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[Intervention Review]

Support surfaces for treating pressure ulcers

Elizabeth McInnes¹, Asmara Jammali-Blasi¹, Sally EM Bell-Syer², Vannessa Leung^{3,4,5}

¹Nursing Research Institute, St Vincent's Health Australia (Sydney) and Australian Catholic University (ACU), School of Nursing, Midwifery and Paramedicine, Australian Catholic University, Darlinghurst, Australia. ²Cochrane Editorial Unit, Cochrane, London, UK. ³Sydney Eye Hospital, Sydney, Australia. ⁴The University of Sydney, Sydney, Australia. ⁵The University of New South Wales, Sydney, Australia

Contact address: Elizabeth McInnes, Nursing Research Institute, St Vincent's Health Australia (Sydney) and Australian Catholic University (ACU), School of Nursing, Midwifery and Paramedicine, Australian Catholic University, Executive Suite, Level 5 DeLacy Building, St Vincent's Hospital, 390 Victoria Road, Darlinghurst, New South Wales, 2010, Australia. liz.mcinnes@acu.edu.au, lizmcinnes@bigpond.com.

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ABSTRACT

Background

Pressure ulcers are treated by reducing pressure on the areas of damaged skin. Special support surfaces (including beds, mattresses and cushions) designed to redistribute pressure, are widely used as treatments. The relative effects of different support surfaces are unclear. This is an update of an existing review.

Objectives

To assess the effects of pressure-relieving support surfaces in the treatment of pressure ulcers.

Search methods

In September 2017 we searched the Cochrane Wounds Specialised Register; the Cochrane Central Register of Controlled Trials (CENTRAL); Ovid MEDLINE (including In-Process & Other Non-Indexed Citations); Ovid Embase and EBSCO CINAHL Plus. We also searched clinical trials registries for ongoing and unpublished studies, and scanned reference lists of relevant included studies as well as reviews, meta-analyses and health technology reports to identify additional studies. There were no restrictions with respect to language, date of publication or study setting.

Selection criteria

We included published or unpublished randomised controlled trials (RCTs), that assessed the effects of support surfaces for treating pressure ulcers, in any participant group or setting.

Data collection and analysis

Data extraction, assessment of 'Risk of bias' and GRADE assessments were performed independently by two review authors. Trials with similar participants, comparisons and outcomes were considered for meta-analysis. Where meta-analysis was inappropriate, we reported the results of the trials narratively. Where possible, we planned to report data as either risk ratio or mean difference as appropriate.

Main results

For this update we identified one new trial of support surfaces for pressure ulcer treatment, bringing the total to 19 trials involving 3241 participants. Most trials were small, with sample sizes ranging from 20 to 1971, and were generally at high or unclear risk of bias.

Primary outcome: healing of existing pressure ulcers

Support surfaces for treating pressure ulcers (Review)

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Low-tech constant pressure support surfaces

It is uncertain whether profiling beds increase the proportion of pressure ulcer which heal compared with standard hospital beds as the evidence is of very low certainty: (RR 3.96, 95% CI 1.28 to 12.24), downgraded for serious risk of bias, serious imprecision and indirectness (1 study; 70 participants).

There is currently no clear difference in ulcer healing between water-filled support surfaces and foam replacement mattresses: (RR 0.93, 95% CI 0.63 to 1.37); low-certainty evidence downgraded for serious risk of bias and serious imprecision (1 study; 120 participants).

Further analysis could not be performed for polyester overlays versus gel overlays (1 study; 72 participants), non-powered mattresses versus low-air-loss mattresses (1 study; 20 participants) or standard hospital mattresses with sheepskin overlays versus standard hospital mattresses (1 study; 36 participants).

High-tech pressure support surfaces

It is currently unclear whether high-tech pressure support surfaces (such as low-air-loss beds, air suspension beds, and alternating pressure surfaces) improve the healing of pressure ulcers (14 studies; 2923 participants) or which intervention may be more effective. The certainty of the evidence is generally low, downgraded mostly for risk of bias, indirectness and imprecision.

