	8
Seat cushions	10
Electric profiling beds	11
Low-tech constant-low-pressure supports	12
Nutritional supplements	13
Repositioning (including regular "turning")	14
Topical lotions and dressings	16
Hydrocellular heel supports (compared with orthopaedic wool padding)	18
Low-air-loss hydrotherapy beds (compared with other pressure-relieving surfaces)	19

Unlikely to be beneficial

Air-filled vinyl boots	17
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TREATMENTS FOR PRESSURE ULCERS

 Likely to be beneficial	
Air-fluidised supports (compared with standard care)	2
 Unknown effectiveness	
Alternating-pressure surfaces (compared with other specialised support surfaces)	21
Debridement	22
Dressings (one type versus any another type)	23
Electrotherapy	26
Low-air-loss beds	27
Low-level laser treatment	29
Low-tech constant-low-pressure supports (compared with other specialised support surfaces)	29
Nutritional supplements	30
Seat cushions	33
Surgery	34
Therapeutic ultrasound	34
Topical negative pressure	35
Topical phenytoin	36

Key points

- Unrelieved pressure or friction of the skin, particularly over bony prominences, can lead to pressure ulcers, which affect up to one third of people in hospitals or community care, and one fifth of nursing home residents.

Pressure ulcers are more likely in people with reduced mobility and poor skin condition, such as older people or those with vascular disease.

- **Alternative foam mattresses** (such as viscoelastic foam) reduce the incidence of pressure ulcers in people at risk compared with standard hospital foam mattresses, although we don't know which is the best alternative to use.

Low-air-loss beds may reduce the risk of pressure ulcers compared with standard intensive-care beds, and **pressure-relieving overlays** on operating tables may reduce the risk of pressure ulcer development.

Medical sheepskin overlays may reduce the risk of pressure ulcers compared with standard care.

- **Hydrocellular heel supports** may decrease the risk of pressure ulcers compared with orthopaedic wool padding, but **air-filled vinyl boots with foot cradles** and **low-air-loss hydrotherapy beds** may increase the risk of ulcers compared with other pressure-relieving surfaces.

We don't know if other physical interventions, such as **alternating-pressure surfaces**, **seat cushions**, **electric profiling beds**, **low-tech constant-low-pressure supports**, **repositioning**, or **topical lotions and dressings** are effective for preventing pressure ulcers. We also don't know whether pressure ulcers can be prevented by use of **nutritional interventions**.

- In people with pressure ulcers, **air-fluidised supports** may improve healing compared with standard care, although they can make it harder for people to get in and out of bed independently.
- We don't know whether healing is improved in people with pressure ulcers by use of other treatments such as one specific specialised support surface (including **alternating-pressure surfaces**, **low-tech constant-low-pressure supports**, **low-air-loss beds**, and **specific seat cushions**) over any other specific specialised support surface, one specific **wound dressing** over any other specific wound dressing, or with **surgery**, **electrotherapy**, **ultrasound**, **low-level laser therapy**, **topical negative pressure**, **topical phenytoin**, or **nutritional interventions**.

DEFINITION Pressure ulcers (also known as pressure sores, bed sores, and decubitus ulcers) may present as persistently hyperaemic, blistered, broken, or necrotic skin, and may extend to underlying structures, including muscle and bone. Pressure ulcers are usually graded on a scale of 1 to 4, with a higher grade indicating greater ulcer severity. ^[1]

INCIDENCE/ PREVALENCE Reported prevalence rates range from 4.7% to 32.1% for hospital populations, 4.4% to 33.0% for community-care populations, and 4.6% to 20.7% for nursing-home populations. ^[2]

AETIOLOGY/ RISK FACTORS Pressure ulcers are caused by unrelieved pressure, shear, or friction. They are most common below the waist and at bony prominences, such as the sacrum, heels, and hips. They occur in all healthcare settings. Increased age, reduced mobility, impaired nutrition, vascular disease, faecal incontinence, and skin condition at baseline consistently emerge as risk factors. ^[3] ^[4] However, the relative importance of these and other factors is uncertain.

PROGNOSIS There are few data on prognosis of untreated pressure ulcers. The presence of pressure ulcers has been associated with a two- to four-fold increased risk of death in elderly people and people in intensive care. ^[5] ^[6] However, pressure ulcers are a marker for underlying disease severity and other comorbidities, rather than an independent predictor of mortality. ^[5]

AIMS OF INTERVENTION To prevent formation of a pressure ulcer; heal existing pressure ulcers; and improve quality of life, with minimal adverse effects of treatment.

OUTCOMES **Prevention of pressure ulcers**, severity of pressure ulcers. **Healing rates**: rate of change of area and volume, time to heal, severity of pressure ulcers. **Adverse effects** of treatment. Interface pressure recorded at various anatomical sites is a surrogate outcome that is sometimes used in studies of preventive interventions, but has not yet been linked to clinical outcomes.

METHODS *Clinical Evidence* search and appraisal June 2010. The following databases were used to identify studies for this systematic review: Medline 1966 to June 2010, Embase 1980 to June 2010, and The Cochrane Database of Systematic Reviews, May 2010 [online] (1966 to date of issue). When editing this review we used The Cochrane Database of Systematic Reviews 2010, Issue 2. An additional search within The Cochrane Library was carried out for the Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment (HTA). We also searched for re-contractions of studies included in the review. Abstracts of the studies retrieved from the initial search were assessed by an information specialist. Selected studies were then sent to the contributor for additional assessment, using predetermined criteria to identify relevant studies. Study design criteria for inclusion in this review were: published systematic reviews of RCTs and RCTs in any language, with any level of blinding, and containing any number of individuals with any level of loss to follow-up. There was no minimum length of follow-up required to include studies. We included studies described as "open", "open label", and not blinded. We included systematic reviews of RCTs and

RCTs where harms of an included intervention were studied applying the same study design criteria for inclusion as we did for benefits. We reviewed all RCTs that used objective clinical outcome measures. For many trials we could not be sure that the size of pressure ulcers was distributed evenly between groups at baseline. Unequal distribution of wound size at baseline would have an impact on all measures of wound healing. Ideally, studies of treatment should stratify randomisation by initial wound area and include enough participants to ensure even distribution of baseline wound size. A further difficulty in assessing the trials of pressure ulcer prevention and treatment is that it can be difficult to determine from reports whether an RCT of a new device, for example a mattress, is sufficiently similar to be assessed with previously described mattresses, or whether it constitutes a new device. It can therefore be difficult to combine data from RCTs and assess overall effects of treatment options. In addition we use a regular surveillance protocol to capture harms alerts from organisations such as the FDA and the MHRA, which are added to the reviews as required. To aid readability of the numerical data in our reviews, we round many percentages to the nearest whole number. Readers should be aware of this when relating percentages to summary statistics such as relative risks (RRs) and odds ratios (ORs). We have performed a GRADE evaluation of the quality of evidence for interventions included in this review (see table, p 41). The categorisation of the quality of the evidence (high, moderate, low, or very low) reflects the quality of evidence available for our chosen outcomes in our defined populations of interest. These categorisations are not necessarily a reflection of the overall methodological quality of any individual study, because the Clinical Evidence population and outcome of choice may represent only a small subset of the total outcomes reported, and population included, in any individual trial. For further details of how we perform the GRADE evaluation and the scoring system we use, please see our website (www.clinicalevidence.com).

QUESTION What are the effects of preventive interventions in people at risk of developing pressure ulcers?

OPTION FOAM ALTERNATIVES VERSUS STANDARD FOAM MATTRESSES TO PREVENT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- Alternative foam mattresses (such as viscoelastic foam) reduce the incidence of pressure ulcers in people at risk compared with standard hospital foam mattresses, although we don't know which is the best alternative to use.



Benefits and harms

Foam alternatives versus standard hospital mattress:

We found two systematic reviews (search dates 2008^[7] and 2006^[8]). The second systematic review^[8] did not report outcomes data for included RCTs or perform a meta-analysis. Instead, it gave a narrative summary of results. We have therefore reported meta-analysis results from the first review.^[7] Both reviews identified the same 6 RCTs (2117 people in hospital).^[7] ^[8] Five RCTs identified by the reviews compared foam alternatives versus a standard hospital mattress, primarily in elderly people in orthopaedic hospital wards.^[7] ^[8]

Prevention of pressure ulcers

Compared with standard hospital mattresses Foam alternatives seem to be more effective than standard hospital mattresses at preventing pressure ulcers in primarily elderly people in orthopaedic hospital wards (*moderate-quality evidence*).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Prevention of pressure ulcers					
^[7] Systematic review	2016 people 5 RCTs in this analysis	Incidence of pressure ulcers , 10 to 15 days with foam alternative mattress with standard hospital mattress Absolute results not reported	RR 0.40 95% CI 0.21 to 0.74		foam alternative mattress
^[7] Systematic review	101 people in the emergency department and after admission to hospital with hip fracture	Incidence of pressure ulcers , 14 days 4/48 (8%) with foam mattress	Reported as not significant P value not reported		Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
	Data from 1 RCT	8/53 (15%) with standard hospital mattress Foam mattress = viscoelastic foam mattress in the emergency department followed by a viscoelastic foam overlay on top of a standard mattress			

Adverse effects

No data from the following reference on this outcome. ^[7] ^[8]

Different foam alternatives versus each other:

We found two systematic reviews (search dates 2008 ^[7] and 2006 ^[8]). The second systematic review ^[8] did not report outcomes data for included RCTs or perform a meta-analysis. Instead, it gave a narrative summary of results. We have therefore reported meta-analysis results from the first review. ^[7] The reviews identified 5 RCTs (795 people) that compared different foam alternatives. ^[7] ^[8] We report the data from one RCT below; however, the other RCTs were too small to detect a difference between the foam alternatives, because few people in the trials developed pressure ulcers. ^[7]

Prevention of pressure ulcers

Foam alternatives compared with each other A foam and fibre replacement mattress consisting of 5 sections may be more effective than a 4-inch thick dimpled foam mattress at preventing pressure ulcers. However, we don't know how other foam alternatives compare in terms of effectiveness ([very low-quality evidence](#)).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Pressure of ulcers					
^[7] Systematic review	40 people Data from 1 RCT	Development of pressure ulcers with foam and fibre replacement mattress consisting of 5 sections with 4-inch (10 cm) thick dimpled foam mattress Absolute results not reported	RR 0.42 95% CI 0.18 to 0.96 NNT for 10 to 21 days' treatment: 3 95% CI 2 to 25		foam and fibre replacement mattress consisting of 5 sections

Adverse effects

No data from the following reference on this outcome. ^[7] ^[8]

Further information on studies

Comment: Most RCTs were small and of poor quality, and few performed the same comparison. Alternative foam mattresses consisted of foam of varying densities, often within the same mattress, and some were sculptured.