Secondary outcomes

No analyses were undertaken with respect to secondary outcomes including participant comfort and surface reliability and acceptability as reporting of these within the included trials was very limited.

Overall, the evidence is of low to very low certainty and was primarily downgraded due to risk of bias and imprecision with some indirectness.

Authors' conclusions

Based on the current evidence, it is unclear whether any particular type of low- or high-tech support surface is more effective at healing pressure ulcers than standard support surfaces.

PLAIN LANGUAGE SUMMARY

Support surfaces for treating pressure ulcers

What is the aim of this review?

The aim of this review was to find out whether different support surfaces such as specially-designed beds, mattresses or cushions can help to treat pressure ulcers. Researchers from Cochrane collected and analysed all relevant studies (randomised controlled trials) to answer this question, and found 19 relevant studies.

Key messages

We cannot be certain which support surfaces are most effective for pressure ulcer treatment as the studies comparing them did not involve enough people and were not well designed.

What was studied in the review?

Pressure ulcers (also called pressure sores, decubitus ulcers and bed sores) are wounds to the skin and underlying tissue caused by pressure or rubbing. They typically form at points on the body which are bony or which bear weight or pressure, such as the hips, buttocks, heels and elbows. People who have mobility problems or who lie in bed for long periods are at risk of developing pressure ulcers. A range of treatments, including wound dressings and support surfaces like special mattresses and cushions, are used to treat pressure ulcers.

Support surfaces for pressure ulcer treatment can include specially-designed beds, mattresses, mattress overlays and cushions that are used to protect vulnerable parts of the body and distribute the surface pressure more evenly. Low-tech support surfaces include mattresses filled with foam, fluid, beads or air; and alternative foam mattresses and overlays. High-tech support surfaces include mattresses and overlays that are electrically powered to alternate the pressure within the surface, beds that are powered to have air mechanically circulated within them and low-air-loss beds that contain warm air moving within pockets inside the bed. Other support surfaces include sheepskins, cushions and operating table overlays.

We wanted to find out which support surfaces were most effective in helping pressure ulcers to heal. We also wanted to compare different support surfaces in terms of cost, reliability, durability, and the benefits or harms for patients using them.

What are the main results of the review?

In September 2017, we searched for trials looking at support surfaces for treating pressure ulcers and which reported their effects on wound healing. We found 19 trials involving 3241 participants, all adults, the majority of whom were older people and bed-bound in hospitals or nursing homes. In studies where participants' sex was reported, the majority were women. Not all studies reported their funding sources, but two of those who did were funded by device manufacturers.

Five studies involving 318 participants compared low-tech constant low-pressure (CLP) support surfaces such as foam mattresses. We cannot be certain how these different support surfaces affect pressure ulcer healing as the evidence is mainly of low certainty. Fourteen studies involving 2923 participants compared different high-tech support surfaces such as air-fluidised beds. Again, we cannot be certain how these different support surfaces affect ulcer healing rates as the certainty of the evidence is mainly low.

We are not able to draw firm conclusions about the effects of different support surfaces for treating pressure ulcers because the overall quality of the evidence is low to very low. Many of the studies included only small numbers of people, did not provide adequate information on their results, or were not well designed. Further, better conducted trials are necessary to determine which support surfaces are most effective in treating pressure ulcers.

How up to date is this review?

We searched for studies that had been published up to September 2017.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Profiling bed with foam mattress compared with hospital bed with foam mattress

Profiling bed with foam mattress compared with hospital bed with foam mattress

Patient or population: patients from two surgical and two medical wards

Settings: multiple hospital wards

Intervention: profiling bed

Comparison: foam mattress

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Foam mattress	Profiling bed				
Pressure ulcer healing Follow-up: 5-10 days	Study population		RR 3.96 (1.28 to 12.24)	70 (1 study)	⊕⊕⊕⊕ Very low ¹	
	200 per 1000	792 per 1000 (256 to 1000)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence

High quality: further research is very unlikely to change our confidence in the estimate of effect.

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

Low quality: 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.