OPTION PRESSURE-RELIEVING OVERLAYS ON OPERATING TABLES TO PREVENT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, [see table, p 41](#) .
- Pressure-relieving overlays on operating tables may reduce the risk of pressure ulcer development.

Benefits and harms

Pressure-relieving overlays on operating tables versus standard table alone:

We found two systematic reviews (search dates 2008^[7] and 2006^[8]), which identified the same 5 RCTs. The second systematic review did not perform a meta-analysis. Instead, it gave a narrative summary of results. We have therefore reported meta-analysis results from the earlier review.^[7] The second review, which reported the RCTs narratively, concluded that mattress overlays on operating tables may decrease the incidence of postoperative pressure ulcers.^[8]

Prevention of pressure ulcers

Compared with standard table alone Pressure-relieving overlays on operating tables may be more effective than no overlays on operating tables at preventing pressure ulcers. However, results were inconsistent between RCTs using different types of overlays (*very low-quality evidence*).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Prevention of pressure ulcers					
^[7] Systematic review	368 people 2 RCTs in this analysis	Incidence of pressure ulcers 3/188 (2%) with alternating-pressure overlay 7 days post surgery 14/180 (8%) with gel pad during surgery, standard mattress 7 days post surgery Whether the reduced incidence of pressure ulcers was caused by intraoperative or postoperative pressure relief, or both, is unclear	RR 0.21 95% CI 0.06 to 0.70 P = 0.01		alternating-pressure overlay 7 days post surgery
^[7] Systematic review	416 people who had had elective major general, gynaecological, or vascular surgery Data from 1 RCT	Incidence of postoperative pressure ulcers , 8 days 22/205 (11%) with viscoelastic polymer pad 43/211 (20%) with standard table alone	RR 0.53 95% CI 0.33 to 0.85 P = 0.008		viscoelastic polymer pad
^[7] Systematic review	413 people Data from 1 RCT	Proportion of people with ulcers of grade 2 or worse 6/206 (3%) with experimental foam overlay 3/207 (1%) with standard table alone	Significance assessment not performed		
^[7] Systematic review	175 people undergoing cardiac surgery Data from 1 RCT	Proportion of people with grade 1 to 2 pressure ulcers 13/85 (15%) with thermoactive 4-cm viscoelastic foam overlay plus standard operating table 9/90 (10%) with standard operating table alone The review reported that the RCT was terminated before the full sample was achieved as more	RR 1.53 95% CI 0.69 to 3.39 P = 0.3		thermoactive 4-cm viscoelastic foam overlay plus standard operating table

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		people in the foam overlay group had pressure ulcers than did those in the control group			

Adverse effects

No data from the following reference on this outcome. ^[7] ^[8]

Further information on studies

^[7] Some of the RCTs identified by the review were small and most were of poor quality; few performed the same comparison.

Comment: None.

OPTION LOW-AIR-LOSS BEDS TO PREVENT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- Low-air-loss beds may reduce the risk of pressure ulcers compared with standard intensive-care beds.

Benefits and harms

Low-air-loss beds versus standard intensive-care beds/alternating-pressure mattresses:

We found two systematic reviews (search dates 2008 ^[7] and 2006 ^[8]). The second systematic review did not report outcomes data for included RCTs or perform a meta-analysis. ^[8] Instead, it gave a narrative summary of results. We have therefore reported results from the first review ^[7] and have reported the further RCT identified by the second review separately.

Prevention of pressure ulcers

Compared with standard intensive-care beds/alternating-pressure mattresses Low-air-loss beds in intensive care may be more effective than standard intensive-care beds at preventing pressure ulcers, but we don't know whether they are more effective than alternating-pressure mattresses (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Prevention of pressure ulcers					
^[7] Systematic review	98 people with expected intensive care unit stay of >3 days Data from 1 RCT	Risk of new pressure ulcers 6/49 (12%) with low-air-loss beds in intensive care 25/49 (51%) with standard intensive-care beds	RR 0.24 95% CI 0.11 to 0.53 The review reported that the intensive-care bed was poorly described, allocation concealment was unclear, and outcome assessment was not blinded		low-air-loss beds
^[7] Systematic review	221 people 2 RCTs in this analysis	Risk of pressure ulcers , 40 days 12/111 (11%) with low-air-loss beds	RR 0.33 95% CI 0.16 to 0.67 P = 0.002		low-air-loss beds

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		37/110 (34%) with static air overlay			
[9] RCT	62 people in intensive care In review [8]	Development of pressure ulcers 3/30 (10%) with low-air-loss beds 6/32 (19%) with alternating-pressure mattresses	P = 0.35 The RCT may have been underpowered to detect a clinically important difference between groups	↔	Not significant

Adverse effects

No data from the following reference on this outcome. [7] [9]

Further information on studies

Comment: None.

OPTION MEDICAL SHEEPSKIN OVERLAYS TO PREVENT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- Medical sheepskin overlays may reduce the risk of pressure ulcers compared with standard care.

Benefits and harms

Medical sheep skin overlays versus standard care:

We found two systematic reviews (search dates 2008 [7] and 2006 [8]). The second systematic review did not report outcomes data for included RCTs or perform a meta-analysis. [8] Instead, it gave a narrative summary of results. We have therefore reported results from the first review. [7]

Prevention of pressure ulcers

Compared with standard care Medical sheepskin overlays plus standard care seem more effective than standard care alone at preventing pressure ulcers (*moderate-quality evidence*).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Prevention of pressure ulcers					
[7] Systematic review	730 people over 18 years of age 2 RCTs in this analysis	Occurrence of pressure ulcers 35/373 (9%) with medical sheepskin overlay with or without usual care 80/365 (22%) with standard hospital mattress/usual care In the second RCT included in this analysis, any person whose risk increased to high as measured by the Baden score (above 12 for 48 hours) was not followed up. The review reported that the rationale for this was not clear	RR 0.42 95% CI 0.22 to 0.81 P = 0.009		medical sheepskin overlay with or without usual care

Adverse effects

No data from the following reference on this outcome. ^[7] ^[8]

Further information on studies

Comment: None.

OPTION ALTERNATING-PRESSURE SURFACES TO PREVENT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- We don't know if alternating-pressure surfaces are effective for preventing pressure ulcers.

Benefits and harms

Alternating-pressure surfaces versus standard foam mattress:

We found two systematic reviews (search date 2008, 11 RCTs; ^[7] and 2006 ^[8]) comparing [alternating-pressure surfaces](#) versus standard foam mattress. The second systematic review ^[8] did not report outcomes data for included RCTs or perform a meta-analysis. Instead, it gave a narrative summary of results. We have therefore reported meta-analysis results from the first review. ^[7] The first review reported that most RCTs on alternating pressure did not adequately describe the equipment being evaluated, including the size of the air cells and cycle time, which may be important in determining effectiveness. ^[7]

Prevention of pressure ulcers

Compared with standard foam mattress Alternating-pressure surfaces may be more effective than standard foam mattresses at preventing pressure ulcers. However, evidence was very weak ([very low-quality evidence](#)).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Prevention of pressure ulcers					
^[7] Systematic review	409 people 2 RCTs in this analysis	Pressure ulcer development 13/221 (6%) with alternating-pressure surfaces 31/188 (16%) with standard foam mattress	RR 0.31 95% CI 0.17 to 0.58 P = 0.0002 The first RCT included in the analysis gave no indication of whether allocation concealment or blinded outcome assessment had been used, and in the second RCT, the denominators were numbers presented by the trial after withdrawals and attrition, and the analysis was not by intention to treat		alternating-pressure surfaces

Adverse effects

No data from the following reference on this outcome. ^[7] ^[8]

Alternating-pressure surfaces versus constant-low-pressure supports:

We found two systematic reviews (search date 2008, 11 RCTs; ^[7] and 2006 ^[8]) comparing [alternating-pressure surfaces](#) versus [constant-low-pressure supports](#). The second systematic review ^[8] did not report outcomes data for included RCTs or perform a meta-analysis. Instead, it gave a narrative summary of results. We have therefore reported meta-analysis results from the first review. ^[7] The first review reported that most RCTs on alternating pressure did not adequately describe the equipment being evaluated, including the size of the air cells and cycle time, which may be important in determining effectiveness. ^[7]

Prevention of pressure ulcers

Compared with constant-low-pressure supports We don't know whether alternating-pressure surfaces are more effective than constant-low-pressure supports at preventing pressure ulcers ([low-quality evidence](#)).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Prevention of pressure ulcers					
^[7] Systematic review	1606 people 10 RCTs in this analysis	<p>Rate of pressure ulcer formation</p> <p>with alternating-pressure surfaces</p> <p>with constant-low-pressure supports</p> <p>Absolute results not reported</p> <p>Constant-low-pressure devices included silicone overlay, a water mattress, a foam pad, a static air mattress, a viscoelastic foam mattress, and a continuous pressure mode of another mattress</p>	<p>RR 0.85</p> <p>95% CI 0.64 to 1.13</p> <p>P = 0.28</p> <p>The meta-analysis pooled trials of several different types of surface and remains underpowered (the wide confidence intervals do not exclude a clinically important treatment effect). The review emphasised that many of the RCTs were small. It reported that further trials are needed to determine whether alternating-pressure devices and constant-low-pressure devices are associated with a clinically important difference in the risk of pressure ulceration</p>	↔	Not significant

Adverse effects

No data from the following reference on this outcome. ^[7] ^[8]

Alternating-pressure surfaces versus each other:

We found two systematic reviews (search date 2008, 11 RCTs; ^[7] and 2006 ^[8]) comparing [alternating-pressure surfaces](#) versus each other. The second systematic review ^[8] did not report outcomes data for included RCTs or perform a meta-analysis. Instead, it gave a narrative summary of results. We have therefore reported meta-analysis results from the first review. ^[7] The first review reported that most RCTs on alternating pressure did not adequately describe the equipment being evaluated, including the size of the air cells and cycle time, which may be important in determining effectiveness. ^[7]

Prevention of pressure ulcers

Compared with each other We don't know whether one alternating-pressure surface is consistently more effective than any other ([low-quality evidence](#)).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Prevention of pressure ulcers					
[10] [11] RCT	1972 acute and elective inpatients at least 55 years old admitted to vascular, or-thopaedic, medical, or care-of-the-elderly wards In review [7]	Proportion of people developing new pressure ulcers of grade 2 or above 101/982 (10%) with alternating-pressure mattresses 106/989 (11%) with alternating-pressure mattress overlays	RR 1.04 95% CI 0.81 to 1.35		Not significant

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[11] RCT	1972 acute and elective inpatients at least 55 years old admitted to vascular, or-thopaedic, medical, or care-of-the-elderly wards In review [7]	Proportion of people who were dissatisfied 186/982 (19%) with alternating-pressure mattresses 230/990 (23%) with alternating-pressure mattress overlays	Mean difference 4.4% 95% CI 0.7% to 7.9% P = 0.02		alternating-pressure mattresses

Further information on studies

[10] [11] A cost-effectiveness assessment of the trial found no significant difference between alternating-pressure mattresses and overlays in mean time to development of an ulcer or hospital stay, although people using pressure mattresses took longer to develop an ulcer, and stayed in hospital for less time than people using overlays (development of an ulcer: mean difference 11 days, 95% CI -24 days to +4 days; hospital stay: 19 days with mattress v 20 days with overlays; reported as not significant; CI not reported; absolute numbers not reported for either outcome). [12]

[7] Most RCTs were small and of poor quality, and few performed the same comparison. Three small RCTs (181 people) identified by the first review compared different alternating-pressure devices versus each other; none found a significant difference (RR values all not significant), although all three RCTs were underpowered.