Very low quality: we are very uncertain about the estimate.

¹ Downgraded twice for multiple high risks of bias, twice for imprecision (low numbers of participants resulting in wide fragile confidence intervals) and once for indirectness as only a minority of participants had pressure ulcers at enrolment

Summary of findings 2. Water mattress overlay compared with low-tech mattress

Water mattress overlay compared with low-tech mattress

Patient or population: nursing home patients, > 59 years old

Settings: nursing home

Intervention: water mattress support

Comparison: foam replacement mattress

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Foam replacement mattress	Water mattress support				
Pressure ulcer healing Follow-up: 4 weeks	Study population		RR 0.93 (0.63 to 1.37)	120 (1 study)	⊕⊕⊕⊕ Low ¹	
	483 per 1000	450 per 1000 (304 to 662)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

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Very low quality: we are very uncertain about the estimate.

¹ Downgraded once for risks of bias including Incomplete outcome data and once for imprecision resulting in wide confidence intervals

Summary of findings 3. Low-air-loss bed compared with low-tech mattress overlay

Low-air-loss bed compared with low-tech mattress overlay

Patient or population: elderly nursing home residents with multiple medical problems

Settings: nursing home

Intervention: low-air-loss bed

Comparison: low-tech mattress overlay

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Low-tech mattress overlay	Low-air-loss bed				
Pressure ulcers completely healed	Study population		RR 1.30 (0.87 to 1.96)	84 (1 study)	⊕⊕⊕⊕ Low ¹ ,	

Follow-up: 33-40 days

463 per 1000
602 per 1000
(403 to 908)

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence

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Very low quality: we are very uncertain about the estimate.

¹ Downgraded once for risks of bias including incomplete outcome data and once for imprecision resulting in wide confidence intervals

Summary of findings 4. Alternating pressure mattresses

Alternating pressure mattresses

Patient or population: varied

Settings: multiple

Intervention: alternating pressure mattress

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Alternating pressure mattress				
Ulcers completely healed Follow-up: 4 weeks	Study population		RR 0.57 (0.26 to 1.27)	30 (1 study)	⊕⊕⊕⊖ Low ¹	
	625 per 1000	356 per 1000 (162 to 794)				
Decrease in pressure ulcer size Follow-up: 4 weeks	Study population		RR 0.58 (0.21 to 1.65)	30 (1 study)	⊕⊕⊕⊖ Low ²	
	429 per 1000	249 per 1000 (90 to 707)				
Ulcers completely healed Follow-up: 18 months	Study population		RR 0.99 (0.90 to 1.09)	141 (1 study)	⊕⊕⊕⊖ Low ³	
	929 per 1000	919 per 1000				

(836 to 1000)

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence

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Low quality: 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.

Very low quality: we are very uncertain about the estimate.

¹ Downgraded once for risk of bias including high rates of withdrawal and once for imprecision resulting in wide confidence intervals

² Downgraded once for risk of bias and once for imprecision

³ Downgraded once for selection bias and once for imprecision resulting in wide confidence intervals which include the possibility of both benefit and harm.

Summary of findings 5. Alternating-pressure mattress compared with alternating-pressure mattress overlay

Alternating-pressure mattress compared with alternating-pressure mattress overlay

Patient or population: varied

Settings: multiple

Intervention: alternating-pressure mattress

Comparison: alternating-pressure mattress overlay

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Alternating-pressure mattress overlay	Alternating-pressure mattress				
Pressure ulcer improvement	Study population		RR 0.97 (0.80 to 1.17)	158 (1 study)	⊕⊕○○ Low ¹	
	747 per 1000	724 per 1000 (597 to 874)				
Pressure ulcer healing Follow-up: 30 days	Study population		RR 0.96 (0.58 to 1.60)	113 (1 study)	⊕⊕○○ Low ²	
	352 per 1000	338 per 1000 (204 to 563)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence

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Low quality: 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.

Very low quality: we are very uncertain about the estimate.