Comment: None.

OPTION SEAT CUSHIONS TO PREVENT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- We don't know if seat cushions are effective for preventing pressure ulcers.

Benefits and harms

Seat cushions versus each other:

We found two systematic reviews (search dates 2008 [7] and 2006 [8]). The second systematic review [8] did not report outcomes data for included RCTs or perform a meta-analysis. Instead, it gave a narrative summary of results. We have therefore reported results from the earlier review. [7]

Prevention of pressure ulcers

Compared with each other We don't know whether any one seat cushion is consistently more effective than the others at preventing pressure ulcers (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Prevention of pressure ulcers					
[7] Systematic review	52 people Data from 1 RCT	Incidence of pressure ulcers , 5 months with slab-foam cushions with bespoke contoured foam cushions Absolute results not reported	RR 1.06 95% CI 0.75 to 1.49 The confidence intervals of the RCTs included in the review suggest that they were probably underpowered to detect a clinically important difference between different cushions. 3 of the RCTs were of poor methodological quality (unclear method of randomisation/allocation concealment)	↔	Not significant
[7] Systematic review	141 people Data from 1 RCT	Incidence of pressure ulcers , 3 months with gel-and-foam wheelchair cushion with foam cushion Absolute results not reported	RR 0.61 95% CI 0.37 to 1.00	↔	Not significant
[7] Systematic review	248 people Data from 1 RCT	Incidence of pressure ulcers , 3 months with slab-foam cushions with contoured foam cushion Absolute results not reported	RR 1.00 95% CI 0.84 to 1.18	↔	Not significant
[7] Systematic review	32 people using wheelchairs Data from 1 RCT	Incidence of pressure ulcers with pressure-reducing seat cushion with foam cushions (3-inch convoluted [eggcrate] foam) Absolute results not reported	RR 0.68 95% CI 0.33 to 1.42	↔	Not significant

Adverse effects

No data from the following reference on this outcome. [7] [8]

Further information on studies

Comment: None.

OPTION ELECTRIC PROFILING BEDS TO PREVENT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .

- We don't know if electric profiling beds are effective for preventing pressure ulcers.

Benefits and harms

Electric profiling beds to prevent pressure ulcers versus standard hospital beds:

We found two systematic reviews (search dates 2008^[7] and 2006^[8]). The second systematic review^[8] did not report outcomes data for included RCTs or perform a meta-analysis. Instead, it gave a narrative summary of results. Both reviews reported the same RCT; therefore, we have reported results from the earlier review.^[7]

Prevention of pressure ulcers

Compared with standard hospital beds We don't know whether an electric profiling bed plus a pressure-relieving foam mattress is more effective than a standard hospital bed plus a pressure-relieving foam or alternating-pressure mattress at preventing pressure ulcers ([low-quality evidence](#)).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Prevention of pressure ulcers					
^[7] Systematic review	70 people in medical or surgical hospital wards Data from 1 RCT	Incidence of pressure ulcers , 10 days 0 with electrically operated profiling bed 0 with standard hospital bed Operated profiling bed consisted of 4 sections plus a pressure-relieving foam mattress Standard hospital bed with pressure-relieving mattress (foam or alternating pressure)	Reported as not significant P value not reported The low event rate means that the RCT was underpowered to detect a clinically important difference between groups	↔	Not significant

Adverse effects

No data from the following reference on this outcome.^[7] ^[8]

Further information on studies

Comment: None.

OPTION LOW-TECH CONSTANT-LOW-PRESSURE SUPPORTS TO PREVENT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, [see table, p 41](#) .
- We don't know if low-tech constant-low-pressure supports are effective for preventing pressure ulcers.

Benefits and harms

Low-tech constant-low-pressure supports versus each other:

We found two systematic reviews (search dates 2008^[7] and 2006^[8]). The reviews identified 11 RCTs about the effects of [low-tech constant-low-pressure supports](#) in preventing pressure ulcers, which were underpowered (because few people in the trial developed pressure ulcers and there was a probability of small differences between surfaces that work in similar ways), or too flawed to produce reliable conclusions.^[7] The first review^[7] did not perform a meta-analysis because of heterogeneity among the trials in types of support and comparisons assessed, and the second review was narrative in character.^[8]

Adverse effects

No data from the following reference on this outcome. ^[7] ^[8]

Further information on studies

^[7] Most RCTs were small and of poor quality, and few performed the same comparison.

Comment: None.

OPTION NUTRITIONAL SUPPLEMENTS TO PREVENT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- We don't know whether pressure ulcers can be prevented by use of nutritional interventions.

Benefits and harms

Nutritional supplements versus control:

We found two systematic reviews (search dates 2002 ^[13] and 2006 ^[8]) assessing parenteral and enteral nutritional supplements. The second systematic review ^[8] did not report outcomes data for included RCTs or perform a meta-analysis. Instead, it gave a narrative summary of results. We have therefore reported results from the earlier review, ^[7] and have reported the further RCT identified by the second review separately. ^[14]

Prevention of pressure ulcers

Compared with control or standard care We don't know whether nutritional supplements are effective at preventing pressure ulcers (*very low-quality evidence*).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Prevention of pressure ulcers					
^[13] Systematic review	672 people acutely ill people aged >5 years Data from 1 RCT	Prevention of pressure ulcers , 15 days 118/295 (40%) with nutritional supplements 181/377 (48%) with control However, treatment groups were not comparable at baseline	RR 0.83 95% CI 0.70 to 0.99		nutritional supplements
^[13] Systematic review	59 people Data from 1 RCT	Prevention of pressure ulcers , 6 months with nutritional supplements with control Absolute results not reported	RR 0.22 95% CI 0.01 to 4.28 The RCT was too small to detect a clinically important difference		Not significant
^[13] Systematic review	140 people Data from 1 RCT	Prevention of pressure ulcers , 2 weeks with nutritional supplements with control Absolute results not reported	RR 0.92 95% CI 0.64 to 1.32 The RCT was too small to detect a clinically important difference		Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
[13] Systematic review	103 people Data from 1 RCT	Prevention of pressure ulcers , 28 days with nutritional supplements with control Absolute results not reported	RR 0.92 95% CI 0.65 to 1.30 The RCT was too small to detect a clinically important difference	↔	Not significant
[14] RCT	501 people newly admitted to long-term care; mean age 80.1 years In review [8]	Prevention of pressure ulcers , 182 days 10% with oral nutritional supplements 12% with control Absolute numbers not reported Oral nutritional supplement (200 mL containing 8 g protein, 8 g fat, 23.6 g carbohydrates, 838 kJ, vitamins, and minerals given twice daily) Standard care (standard hospital diet of 2200 kcal/day)	P value not reported		

Adverse effects

No data from the following reference on this outcome. [8] [13]

Further information on studies

[8] [13] Most of the RCTs in the reviews had weak methods. Flaws included lack of information about the method of randomisation, lack of blinding of outcome assessment, high withdrawal rates, and lack of intention-to-treat analyses.

Comment: None.

OPTION REPOSITIONING (INCLUDING REGULAR "TURNING") TO PREVENT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- We don't know if repositioning (regular turning) is effective for preventing pressure ulcers.

Benefits and harms

Repositioning versus control, usually standard care:

We found two systematic reviews (search dates 1995 [15] and 2006 [8]). The second systematic review [8] did not report outcomes data for included RCTs or perform a meta-analysis, but instead gave a narrative summary of results. We have therefore reported results from the earlier review, [15] and have reported a further RCT identified by the second review [8] separately.

Prevention of pressure ulcers

Compared with standard care We don't know whether any specific repositioning regimen is more effective than standard care alone at preventing pressure ulcers (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Prevention of pressure ulcers					
[15] Systematic review	217 people 3 RCTs in this analysis	Incidence of pressure ulcers with manual repositioning with control Absolute results not reported Control was standard care in 2 RCTs. The third RCT compared 4 interventions: repositioning, small-cell ripple bed, foam mattress, and standard care	Reported as not significant P value not reported The review reported that the RCTs were all too small and weak to detect clinically important differences between treatments	↔	Not significant
[16] RCT 5-armed trial	838 people with Braden scores <17 In review [8]	Development of pressure ulcers , 4 weeks 14% with turning every 2 hours on a standard mattress 24% with turning every 3 hours on a standard mattress 3% with turning every 4 hours on a viscoelastic foam mattress 16% with turning every 6 hours on a viscoelastic foam mattress 20% with standard care Standard care involved preventive measures, including water mattresses, alternating mattresses, sheepskins, and gel cushions, given at the nurses' discretion	4-hour turning v standard care: OR 0.12, 95% CI 0.03 to 0.48 4-hour turning v other regimens: reported as significant; P value not reported Other turning regimens v standard care: P >0.05	● ● ●	turning every 4 hours on a viscoelastic foam mattress

Adverse effects

No data from the following reference on this outcome. [15] [16]

Repositioning at 30 degree tilt versus a 90 degree lateral and supine position:

We found two systematic reviews (search dates 1995 [15] and 2006 [8]). The second systematic review [8] did not report outcomes data for included RCTs or perform a meta-analysis, but instead gave a narrative summary of results. We have therefore reported results from the earlier review, [15] and have reported further RCTs identified by the second review [8] separately.

Prevention of pressure ulcers

Repositioning at 30 degree tilt versus a 90 degree lateral and supine position We don't know whether repositioning at 30 degree tilt is more effective than a 90 degree lateral and supine position at preventing pressure ulcers at 24 hours in hospitalised elderly people (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Prevention of pressure ulcers					
[17] RCT	46 hospitalised elderly people In review [8]	Non-blanching erythema , 24 hours 3/23 (13%) with 30° tilt position 2/23 (9%) with 90° lateral and supine position	P >0.05	↔	Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		30° tilt position (pillows placed under 1 buttock and under each leg so that pelvis was tilted at 30° and the sacrum and heels were not in contact with support surface)			
[17] RCT	46 hospitalised elderly people In review [8]	Visible breaks in the epidermis, 24 hours 0/23 (0%) with 30° tilt position 0/23 (0%) with 90° lateral and supine position	Reported as non-significant P value and significance not reported	↔	Not significant
[17] RCT	46 hospitalised elderly people In review [8]	Proportion of people who found the position difficult to maintain 20/23 (87%) with 30° tilt position 5/23 (22%) with 90° lateral and supine position	P <0.05	○○○	90° lateral and supine position

No data from the following reference on this outcome. [15]

Adverse effects

No data from the following reference on this outcome. [8] [15]

Further information on studies

Comment: The three RCTs identified by the first review were small, of poor quality, and no comparisons were undertaken more than once. [15] In one of the RCTs of regular repositioning identified by the review, 23 people were randomised to repositioning, but only 10 people actually were repositioned regularly. [15] The first RCT [16] identified by the second review [8] cluster-randomised hospital wards to each turning regimen. Within each ward, 5 people were randomly selected for the intervention, and the remainder were allocated to standard care.