¹ Downgraded once for risk of attrition bias and once for imprecision resulting in wide confidence intervals

² Downgraded once for risk of attrition bias and once for imprecision resulting in wide confidence intervals

Summary of findings 6. Alternating-pressure mattress compared with air-filled devices

Alternating-pressure mattress compared with air-filled devices

Patient or population: patients with pressure ulcers

Settings: aged care facility, acute care hospital and home setting

Intervention: alternating-pressure mattress

Comparison: air-filled devices

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Air-filled devices	Alternating-pressure mattress				
Proportion of patients with healed pressure ulcer Follow-up: 0-42 days	Study population		RR 5.50 (0.73, 41.44)	50 (1 study)	⊕⊕⊕⊖ Low ¹	
	38 per 1000	206 per 1000 (27 to 1000)				
	Moderate					
	39 per 1000	209 per 1000 (27 to 1000)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence

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

Low quality: 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.

Very low quality: we are very uncertain about the estimate.

¹ Downgraded once for possible selection bias and attrition bias due to limited details provided and once due to imprecision resulting in wide confidence intervals

Summary of findings 7. Alternating-pressure cushion compared with dry flotation cushion

Alternating-pressure cushion compared with dry flotation cushion

Patient or population: patients with pressure ulcers

Settings: acute care hospital and nursing homes

Intervention: alternating-pressure cushion

Comparison: dry flotation cushion

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Dry flotation cushion	Alternating-pressure cushion				
Pressure ulcers completely healed Follow-up: median 43-58 days	Study population		RR 0.47 (0.14 to 1.56)	25 (1 study)	⊕⊕○○ Low ¹	
	455 per 1000	214 per 1000 (64 to 709)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

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

Low quality: 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.

Very low quality: we are very uncertain about the estimate.

¹ Downgraded once for risk of bias due to lack of an ITT analysis and once for imprecision resulting in wide confidence intervals

BACKGROUND

Description of the condition

Pressure ulcers (also known as pressure sores, decubitus ulcers and bed sores) are areas of localised damage to the skin and underlying tissue, believed to be caused either by pressure, or by a combination of pressure and shear (Alderden 2011; Coleman 2013; Coleman 2014; NPUAP-EPUAP-PPPIA 2014). Pressure ulcers are more likely to occur in those who are seriously ill or who are neurologically compromised, e.g. individuals with spinal cord injuries, who have impaired mobility (Cooper 2015; Gefen 2014; Van de Wielen 2016), or are immobilised (including by a prostheses, body brace or plaster cast). People with impaired nutrition are also at risk of developing pressure ulcers (Banks 2013; Casey 2003; Delmore 2015; Ferguson 2000; Langer 2014; Posthauer 2015; Roberts 2014). Other risk factors include obesity (Mathison 2003; Pokorny 2014; Wilson 2004); poor posture, or use of equipment such as beds or seating that do not provide appropriate pressure relief; increased age (Bosanquet 2016; Brienza 2010; Hanonu 2016; Horn 2004; Khor 2014; Russo 2008; Stockton 2009; Wipke-Tevis 2004); and being pregnant (Bick 2011; Cheesman 2010). Serious consequences of pressure ulcers include an increased incidence of infection, including osteomyelitis (Bodavula 2015; Rennert 2009).

Description of the intervention

Strategies for treating pressure ulcers usually comprise a combination of pressure-relieving devices such as mattresses and cushions, wound care and repositioning. Wound management strategies, such as wound dressings, debridement techniques, physical therapies and nutritional interventions, are the focus of other recent systematic reviews (Chen 2014; Cullum 2017; Dumville 2015a; Dumville 2015b; Dumville 2015c; Gillespie 2014; Langer 2014; McGinnis 2015; Moore 2013; Moore 2015a; Smith 2013; Zhang 2015).

The aim of pressure-relieving devices is to reduce the magnitude or duration of pressure, or both (including shear and friction) between patients and their support surface (this is called the "interface pressure"). Such devices include cushions, mattress overlays, replacement mattresses, or whole bed-replacements. The cost of these interventions varies widely, from over GBP 30,000 (UK) for some bed replacements to less than GBP 100 for some foam overlays. Information on the relative cost-effectiveness of this equipment is needed to aid rational use.