OPTION TOPICAL LOTIONS AND DRESSINGS TO PREVENT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- We don't know if topical lotions and dressings are effective for preventing pressure ulcers.

Benefits and harms

Topical lotions and dressings versus placebo or other lotions and dressings:

We found two systematic reviews (search date 2000, 2 RCTs; [18] and 2006, 3 RCTs [8]). The second systematic review [8] did not report outcomes data for included RCTs or perform a meta-analysis. Instead, it gave a narrative summary of results. We have therefore reported results from the earlier review, [18] and have reported further RCTs identified by the second review individually. The first review identified no RCTs assessing dressings for pressure ulcer prevention. [18]

Prevention of pressure ulcers

Compared with placebo/other lotions We don't know whether any specific topical lotion or dressing is more effective than any other specific topical lotion or dressing at preventing pressure ulcers (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Prevention of pressure ulcers					
[18] Systematic review	319 people Data from 1 RCT	Incidence of new pressure ulcers , 3 weeks with hexachlorophene (hexachlorophane) lotion with cetrimide lotion Absolute results not reported	OR 0.87 95% CI 0.46 to 1.65 These results must be interpreted with caution, as they were based on a completer analysis of 167 people	↔	Not significant
[18] Systematic review	120 people Data from 1 RCT	Changes in skin condition , 3 weeks with hexachlorophene lotion with inert lotion Absolute results not reported	Reported as not significant P value not reported	↔	Not significant
[19] RCT	380 people In review [8]	Proportion of people who developed pressure ulcers 12/164 (7%) with twice-daily topical application of a compound of 8 hyperoxygenated fatty acids 29/167 (17%) with placebo compound	RR 0.42 95% CI 0.22 to 0.80 Completer analysis; 13% of those randomised were not included in the analysis so results must be viewed with caution	●●○	fatty acids

Adverse effects

No data from the following reference on this outcome. [8] [18] [19]

Further information on studies

Comment: None.

OPTION AIR-FILLED VINYL BOOTS TO PREVENT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- Air-filled vinyl boots with foot cradles may increase the risk of ulcers compared with other pressure-relieving surfaces.

Benefits and harms

Air-filled vinyl boot versus hospital pillow:

We found two systematic reviews (search date 2008 [7] and 2006 [8]). The second systematic review [8] did not report outcomes data for included RCTs or perform a meta-analysis, but instead gave a narrative summary of results. Both reviews reported the same RCT; therefore, we have reported results from the first review. [7]

Prevention of pressure ulcers

Compared with hospital pillows An air-filled vinyl boot with built-in foot cradle may be less effective than hospital pillows at preventing pressure ulcers (*low-quality evidence*).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Prevention of pressure ulcers					
[7] [8] Systematic review	52 people Data from 1 RCT	Mean time to skin breakdown 10 days with vinyl boot 13 days with pillow	P <0.036		pillow
[7] Systematic review	52 people Data from 1 RCT	Development of heel ulcers 6 ulcers with vinyl boot 2 ulcers with pillow	Reported as not significant P value not reported		Not significant

Adverse effects

No data from the following reference on this outcome. [7] [8]

Further information on studies

Comment: The first review also identified one further RCT, which compared a bunny boot (fleece) high cushion heel protector, an egg crate (holds the foot suspended above the bed surface with heel through a window) heel lift positioner, and a foot waffle (felt-coated inflatable plastic pillow that encircles the foot) air cushion. [7] The RCT found no significant differences between the devices in terms of pressure ulcer incidence. However, the review reported that it was unclear whether the number of incident ulcers or the number of participants with incident ulcers were being reported, only 240/338 (71%) people had follow-up data (53 people excluded who did not wear devices for 48 hours, 45 people excluded who were non-compliant), analysis was not by intention to treat, and there was a baseline difference between groups in sex. [7]

OPTION HYDROCELLULAR HEEL SUPPORTS TO PREVENT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- Hydrocellular heel supports may decrease the risk of pressure ulcers compared with orthopaedic wool padding.

Benefits and harms

Hydrocellular heel supports versus orthopaedic wool padding/standard care:

We found one systematic review (search date 2006), [8] which identified one RCT [20] comparing the use of hydrocellular heel supports versus orthopaedic wool padding to prevent heel pressure ulcers.

Prevention of pressure ulcers

Compared with orthopaedic wool padding or standard care Hydrocellular heel supports may be more effective than orthopaedic wool padding at preventing heel pressure ulcers at 8 weeks, but we don't know whether they are more effective than other standard interventions (*low-quality evidence*).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Prevention of pressure ulcers					
[20] RCT	130 people In review [8]	Incidence of pressure ulcers , 8 weeks 2/61 (3%) with hydrocellular heel supports 22/50 (44%) with orthopaedic wool padding	RR 0.07 95% CI 0.02 to 0.30 These results should be interpreted with caution because of the lack of intention-to-treat analysis		hydrocellular heel supports

Adverse effects

No data from the following reference on this outcome. [8] [20]

Further information on studies

Comment: None.

OPTION LOW-AIR-LOSS HYDROTHERAPY BEDS TO PREVENT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- Low-air-loss hydrotherapy beds may increase the risk of ulcers compared with other pressure-relieving surfaces.

Benefits and harms

Low-air-loss hydrotherapy beds versus other specialised support surfaces:

We found two systematic reviews (search dates 2008 [7] and 2006 [8]). The second systematic review [8] did not report outcomes data for included RCTs or perform a meta-analysis. Instead, it gave a narrative summary of results. Both reviews have reported the same RCT; therefore, we have reported results from the first review. [7]

Prevention of pressure ulcers

Compared with other specialised support surfaces We don't know whether low-air-loss hydrotherapy beds and a range of support surfaces differ in effectiveness at reducing the proportion of people with grade 2 to 4 pressure ulcers at 60 days in people with incontinence on acute and long-stay wards, as differences between groups were not significant. However, more people developed ulcers with low-air-loss hydrotherapy beds (*low-quality evidence*).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Prevention of pressure ulcers					
[7] Systematic review	98 people with incontinence, admitted to acute and long-stay hospital wards Data from 1 RCT	Development of pressure ulcers (grade 2 to 4) , 60 days 8/42 (19%) with <i>low-air-loss hydrotherapy beds</i> 4/56 (7%) with support surfaces Allocation concealment was unclear and outcome assessment was not blinded	RR 2.67 95% CI 0.86 to 8.37 The RCT is likely to have been underpowered to detect a clinically important difference between groups		Not significant

Adverse effects

No data from the following reference on this outcome. ^[7] ^[8]

Further information on studies

Comment: None.

QUESTION What are the effects of treatments in people with pressure ulcers?

OPTION AIR-FLUIDISED SUPPORT TO TREAT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- In people with pressure ulcers, air-fluidised supports may improve healing compared with standard care, although they can make it harder for people to get in and out of bed independently.

Benefits and harms

Air-fluidised supports versus standard care:

We found two systematic reviews. ^[21] ^[22] The first systematic review (search date 2000, 3 RCTs, 202 people) compared air-fluidised supports versus standard care. ^[21] The second systematic review (search date 2008), which had different inclusion criteria, included one RCT identified by the first review (the first RCT reported above) and included further detail. ^[22]

Healing rates

Compared with standard care Air-fluidised supports may be more effective than standard care (alternating-pressure mattresses, regular changes of position, sheepskin, gel pads, or limb protectors) at healing established pressure ulcers after a mean of 15 days in people in hospital, although we don't know about in people being cared for at home (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Healing rates					
^[21] Systematic review	Number of participants unclear (see further information on studies) Data from 1 RCT	Median change in total ulcer surface area , mean 15 days -1.2 cm ² with air-fluidised supports +0.5 cm ² with standard care	Reported as significant P value not reported	○○○	air-fluidised supports
^[21] Systematic review	Number of participants unclear (see further information on studies) Data from 1 RCT	Median change in total ulcer surface area , mean 15 days with air-fluidised support with standard care Absolute results not reported	P = 0.05	○○○	air-fluidised support
^[21] Systematic review	97 people being cared for at home Data from 1 RCT	Median change in total ulcer surface area , 36 weeks with air-fluidised support with standard care Absolute results not reported	Reported as not significant P value not reported This RCT had a 13% withdrawal rate and did not perform an intention-to-treat analysis	↔	Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
[22] Systematic review	72 people, 65 people completed study, aged >18 years, acute care, grade I to IV ulcers	Median change in wound surface area -1.2 cm ² with air-fluidised mattress +0.5 cm ² with alternating-pressure mattress covered in foam	95% CI for difference -9.2 cm ² to -0.6 cm ² P = 0.01		air-fluidised mattress

Adverse effects

No data from the following reference on this outcome. [21] [22]

Further information on studies

[21] The two RCTs reported from the systematic review had a combined population of 105 people; information about the population of the individual RCTs was not reported.

Comment: People are unable to move in and out of bed independently when they use air-fluidised beds, and this limits the number of people for whom they are suitable.

OPTION ALTERNATING-PRESSURE SURFACES TO TREAT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- We don't know whether healing is improved in people with pressure ulcers by use of alternating-pressure surfaces.

Benefits and harms

Alternating-pressure surfaces versus standard/other care:

We found one systematic review (search date 2008), which found 5 RCTs. [22] The review did not pool data.

Healing rates

Compared with each other/standard care We don't know whether alternating-pressure surfaces are more effective than standard care at healing pressure ulcers, or whether any one alternating-pressure surface is consistently more effective than all the others (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Healing rates					
[22] Systematic review	199 people, 158 people completed study, mean age 80 years, acute care, grade I to IV ulcers Data from 1 RCT	Wound surface area ulcer progress 72% with alternating-pressure mattress 75% with fluid mattress overlay Absolute numbers not reported	P = 0.76		Not significant
[22] Systematic review	113 people completed study, 55 years or over, acute care, grade II ulcers	Complete wound healing 10.3% with one type of alternating-pressure mattress	P = 0.75		Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
	Data from 1 RCT	10.7% with another type of alternating-pressure overlay Absolute numbers not reported			
[22] Systematic review	32 people completed study, aged 65 years or over, acute and long-term care, grade II or III ulcers Data from 1 RCT	Reduction in median wound surface area , per day 0.12 cm with one type of alternating-pressure mattress 0.08 cm with another type of alternating-pressure mattress	P = 0.57	↔	Not significant
[22] Systematic review	17 people, age range 66 to 99 years, acute and long-term care, grade II to IV ulcers Data from 1 RCT	Wound surface area with one type of alternating-pressure mattress with another type of alternating-pressure mattress or overlay Absolute results not reported	Reported as no significant difference in healing sores P value not reported	↔	Not significant
[22] Systematic review	183 people, 112 completed study, age described as elderly, acute care, grade II to IV ulcers	Complete heel ulcer healing with one type of alternating-pressure mattress plus cushion with another type of alternating-pressure mattress plus cushion Absolute results not reported	P = 0.02	○○○	alternating-pressure mattress plus cushion

Adverse effects

No data from the following reference on this outcome. [22]

Further information on studies

Comment: People often have difficulty moving in bed independently on alternating-pressure mattresses. [10]

OPTION DEBRIDEMENT TO TREAT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- We found no clinically important results from RCTs about the effects of debridement compared with no debridement in the treatment of people with pressure ulcers.

Benefits and harms

Debridement versus no debridement or different debriding agents versus each other:

We found two systematic reviews (search dates 1998 [23] and 2008 [22]), which did not pool data. The first systematic review found no RCTs comparing debridement versus no debridement. [23] It identified 32 RCTs comparing different debriding agents such as dextranomer paste, but the studies were small, included a range of wounds, and few comparisons were undertaken in more than one RCT. The review concluded that there was insufficient evidence to promote the use of any particular debriding agent over another. The second systematic review categorised dressings by their primary purpose (e.g., debriding, hydrating, etc.) and only included RCTs that calculated wound size, used evaluation tools that incorporated these measurements, or used complete wound healing as end points. [22]

Healing rates

Debriding agents compared with each other We don't know whether any one debriding agent is consistently more effective than the other debriding agents at healing pressure ulcers (*very low-quality evidence*).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Healing rates					
[22] Systematic review	28 people (26 people completed the study) Data from 1 RCT	Reduction in wound surface with collagenase with papain-urea-chlorophyllin copper Absolute results not reported	Reported as not significant P value not reported	↔	Not significant
[22] Systematic review	135 people (78 people completed the study) Data from 1 RCT	Reduction in wound surface with collagenase with fibrinolysin or deoxyribonuclease Absolute results not reported	P = 0.12	↔	Not significant
[22] Systematic review	102 people (63 people completed the study) Data from 1 RCT	Reduction in wound surface with collagenase daily with collagenase every 2 days Absolute results not reported	P = 0.64	↔	Not significant

Adverse effects

No data from the following reference on this outcome. [22] [23]

Further information on studies

[22] The review also found further RCTs comparing debriding agents versus a variety of agents (including hydrating agents, absorbent agents, moist saline gauze, and sugar and egg white). Overall, the review concluded that no debriding agent was consistently superior to other dressings for wound healing.

Comment: None.

OPTION DRESSINGS (HYDROCOLLOID AND NON-HYDROCOLLOID) VERSUS EACH OTHER TO TREAT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- We don't know which type of dressing is better for treating pressure ulcers.

Benefits and harms

Hydrocolloid dressings versus gauze soaked in saline, hypochlorite, or povidone iodine:

We found two systematic reviews (search dates 1997 [24] and 2008 [22]) assessing dressings or topical agents for pressure ulcers. The second review did not pool data. [22] It found 7 RCTs (32–94 people; 2 RCTs included in the first review) comparing hydrocolloid dressings versus moist saline gauze (6 RCTs) or moist povidone-iodine gauze (1 RCT). Of the 7 RCTs, 4 RCTs found no significant difference between groups in wound healing. One RCT (94

people) with weak methods did not report a statistical analysis between groups. Two RCTs (first RCT: 83 people; second RCT: 32 people [12 people completed]) found a significant benefit with hydrocolloid versus moist saline gauze. One of these RCTs (32 people) had weak methods (CLEAR NPT criteria [maximum 6]: RCT score 1). The remaining RCT had baseline differences between groups in ulcer size. Although these differences were not statistically significant, they may have biased the results against standard dressings. ^[22]

Healing rates

Hydrocolloid dressings compared with gauze soaked in saline, hypochlorite, or povidone iodine We don't know whether hydrocolloid dressings are more effective at healing pressure ulcers (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Healing rates					
^[24] Systematic review	396 people 5 RCTs in this analysis	Healing rate , up to 75 days 102/205 (50%) with hydrocolloid dressings 59/191 (31%) with standard dressings Standard dressings included gauze soaked in saline, hypochlorite, or povidone iodine Overall, RCTs were small and of poor quality, and the significance of the meta-analysis in the first review was sensitive to the method of calculation (see comment below)	OR 2.57 95% CI 1.58 to 4.18		hydrocolloid dressings

Adverse effects

No data from the following reference on this outcome. ^[22] ^[24]

Hydrocolloid dressings versus non-hydrocolloid dressings other than gauze soaked in saline, hypochlorite, or povidone iodine:

We found one systematic review (search date 2008), which compared hydrocolloid dressings versus other dressings. ^[22] The review did not pool data. Overall, the review concluded that no one dressing was consistently superior to the alternatives. ^[22]

Healing rates

Hydrocolloid dressings compared with non-hydrocolloid dressings other than gauze soaked in saline, hypochlorite, or povidone iodine We don't know whether hydrocolloid dressings are more effective at healing pressure ulcers (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Healing rates					
^[22] Systematic review	Number of people unclear 8 RCTs in this analysis	Wound healing with hydrocolloid dressings with other types of dressing Absolute results not reported Other types of dressing included: debriding dressings (3 RCTs), hydrating dressings (6 RCTs), absorbent dressings (1 RCT),	Reported as not significant P value not reported		Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
		and other specific dressings (5 RCTs) Many of the RCTs were of poor methodological quality			

Adverse effects

No data from the following reference on this outcome. ^[22]

Hydrocolloid dressings versus topical phenytoin:

See option on topical phenytoin, p 36 .

Dressings other than hydrocolloid versus each other:

We found one systematic review (search date 2008), which compared dressings other than hydrocolloid versus each other. ^[22] The review categorised dressings by their primary purpose (e.g., debriding, hydrating, absorbent, etc.) and only included studies that calculated wound size, used evaluation tools that incorporated these measurements, or used complete wound healing as end points. Overall, the review found no clear evidence that any one dressing was consistently superior to any other dressing (no further data reported; see further information on studies for details of RCTs). ^[22]

Adverse effects

No data from the following reference on this outcome. ^[22]

Further information on studies

^[22] The review included RCTs comparing different debriding dressings (3 RCTs), debriding versus absorbent dressings (1 RCT), absorbent dressings versus each other (2 RCTs), absorbent versus other specific dressings (3 RCTs), hydrating versus absorbent dressings (2 RCTs), hydrating versus antimicrobial dressings (1 RCT), hydrating versus other specific dressings (3 RCTs), antimicrobial versus other specific dressings (4 RCTs), and other specific dressings versus other specific dressings (13 RCTs). Many of the RCTs were of poor methodological quality (CLEAR NPT criteria [maximum 6]: 24 RCTs scored 2 or less), were small (20 RCTs included 40 people or less), and many had large differences between the number randomised and those who completed the study.

^[24] **Hydrocolloid dressings versus gauze soaked in saline, hypochlorite, or povidone iodine:** Given the large absolute risks of events in this review, a relative risk would be a preferable outcome measure for results. ^[25] If the meta-analysis is re-worked using relative risk instead of odds ratio, the result is no longer significant (Cullum N, 2004; personal communication).

Comment: None.

OPTION ELECTROTHERAPY TO TREAT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- We don't know whether electrotherapy improves healing in people with pressure ulcers.

Benefits and harms


Electrotherapy versus sham electrotherapy or standard treatment:

We found two systematic reviews (search dates 2000^[21] and 2008^[22]) and one subsequent RCT.^[26] The second review did not pool data.^[22]

Healing rates

Compared with sham electrotherapy or standard treatment We don't know whether electrotherapy is more effective than sham electrotherapy or standard care at healing pressure ulcers as we found insufficient evidence (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Healing rates					
^[21] Systematic review	Number of people unclear 2 RCTs in this analysis	Healing rates , 3 to 5 weeks with electrotherapy with sham treatment Absolute results not reported These RCTs were small, however, and had important weaknesses in their methods. Results should therefore be interpreted with caution	RR 7.92 95% CI 2.40 to 26.30		electrotherapy
^[27] Systematic review	49 people In review ^[21]	Percentage area of pressure ulcer healed , 4 weeks 50% with electrotherapy 23% with sham treatment These RCTs were small, however, and had important weaknesses in their methods. Results should therefore be interpreted with caution	P = 0.04		electrotherapy
^[22] Systematic review	7 people Data from 1 RCT	Reduction in wound surface area 22% with interrupted direct current 3% with placebo-interrupted direct current The RCT was too small to draw reliable conclusions	P value not reported		
^[28] RCT	63 people In review ^[22]	Proportion of people completely healed , 8 weeks 5/35 (14%) with electrotherapy 3/28 (11%) with sham treatment	P = 0.39		Not significant
^[28] Systematic review	63 people In review ^[22]	Proportion of people completely healed , 12 weeks 9/35 (26%) with electrotherapy 10/28 (36%) with sham treatment	P = 0.28		Not significant
^[28] RCT	63 people In review ^[22]	Mean time to complete healing 63 days with electrotherapy 90 days with sham treatment	P = 0.16		Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
[26] RCT	34 people with spinal cord injury, grade II to IV ulcers, average age 50 years	Mean decrease in percentage wound surface area , 3 months 70% with high-voltage pulsed current plus standard care 36% with standard care	P = 0.048 Borderline significance		high-voltage pulsed current plus standard care

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[28] RCT	63 people In review [22]	Adverse effects with electrotherapy with sham treatment Absolute results not reported	2 people in the electrotherapy group had hypergranulation of the ulcer, and 2 had local irritation (2/35 [6%] for either outcome), possibly as a result of concomitant use of topical sulfadiazine cream		
[26] RCT	34 people	Adverse effects with electrotherapy plus standard care with standard care alone Absolute results not reported	The RCT noted that adverse effects were minor and rare, the most common with electrotherapy plus standard care was red, raised, itchy skin under the large dispersive electrode, which was attributed to contact dermatitis		

No data from the following reference on this outcome. [21] [22]

Further information on studies

Comment: None.

OPTION LOW-AIR-LOSS BEDS TO TREAT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, [see table, p 41](#) .
- We don't know whether low-air-loss beds improve healing in people with pressure ulcers.

Benefits and harms

Low-air-loss beds versus standard beds or standard care:

We found two systematic reviews (search dates 2000 [21] and 2008 [22]).