How the intervention might work

Pressure-relieving support surfaces either mould around the shape of the person to distribute his/her weight over a larger area (constant low-pressure devices) (CLP), or vary the pressure beneath the person mechanically, thus reducing the duration of the pressure applied (alternating-pressure devices) (AP) (Nixon 2006b; Vanderwee 2008). CLP devices (either overlays, mattresses or replacement beds) can be grouped according to their construction (foam, foam and air, foam and gel, profiled foam, hammocks, air suspension, water suspension and air-particulate suspension/air-fluidised). These devices envelop the body so that pressure is dispersed over a large area. AP devices generate alternating high- and low-interface pressures between the body and the support, usually by sequential inflation and deflation of air-filled cells. Such devices are available as cushions, mattress overlays, and single or multi-layer mattress replacements. Other pressure relieving

surfaces move the person. These can include turning beds, such as turning frames, net beds, and turning/tilting beds. These devices, either manually or automatically, assist people who are unable to turn themselves to rotate laterally.

Why it is important to do this review

Research indicates that pressure ulcers represent a major burden of sickness and reduced quality of life for those with a pressure ulcer, their carers and their families (Gorecki 2010; Gorecki 2012; Gorecki 2014; Lourenco 2014; McGinnis 2014; McGinnis 2015; Spilsbury 2007). Often those affected by pressure ulcers require prolonged and frequent contact with the healthcare system, and experience high levels of pain, discomfort and inconvenience (Briggs 2013; Pieper 2009).

The development of pressure ulcers is relatively common. Estimates of pressure ulcer incidence and prevalence from hospital-based studies vary widely according to the definition and grade of ulcer, the patient population and care setting. A review of epidemiological studies in Europe, Canada and the USA describes reported pressure ulcer prevalence in European hospitals as ranging from 8.3% to 23% (Kaltenhalter 2001). In the UK, an estimate of the overall prevalence of pressure ulcers within care settings was 10.2%, with 59% of these being hospital-acquired (Phillips 2009). In US healthcare facilities, reports of prevalence have been estimated at 12.3% (VanGilder 2009), while in Canadian healthcare settings incidence has been reported as 26% (Woodbury 2004).

In Australia, the prevalence of pressure ulcers estimated for the period of 1983 to 2002, ranged from 3% to 37%. This wide variation has been attributed to different healthcare settings and their prevention practices as well as to data collection methods. For example, pressure ulcer prevalence ranged from 9.5% to 17.6% in acute care hospitals and in nursing homes was estimated as 8.9% (Ngyuen 2015).

The presence of pressure ulcers has been associated with a two-to-four-fold increase in risk of death in older people in intensive care units (Bo 2003; Clough 1994; Thomas 1996). Based on the data available, between one-in-four and one-in-five patients within an acute hospital will experience a pressure ulcer (Posnett 2009). The community incidence rate within the UK ranges from 4.4% to 6.8%, and is as high as 16.5% in the USA and Canada (Kaltenhalter 2001).

The annual cost of treating pressure ulcers in Australia was estimated to be AUD 983 million (95% CI 815 to 1151 million) at 2012/13 prices, with opportunity costs valued at a further AUD 819 million (95% CI 572 to 1067 million) (Ngyuen 2015). The cost of treating a pressure ulcer in the UK has been estimated to range from GBP 1214 (category 1 ulcer) to GBP 14,108 for a category 4 ulcer; these are conservative estimates which exclude the impact of more costly negative pressure wound therapy (Dealey 2012). A 2015 systematic review identified treatment costs associated with pressure ulcers, per patient, per day of between EUR 1.71 and 470.49, based on 14 studies across a wide range of settings in Europe and North America between 2001 and 2013 (Demarré 2015). A Canadian study used data from the period 2002-2006 in a single province to estimate treatment costs of pressure ulcers identified as being hospital-acquired as ranging from CAD 44,000 (category 2) to CAD 90,000 (category 4); in each case these costs were higher

than estimates for the cost of treatment of pressure ulcers present on admission to hospital ([Chan 2013](#)).