Healing rates

Compared with standard beds or standard care We don't know whether low-air-loss beds are more effective at increasing pressure ulcer healing ([low-quality evidence](#)).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Healing rates					
[21] Systematic review	133 people 2 RCTs in this analysis	Healing rate with low-air-loss beds with convoluted foam Absolute results not reported	RR 1.25 95% CI 0.84 to 1.86 The meta-analysis may have been underpowered to detect a clinically important difference between groups	↔	Not significant
[22] Systematic review	20 people, age range 36 to 100 years, acute and long-term care, grade III or IV ulcers	Mean rate of wound closure , per week 5% with low-air-loss mattress 9% with air and foam mattress	P value not reported		
[22] Systematic review	207 people, mean age 69 years, long-term care, grade III or IV ulcers Data from 1 RCT 3-armed trial	Time to complete healing 4.38 months with low-air-loss mattress 4.55 months with specialised foam mattress overlay 3.33 months with alternating pressure	P value not reported		
[22] Systematic review	207 people, mean age 69 years, long-term care, grade III or IV ulcers Data from 1 RCT 3-armed trial The remaining arm assessed specialised foam mattress overlay	Mean improvement in Pressure Sore Status Score 18.4 with low-air-loss mattress 34.3 with alternating-pressure mattress Number of people in this analysis unclear	P <0.001	○○○	alternating-pressure mattress

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[29] RCT	Number of participants unclear In review [21]	Hypothermia with low-air-loss hydrotherapy beds with standard care Absolute results not reported	Hypothermia was found in a small number of people who used low-air-loss hydrotherapy beds (no further data reported by review)		

No data from the following reference on this outcome. [22]

Further information on studies

Comment: None.

OPTION LOW-LEVEL LASER TREATMENT TO TREAT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- We don't know whether low-level laser therapy improves healing in people with pressure ulcers.

Benefits and harms

Low-level laser treatment versus standard care or sham treatment:

We found one systematic review (search date 2008), which included RCTs that calculated wound size with wound volume or surface area, used evaluation tools that included these measurements, or used complete wound healing as an end point.^[22] The review included two RCTs.

Healing rates

Compared with standard care/sham treatment We don't know whether laser treatment is more effective than standard care at increasing pressure ulcer healing (low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Healing rates					
^[22] Systematic review	86 people (79 people completed study), age range 49 to 100 years, long-term care, grade III ulcers Data from 1 RCT	Reduction in wound surface area with low-level laser with standard care Absolute results not reported	P = 0.23	↔	Not significant
^[22] Systematic review	35 people (25 people completed study), age range 8 to 65 years, rehabilitation, grade II to IV ulcers Data from 1 RCT	Time to complete wound healing 2.45 weeks with laser plus moist saline gauze 1.78 weeks with saline gauze alone	P = 0.33	↔	Not significant

Adverse effects

No data from the following reference on this outcome.^[22]

Low-level laser treatment versus ultrasound plus ultraviolet light:

See option on therapeutic ultrasound, p 34 .

Further information on studies

Comment: None.

OPTION LOW-TECH CONSTANT-LOW-PRESSURE SUPPORTS TO TREAT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .

- We don't know whether low-tech constant-low-pressure supports improve healing in people with pressure ulcers.

Benefits and harms

Low-tech constant-low-pressure supports versus each other:

We found two systematic reviews (search dates 2000^[21] and 2008^[22]), which identified the same RCT.

Healing rates

Compared with each other We don't know whether a layered-foam replacement mattress is more effective than a water mattress at increasing healing of pressure ulcers at 4 weeks in elderly people in a nursing home (*low-quality evidence*).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Healing rates					
^[21] ^[22] Systematic review	120 elderly people with pressure ulcers in a nursing home, 101 completed study, grade III or IV Data from 1 RCT	Complete ulcer healing , 4 weeks 45% with layered-foam replacement mattress 48% with water mattress Absolute numbers not reported	Reported as not significant P value not reported	↔	Not significant

Adverse effects

No data from the following reference on this outcome. ^[21] ^[22]

Further information on studies

Comment: None.

OPTION NUTRITIONAL SUPPLEMENTS TO TREAT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, [see table, p 41](#) .
- We don't know whether nutritional interventions improve healing in people with pressure ulcers.

Benefits and harms

Nutritional supplements versus control:

We found two systematic reviews (search dates 2002^[13] and 2008^[22]) and one subsequent RCT. ^[30]

Healing rates

Compared with control (low dose or no supplements) We don't know whether nutritional supplements are more effective than control at increasing healing of pressure ulcers (*very low-quality evidence*).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Healing rates					
[13] Systematic review	88 people with pressure ulcers in nursing homes or hospital, some of whom were receiving ultrasound treatment for their pressure ulcers Data from 1 RCT	Ulcer healing , 84 days 17/43 (39%) with ascorbic acid 1000 mg daily 22/45 (49%) with ascorbic acid 20 mg daily	RR 0.81 95% CI 0.50 to 1.30	↔	Not significant
[13] Systematic review	20 people with pressure ulcers having surgery Data from 1 RCT	Ulcer healing , 4 weeks with ascorbic acid 1000 mg daily with placebo Absolute results not reported	RR 2.00 95% CI 0.68 to 5.85	↔	Not significant
[13] Systematic review	12 institutionalised people being fed through a tube Data from 1 RCT	Ulcer healing , 8 weeks with very high-protein diet with high-protein diet Absolute results not reported	RR 0.11 95% CI 0.01 to 1.70	↔	Not significant
[22] Systematic review	20 people with pressure ulcers having surgery Data from 1 RCT	Mean reduction in wound surface , 1 month 84% with ascorbic acid 1000 mg daily 43% with placebo	P <0.005	○○○	ascorbic acid
[31] RCT 3-armed trial	16 people with stage 2 or 3 pressure ulcers In review [22]	Mean score Pressure Ulcer Scale for Healing (PUSH) , 3 weeks 7 with diet A 6 with diet B 2.6 with diet C Diet A: standard hospital diet Diet B: standard hospital diet plus a daily supplement of 500 kcal, protein 18 g, vitamin C 72 mg, and zinc 7.5 g Diet C: a standard hospital diet plus 500 kcal, protein 21 g, vitamin C 500 mg, zinc 30 mg, and arginine 9 g PUSH score range 0 (completely healed) to 17 (greatest severity)	Diet C v Diet A and B: P <0.05 This study randomised only 16 people between the 3 groups and did not report the proportion of participants with complete healing	○○○	standard hospital diet plus 500 kcal, protein 21 g, vitamin C 500 mg, zinc 30 mg, and arginine 9 g
[32] RCT	89 people resident in long-term care facilities with stage II, III, or IV pressure ulcers In review [22]	PUSH , 8 weeks 3.55 with concentrated, fortified, collagen protein hydrolysate supplement 3.22 with placebo Treatment administered orally or via feeding tubes PUSH score range 0 (completely healed) to 17 (greatest severity)	P <0.05 However, these results should be interpreted with caution, as groups were imbalanced at baseline (mean PUSH scores at baseline: 9.11 in people taking supplements v 6.07 in people taking placebo) and results were not based on an intention-to-treat analysis	○○○	nutritional supplements
[22] Systematic review	95 people (80 completed study), age range 22 to 102 years, acute care, grade I to IV	Adjusted mean change in ulcer size on wound surface area 2.70 with standard care plus standard diet	Reported as not significant for any comparison P value not reported	↔	Not significant

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
	ulcers, trial duration 1 week Data from 1 RCT 4-armed trial	2.76 with consistent wound care 2.60 with controlled nutritional support 2.34 with consistent wound care plus controlled nutritional support Units of measurement not reported			
[30] RCT	30 people, aged 65 years or over, recent onset (<1-month history) grade II to IV ulcers, orally or tube fed	PUSH change from baseline , 12 weeks 6.1 with disease-specific nutrition treatment 3.3 with standard diet Disease-specific nutrition treatment (standard diet plus oral supplement or specific enteral formula enriched with protein, arginine, zinc, and vitamin C) PUSH scale 0 to 17	P <0.05 Analysis was not by intention to treat (2 people were excluded), only people with recent pressure ulcers were included in the trial, and people who were tube fed or fed orally were not analysed separately	○ ○ ○	disease-specific nutrition treatment

Adverse effects

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Adverse effects					
[32] RCT	Number of people unclear In review [22]	Adverse effects with nutritional supplements with placebo	11/44 (25%) people discontinued treatment because of adverse effects (2 with hip fracture because of fall; 3 because of changes in renal laboratory values; 4 with nausea or distension; 2 died), but the RCT did not report data for each group separately, except to say that 1 person in each group died from causes unrelated to treatment		

No data from the following reference on this outcome. [13] [22] [30]

Further information on studies

[13] Many of the RCTs were small and may have lacked power to detect clinically important differences between treatments. The fourth included RCT (14 people) identified by the first review was a crossover RCT that did not report results before the crossover period, and had a high withdrawal rate.

[22] This review included three RCTs included in the first review and 4 further RCTs. Many of the RCTs were small and may have lacked power to detect clinically important differences between treatments. The third included RCT (36 people, age range 72–91 years, 2 weeks' trial duration) identified by the second review compared standard hospital diet, standard diet plus high protein, and standard diet plus high protein plus arginine, zinc, and antioxidants. The RCT was of poor methodological quality and data on Pressure Score Status Tool scores were not available.

Comment: None.

OPTION SEAT CUSHIONS TO TREAT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- We don't know whether seat cushions improve healing in people with pressure ulcers.

Benefits and harms

Seat cushions versus each other or standard care:

We found two systematic reviews (search dates 2000^[21] and 2008^[22]).

Healing rates

Compared with each other or standard care We don't know whether seat cushions are more effective than standard care at reducing time to complete healing, or whether different seat cushions differ in effectiveness at increasing pressure ulcer healing (*very low-quality evidence*).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Healing rates					
^[21] Systematic review	28 people Data from 1 RCT	Complete healing with cushion with dry flotation with alternating-pressure cushion Absolute results not reported	Reported as not significant P value not reported	↔	Not significant
^[33] RCT 3-armed trial	207 people with grade 3 and 4 pressure ulcers In review ^[22]	Mean time to complete healing , 6 months 3.33 months with bespoke, moulded seat containing alternating-pressure air sacs 4.55 months with solid-foam bed overlay 8.9 cm thick 4.38 with low-air-loss mattress	P value not reported See further information about studies for details on trial methods		
^[33] RCT 3-armed trial	207 people with grade 3 and 4 pressure ulcers In review ^[22] The remaining arm assessed solid-foam bed overlay 8.9 cm thick	Mean improvement in Pressure Sore Status Score 34.3 with bespoke, moulded seat containing alternating-pressure air sacs 18.4 with low-air-loss mattress	P <0.001 See further information about studies for details on trial methods	○○○	alternating-pressure mattress

Adverse effects

No data from the following reference on this outcome. ^[21] ^[22]

Further information on studies

^[33] The RCT had several flaws, including a lack of intention-to-treat analysis (participants who worsened were excluded from analysis), and a primary outcome that was determined by the results of the trial.

Comment: None.

OPTION SURGERY TO TREAT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- We found no direct information from RCTs about surgery in the treatment of pressure ulcers.

Benefits and harms

Surgery versus no surgery/other interventions:

We found no systematic review or RCTs of surgical treatments for pressure ulcers.

Further information on studies

Comment: None.

OPTION THERAPEUTIC ULTRASOUND TO TREAT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- We don't know whether ultrasound improves healing of pressure ulcers.

Benefits and harms

Ultrasound versus sham ultrasound:

We found one systematic review (search date 2008, 3 RCTs).^[34] The review reported that all three RCTs were small (40 people; 18 people; 88 people), allocation concealment was not stated in two RCTs, and an intention-to-treat analysis was not performed in two RCTs. All three RCTs used blinded outcomes assessments.

Healing rates

Compared with sham ultrasound We don't know whether therapeutic ultrasound is more effective than sham ultrasound at increasing the number of sores healed (**very low-quality evidence**).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Healing rates					
^[34] Systematic review	128 people 2 RCTs in this analysis	Number of sores healed with therapeutic ultrasound with sham ultrasound Absolute results not reported 1 included RCT assessed outcomes at 12 weeks; the other RCT did not report the timing of outcome assessment	RR 0.97 95% CI 0.65 to 1.45	↔	Not significant

Adverse effects

No data from the following reference on this outcome.^[34]

Ultrasound plus ultraviolet light versus standard care or versus laser treatment:

We found one systematic review (search date 2008, 3 RCTs).^[34] The review reported that all three RCTs were small (40 people; 18 people; 88 people), allocation concealment was not stated in two RCTs, and an intention-to-treat analysis was not performed in two RCTs. All three RCTs used blinded outcomes assessments.

Healing rates

Ultrasound plus ultraviolet light compared with standard care or laser treatment We don't know whether ultrasound plus ultraviolet light is more effective than standard care or laser treatment at increasing the number of sores healed at 12 weeks. (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Healing rates					
^[34] Systematic review	20 people Data from 1 RCT 3-armed trial The remaining arm assessed laser treatment	Number of sores healed , 12 weeks 6/6 (100%) with ultrasound plus UV 5/6 (83%) with standard care	RR 1.18 95% CI 0.76 to 1.83 The RCT was underpowered to detect clinically important differences between groups	↔	Not significant
^[34] Systematic review	20 people Data from 1 RCT 3-armed trial The remaining arm assessed standard care	Number of sores healed , 12 weeks 6/6 (100%) with ultrasound plus UV 4/6 (67%) with laser treatment	RR 1.44 95% CI 0.80 to 2.60 The RCT was underpowered to detect clinically important differences between groups	↔	Not significant

Adverse effects

No data from the following reference on this outcome.^[34]

Further information on studies

Comment: None.

OPTION TOPICAL NEGATIVE PRESSURE TO TREAT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- We don't know whether topical negative pressure improves healing of pressure ulcers.

Benefits and harms

Topical negative pressure versus control:

We found three systematic reviews (search dates 2007^[35] ^[36] and 2008^[22]), which examined the effects of topical negative pressure. One review identified 5 RCTs^[36] and one review of topical negative pressure for treating chronic wounds identified 7 RCTs.^[35] However, not all the RCTs were solely in people with pressure ulcers, and the RCTs did not separately report results for people with pressure ulcers only, so we have not reported these RCTs further. All three reviews identified the same two RCTs, which were solely in people with pressure ulcers. Both RCTs were of poor methodological quality (CLEAR NPT criteria [maximum 6]; first RCT, score 0; second RCT, score 2).^[22]

Healing rates

Compared with control We don't know whether topical negative pressure is more effective than gauze soaked in Ringer's solution or a regimen of three gel products at increasing healing of pressure ulcers (*very low-quality evidence*).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Healing rates					
[35] [36] Systematic review	22 people Data from 1 RCT There were differences between groups at baseline (the mean age of people receiving topical negative pressure was 41.7 years compared with 54.4 years in people receiving gauze soaked in Ringer's solution)	Mean time to reach 50% reduction in initial wound volume with topical negative pressure with gauze soaked in Ringer's solution Absolute results not reported	Mean difference -1.00 days 95% CI -0.82 days to +6.21 days	↔	Not significant
[35] [22] Systematic review	35 people Data from 1 RCT	Wound surface reduction 51.8% with topical negative pressure 42.1% with regimen of three gel products Absolute numbers not reported Three gel products included: papain-urea debridement ointment, cadexomer iodine, papain-urea-chlorophyllin-copper ointment There were differences between groups in wound size at baseline	P = 0.46	↔	Not significant

Adverse effects

No data from the following reference on this outcome. [22] [35] [36]

Further information on studies

Comment: None.

OPTION TOPICAL PHENYTOIN TO TREAT PRESSURE ULCERS

- For GRADE evaluation of interventions for Pressure ulcers, see table, p 41 .
- We don't know whether phenytoin improves healing of pressure ulcers.

Benefits and harms

Topical phenytoin versus control/standard treatment:

We found one systematic review (search date 2008), which found three RCTs. [22]

Healing rates

Compared with hydrocolloid/standard dressings or antibiotic ointment We don't know whether topical phenytoin ointment is more effective at increasing pressure ulcer healing (very low-quality evidence).

Ref (type)	Population	Outcome, Interventions	Results and statistical analysis	Effect size	Favours
Healing rates					
[37] RCT	48 people In review [22]	Mean time to healing 35.3 days with topical phenytoin suspension (100 mg capsule in 5 mL saline) 51.8 days with hydrocolloid dressings or antibiotic ointment No data that showed baseline equivalence for wound size were presented	P <0.005		topical phenytoin suspension
[38] RCT 3-armed trial	83 people In review [22] The remaining arm assessed standard dressings	Complete ulcer healing 11/28 (39%) with topical phenytoin 20/28 (71%) with hydrocolloid dressings In this RCT there were important between-group differences at baseline for ulcer size (mean size: 5 cm ² with topical phenytoin v 7 cm ² with hydrocolloid dressings v 10 cm ² with standard dressings; P >0.10). Although these difference were not significant, they are likely to have biased the results against standard dressings	ARR 32% 95% CI 7.4% to 56.7%		topical phenytoin
[38] RCT 3-armed trial	83 people In review [22] The remaining arm assessed hydrocolloid dressings	Complete ulcer healing 11/28 (39%) with topical phenytoin 8/27 (30%) with standard dressings In this RCT there were important between-group differences at baseline for ulcer size (mean size: 5 cm ² with topical phenytoin v 7 cm ² with hydrocolloid dressings v 10 cm ² with standard dressings; P >0.10). Although these difference were not significant, they are likely to have biased the results against standard dressings	P value not reported		
[22] Systematic review	28 people, mean age 31 to 34 years, rehabilitation, trial duration 2 weeks, grade II ulcers Data from 1 RCT	Mean reduction in Pressure Ulcer Scale for Healing (PUSH) scores , 2 weeks 19.53 with phenytoin solution 11.39 with normal saline	P = 0.26		Not significant

Adverse effects

No data from the following reference on this outcome. [22] [37] [38]

Further information on studies

Comment: **Clinical guide:**
Topical phenytoin is an experimental treatment rarely used in current clinical practice.

GLOSSARY

Air-fluidised supports Membranes that cover a layer of particles that are fluidised by having air forced through them. The airflow can be turned off, which makes the surface solid again, to allow the person to be moved. People find it difficult to get in and out of these beds independently; therefore, they are usually reserved for people who spend most of the day in bed.

Alternating-pressure surfaces Mattresses or overlays made of one or two layers of parallel air sacs. Alternate sacs are inflated and deflated, which provides alternating pressure and release for each area of skin.

Dextranomer paste Anhydrous, porous beads 0.1 mm to 0.3 mm in diameter. These beads are hydrophilic and absorb and adsorb exudate, wound debris, and bacteria, depending on particle size.

Electrotherapy The application of electrical fields by placing electrodes near a wound. Treatments include pulsed electromagnetic therapy, low-intensity direct current, negative-polarity and positive-polarity electrotherapy, and alternating-polarity electrotherapy.

Low- or high-tech constant-low-pressure supports Mattresses, overlays, and cushions made of high-density or contoured foam or filled with fibre, gel, water, beads, or air. They increase the area of contact between the person and the support surface and thus reduce the pressure at the interface. See also air-fluidised supports, low-air-loss beds, and low-air-loss hydrotherapy beds.

Low-air-loss beds Mattresses that consist of inflatable upright sacs of semipermeable fabric. Inflation of the sacs increases the area of contact between the individual and the support surface and reduces the pressure on the skin. People find it difficult to get in and out of these beds independently; therefore, they are usually reserved for people who spend most of the day in bed.

Low-air-loss hydrotherapy beds A mattress that consists of cushions covered by a permeable, fast-drying filter sheet, through which air is circulated. The bed also contains a urine-collecting device.

Low-quality evidence Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Moderate-quality evidence Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Therapeutic ultrasound The application of ultrasound to a wound with a transducer and water-based gel. The power of ultrasound waves used in wound healing is low to avoid heating the tissues.

Topical negative pressure Negative pressure (suction) applied to a wound through an open-cell dressing (e.g., foam or felt).

Very low-quality evidence Any estimate of effect is very uncertain.

SUBSTANTIVE CHANGES

Air-filled vinyl boots to prevent pressure ulcers Search updated for an already included systematic review.^[7] New evidence added. Categorisation unchanged (Unlikely to be beneficial).

Air-fluidised support to treat pressure ulcers New evidence added.^[22] Categorisation unchanged (Likely to be beneficial).

Alternating-pressure surfaces to prevent pressure ulcers Search updated for an already included systematic review.^[7] New evidence added. Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Alternating-pressure surfaces to treat pressure ulcers New evidence added.^[22] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Debridement to treat pressure ulcers New evidence added.^[22] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Dressings (hydrocolloid and non-hydrocolloid) versus each other to treat pressure ulcers Option restructured. Previous options of 'Hydrocolloid dressings to treat pressure ulcers' and 'Dressings other than hydrocolloid to treat

pressure ulcers' reported in one option of 'Dressings (hydrocolloid and non-hydrocolloid) versus each other to treat pressure ulcers'. New evidence added. ^[22] 'Dressings (one type versus any other type)' categorised as Unknown effectiveness as we found no evidence that any one type of dressing is consistently more effective than all other types of dressings.

Electric profiling beds to prevent pressure ulcers Search updated for an already included systematic review. ^[7] No new evidence added. Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Electrotherapy to treat pressure ulcers New evidence added. ^[22] ^[26] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Foam alternatives versus standard foam mattresses to prevent pressure ulcers Search updated for an already included systematic review. ^[7] No new evidence added. Categorisation unchanged (Beneficial).