The presence of a pressure ulcer creates a number of difficulties (psychologically, physically and clinically) for those affected, carers and their families. Clinicians, working in a variety of clinical and non-clinical settings (including primary care and acute trusts) also face challenges when providing holistic, person-centred services for the assessment and treatment of pressure ulcers. These challenges include clinical decisions regarding methods of assessment, and treatments that should be used for individuals with an existing pressure ulcer.

Regardless of the strategies employed to identify people at high risk for developing pressure ulcers, and the numerous interventions deployed to prevent them, pressure ulcers still occur. Treatment should use initiatives based on the best available evidence of clinical- and cost-effectiveness. Hence, we have undertaken a systematic review of the evidence for the effects of pressure-relieving support surfaces, such as beds, mattresses and cushions, in the treatment of pressure ulcers.

Healthcare professionals attempt to prevent the incidence of pressure ulcers using various pressure-relieving devices including, but not limited to, mattresses, beds, overlays, cushions and chairs. A summary of the available devices for pressure ulcer prevention is the subject of another Cochrane Review ([McInnes 2015](#)).

OBJECTIVES

To assess the effects of pressure-relieving support surfaces in the treatment of pressure ulcers.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) of support surfaces that measured the healing of pressure ulcers. No restrictions were imposed on the basis of language of publication of the reports. Studies that also included the incidence of new pressure ulcers were referred for consideration for inclusion in another Cochrane Review, *Support surfaces for pressure ulcer prevention* ([McInnes 2015](#)).

Types of participants

People with existing pressure ulcers (of any grade) in any setting. A range of pressure ulcer grading systems are used in pressure ulcer trials. An example of a commonly used grading system which is adapted from an EPUAP classification system (www.epuap.org.uk) is presented below ([EPUAP-NPUAP 2009](#)).

Grade 1: persistent discolouration of the skin including non-blanchable erythema; blue, purple, or black discolouration.
Grade 2: partial-thickness skin loss involving epidermis and dermis.
Grade 3: full-thickness skin loss involving damage or necrosis of subcutaneous tissues, but not through the underlying fascia, and not extending to the underlying bone, tendon or joint capsule.
Grade 4: full-thickness skin loss with extensive destruction and tissue necrosis extending to the underlying bone, tendon or joint capsule.

Types of interventions

Trials that evaluated the following interventions for pressure ulcer treatment were eligible for inclusion.

Low-tech (non-powered) constant low-pressure (CLP) support surfaces

- Standard foam mattresses.
- Alternative foam mattresses/overlays (e.g. convoluted foam, cubed foam): these are conformable and aim to redistribute pressure over a larger contact area.
- Gel-filled mattresses/overlays: mode of action as above.
- Fibre-filled mattresses/overlays: mode of action as above.
- Air-filled mattresses/overlays: mode of action as above.
- Water-filled mattresses/overlays: mode of action as above.
- Bead-filled mattresses/overlays: mode of action as above.
- Sheepskins.

High-tech support surfaces

- Alternating-pressure (AP) mattresses/overlays: person lies on air-filled sacs which sequentially inflate and deflate and relieve pressure at different anatomical sites for short periods; may incorporate a pressure sensor.
- Air-fluidised beds: warmed air circulated through fine ceramic beads covered by a permeable sheet; allows support over a larger contact area (CLP).
- Low-air-loss beds: patients are supported on a series of air sacs through which warmed air passes (CLP).

Other support surfaces

- Turning beds/frames: these devices work by either aiding manual repositioning of the individual, or by automatic motor-driven turning and tilting. They may have a static or an alternating support surface in conjunction with the frame.
- Operating table overlays: mode of action as above.
- Wheelchair cushions: may be conforming and reduce contact pressures by increasing the surface area in contact with the individual, or mechanical e.g. alternating-pressure mattresses/overlays.

We included trials that compared the interventions listed above, and those where the intervention was compared with "usual" or "standard" care.