Low-air-loss beds to prevent pressure ulcers Search updated for an already included systematic review. ^[7] New evidence added. Categorisation unchanged (Likely to be beneficial). However, all RCTs conducted in an intensive care setting, which may limit generalisability of results.

Low-air-loss beds to treat pressure ulcers New evidence added. ^[22] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence on effects of this intervention.

Low-level laser treatment to treat pressure ulcers New evidence added. ^[22] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Low-tech constant-low-pressure supports to prevent pressure ulcers Search updated for an already included systematic review. ^[7] New evidence added. Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Low-tech constant-low-pressure supports to treat pressure ulcers New evidence added. ^[22] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Medical sheepskin overlays to prevent pressure ulcers Search updated for an already included systematic review. ^[7] New evidence added. Categorisation unchanged (Likely to be beneficial).

Nutritional supplements to treat pressure ulcers New evidence added. ^[22] ^[30] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Seat cushions to prevent pressure ulcers Search updated for an already included systematic review. ^[7] New evidence added. Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Seat cushions to treat pressure ulcers New evidence added. ^[22] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Therapeutic ultrasound to treat pressure ulcers Search updated for already included systematic review. ^[34] New evidence added. Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Topical negative pressure to treat pressure ulcers New evidence added. ^[22] ^[35] ^[36] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Topical phenytoin to treat pressure ulcers New evidence added. ^[22] Categorisation unchanged (Unknown effectiveness), as there remains insufficient evidence to judge the effects of this intervention.

Low-air-loss hydrotherapy beds to prevent pressure ulcers Search updated for an already included systematic review. ^[7] No new evidence added. Existing evidence reassessed. Categorisation changed from Unlikely to be beneficial to Unknown effectiveness, as there remains insufficient evidence to judge the effects of this intervention.

Pressure-relieving overlays on operating tables to prevent pressure ulcers Search updated for an already included systematic review. ^[7] New evidence added. Categorisation changed from Unknown effectiveness to Likely to be beneficial.

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GRADE Evaluation of interventions for Pressure ulcers.

Important outcomes	Healing rates, Prevention of pressure ulcers								GRADE	Comment
	Studies (Participants)	Outcome	Comparison	Type of evidence	Quality	Consistency	Directness	Effect size		
<i>What are the effects of preventive interventions in people at risk of developing pressure ulcers?</i>										
6 (2117) ^[7]	Prevention of pressure ulcers	Foam alternatives versus standard hospital mattress	4	-1	0	0	0	Moderate	Quality point deducted for incomplete reporting of results	
5 (795) ^[7]	Prevention of pressure ulcers	Different foam alternatives versus each other	4	-1	0	-2	0	Very low	Quality point deducted for incomplete reporting of results. Directness points deducted for underpowered RCTs and small number of comparators	
5 (1402) ^[7]	Prevention of pressure ulcers	Pressure-relieving overlays on operating tables versus standard table alone	4	-1	-1	-1	0	Very low	Quality point deducted for weak methods. Consistency point deducted for conflicting results between RCTs. Directness point deducted for early termination of 1 RCT	
3 (283) ^[7] ^[8]	Prevention of pressure ulcers	Low-air-loss beds versus standard intensive-care beds/alternating-pressure mattresses	4	-2	0	0	0	Low	Quality points deducted for incomplete reporting of intervention and weak methods	
2 (730) ^[7] ^[8]	Prevention of pressure ulcers	Medical sheep skin overlays versus standard care	4	0	0	-2	+1	Moderate	Directness points deducted for selective exclusion of high-risk participants and no intention-to-treat analysis. Effect size point added for RR <0.5	
2 (409) ^[7]	Prevention of pressure ulcers	Alternating-pressure surfaces versus standard foam mattress	4	-3	0	-1	+1	Very low	Quality points deducted for unclear allocation concealment, blinding, and incomplete reporting of results. Directness point deducted for no intention-to-treat analysis. Effect size point added for RR <0.5	
10 (1606) ^[7]	Prevention of pressure ulcers	Alternating-pressure surfaces versus constant-low-pressure supports	4	-1	0	-1	0	Low	Quality point deducted for weak methods. Directness point deducted for unclear clinical relevance (heterogeneity in comparators, and wide confidence intervals not excluding clinically important effect)	
4 (2153) ^[7]	Prevention of pressure ulcers	Alternating-pressure surfaces versus each other	4	-1	0	-1	0	Low	Quality point deducted for weak methods. Directness point deducted for 3 underpowered RCTs	
4 (473) ^[7]	Prevention of pressure ulcers	Seat cushions versus each other	4	-1	0	-1	0	Low	Quality point deducted for weak methods. Directness point deducted for underpowered individual trials	
1 (70) ^[7]	Prevention of pressure ulcers	Electric profiling beds to prevent pressure ulcers versus standard hospital beds	4	-1	0	-1	0	Low	Quality point deducted for sparse data. Directness point deducted for small number of events (no events in either group)	
5 (1475) ^[8] ^[13]	Prevention of pressure ulcers	Nutritional supplements versus control	4	-3	0	-2	0	Very low	Quality points deducted for unclear randomisation, lack of blinding, and high withdrawal rates. Directness points deducted for no intention-to-treat analysis and no between-group analysis in 1 RCT	

Important outcomes		Healing rates, Prevention of pressure ulcers							
Studies (Participants)	Outcome	Comparison	Type of evidence	Quality	Consistency	Directness	Effect size	GRADE	Comment
4 (1055) ^[15] ^[16]	Prevention of pressure ulcers	Repositioning versus control, usually standard care	4	-2	0	-1	0	Very low	Quality points deducted for weak methods and incomplete reporting of results. Directness point deducted for co-intervention in 1 RCT (change of mattress as well as frequency of repositioning)
1 (46) ^[8] ^[17]	Prevention of pressure ulcers	Repositioning at 30 degree tilt versus a 90 degree lateral and supine position	4	-2	0	-1	0	Very low	Quality points deducted for sparse data and incomplete reporting of results. Directness point deducted for short follow-up (24 hours)
3 (618) ^[8] ^[18]	Prevention of pressure ulcers	Topical lotions and dressings versus placebo or other lotions and dressings	4	-2	0	-1	0	Very low	Quality points deducted for incomplete reporting of results and poor follow-up. Directness point deducted for no intention-to-treat analysis
1 (52) ^[7] ^[8]	Prevention of pressure ulcers	Air-filled vinyl boot versus hospital pillow	4	-2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
1 (111) ^[8] ^[20]	Prevention of pressure ulcers	Hydrocellular heel supports versus orthopaedic wool padding/standard care	4	-2	0	0	0	Low	Quality points deducted for sparse data and no intention-to-treat analysis
1 (98) ^[7]	Prevention of pressure ulcers	Low-air-loss hydrotherapy beds versus other specialised support surfaces	4	-2	0	0	0	Low	Quality points deducted for sparse data and weak methods
<i>What are the effects of treatments in people with pressure ulcers?</i>									
3 (202) ^[21] ^[22]	Healing rates	Air-fluidised supports versus standard care	4	-1	0	-1	0	Low	Quality point deducted for incomplete reporting of results. Directness point deducted for no intention-to-treat analysis
5 (372) ^[22]	Healing rates	Alternating-pressure surfaces versus standard/other care	4	-2	0	0	0	Low	Quality points deducted for incomplete reporting of results and poor study completion rate
at least 32 (at least 208) ^[22] ^[23]	Healing rates	Debridement versus no debridement or different debriding agents versus each other	4	-3	0	0	0	Very low	Quality points deducted for incomplete reporting of results, weak methods, and poor trial completion
7 (at least 396) ^[22] ^[24]	Healing rates	Hydrocolloid dressings versus gauze soaked in saline, hypochlorite, or povidone iodine	4	-1	0	-1	0	Low	Quality point deducted for weak methods. Directness point deducted for significance of meta-analysis result being sensitive to the method of calculation
15 (unclear) ^[22]	Healing rates	Hydrocolloid dressings versus non-hydrocolloid dressings other than gauze soaked in saline, hypochlorite, or povidone iodine	4	-2	0	0	0	Low	Quality points deducted for weak methods and incomplete reporting of results
6 (154) ^[21] ^[22] ^[26]	Healing rates	Electrotherapy versus sham electrotherapy or standard treatment	4	-2	0	0	0	Low	Quality points deducted for weak methods and incomplete reporting of results
4 (360) ^[21] ^[22]	Healing rates	Low-air-loss beds versus standard beds or standard care	4	-1	0	-1	0	Low	Quality point deducted for incomplete reporting of results. Directness point deducted for no statistical analysis between groups for 2 analyses
2 (104) ^[22]	Healing rates	Low-level laser treatment versus standard care or sham treatment	4	-2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results

Important outcomes		Healing rates, Prevention of pressure ulcers								
Studies (Participants)	Outcome	Comparison	Type of evidence	Quality	Consistency	Directness	Effect size	GRADE	Comment	
1 (120) [21] [22]	Healing rates	Low-tech constant-low-pressure supports versus each other	4	-2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results	
9 (400) [13] [22] [30]	Healing rates	Nutritional supplements versus control	4	-2	0	-1	0	Very low	Quality points deducted for weak methods and incomplete reporting of results. Directness point deducted for no intention-to-treat analysis in some trials	
2 (235) [21] [22]	Healing rates	Seat cushions versus each other or standard care	4	-2	0	-1	0	Very low	Quality points deducted for incomplete reporting of results and weak methods. Directness point deducted for no intention-to-treat analysis (selective exclusion of participants from analysis)	
2 (128) [34]	Healing rates	Ultrasound versus sham ultrasound	4	-3	0	0	0	Very low	Quality points deducted for sparse data, weak methods, and incomplete reporting of results	
1 (18) [34]	Healing rates	Ultrasound plus ultraviolet light versus standard care or versus laser treatment	4	-3	0	0	0	Very low	Quality points deducted for sparse data, weak methods, and small number of events (3 failures in total in trial)	
2 (57) [22] [35] [36]	Healing rates	Topical negative pressure versus control	4	-3	0	0	0	Very low	Quality points deducted for sparse data, weak methods, and differences between groups at baseline	
3 (159) [22]	Healing rates	Topical phenytoin versus control/standard treatment	4	-2	-1	-1	0	Very low	Quality points deducted for sparse data and weak methods. Consistency point deducted for conflicting results. Directness point deducted for baseline differences	

We initially allocate 4 points to evidence from RCTs, and 2 points to evidence from observational studies. To attain the final GRADE score for a given comparison, points are deducted or added from this initial score based on preset criteria relating to the categories of quality, directness, consistency, and effect size. Quality: based on issues affecting methodological rigour (e.g., incomplete reporting of results, quasi-randomisation, sparse data [<200 people in the analysis]). Consistency: based on similarity of results across studies. Directness: based on generalisability of population or outcomes. Effect size: based on magnitude of effect as measured by statistics such as relative risk, odds ratio, or hazard ratio.