The classifications of the support surfaces included in this review are in line with classifications used previously. It is acknowledged that these categories have since been updated by the National Pressure Ulcer Advisory Panel ([EPUAP-NPUAP 2009](#)), and this will be considered in future updates of this review.

Types of outcome measures

Trials that measured only surrogate outcome measures, such as interface pressure, were excluded on the basis that interface pressure measurements have not been demonstrated to predict the clinical performance of support surfaces reliably.

Primary outcomes

Healing rates of existing pressure ulcers was the primary outcome examined. Currently, there is no consensus regarding the most valid

and reliable means of measuring healing rates of pressure ulcers. Therefore, trials were included if they measured healing by some objective method, such as time to complete healing, rate of change in the area/volume of the ulcer(s), or number of ulcers healed.

Secondary outcomes

- Costs of the devices
- Participant comfort
- Durability of the devices
- Reliability of the devices
- Acceptability of the devices

Search methods for identification of studies

Electronic searches

For this review we searched the following databases to identify reports of relevant clinical trials:

- Cochrane Wounds Specialised Register (searched 13 September 2017);
- Cochrane Central Register of Controlled Trials (CENTRAL; 2017, Issue 8) in the Cochrane Library (searched 13 September 2017);
- Ovid MEDLINE including In-Process & Other Non-Indexed Citations (1946 to 13 September 2017);
- Ovid Embase (1974 to 13 September 2017);
- EBSCO CINAHL Plus (1937 to 13 September 2017).

The search strategies for the Cochrane Wounds Specialised Register, CENTRAL, Ovid MEDLINE, Ovid Embase and EBSCO CINAHL Plus can be found in [Appendix 1](#). We combined the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximizing version (2008 revision) ([Lefebvre 2011](#)). We combined the Embase search with the Ovid Embase filter developed by the UK Cochrane Centre ([Lefebvre 2011](#)). We combined the EBSCO CINAHL Plus with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN) ([SIGN 2018](#)). There were no restrictions on the basis of date, or language, of publication.

We also searched the clinical trial registries using the keywords 'pressure ulcer*' or 'pressure injur*':

- ClinicalTrials.gov (www.clinicaltrials.gov);
- World Health Organization International Clinical Trials Registry Platform (ICTRP) (www.who.int/trialsearch).

Details of the search strategies used for the previous version of the review are given in ([McInnes 2011](#)).

Studies were added to awaiting classification and ongoing studies as detailed below.

Searching other resources

Originally, we contacted experts in the field of wound care to enquire about ongoing and recently published trials in this field. In addition, we also contacted manufacturers of wound care materials for details of any trials they were conducting. We did not repeat this process for this version of the review, since previously it was unproductive.

We aimed to identify other potentially eligible trials or ancillary publications by searching the reference lists of retrieved included trials, as well as relevant systematic reviews, meta-analyses and health technology assessment reports.

Data collection and analysis

We carried out data collection and analysis according to methods based on the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)).

Selection of studies

The titles and abstracts of the papers identified by the search were independently assessed for relevance by at least two review authors (VL, AJ-B), and full copies of all potentially-relevant studies were obtained. Decisions on final inclusion were then made by one review author (VL) and checked by a second review author (AJ-B); disagreements were resolved by discussion with a third review author (EMcI). A third review author (EMcI) checked any rejected studies.

Data extraction and management

Two review authors independently extracted details of eligible studies and summarised the information using a data extraction sheet.

The following data were extracted for each study:

- inclusion/exclusion criteria;
- care setting;
- key baseline variables by group e.g. age, sex, baseline risk, baseline area of existing ulcers;
- description of the interventions and numbers of those randomised to each intervention;
- description of any co-interventions/standard care;
- follow-up period;
- outcomes;
- acceptability and reliability of equipment, if reported.

Individual study details are presented in structured tables (see [Characteristics of included studies](#)).

Assessment of risk of bias in included studies

For this version of the review, two review authors (AJB and VL) independently assessed each included study using the Cochrane tool for assessing risk of bias ([Higgins 2011](#)). This tool addresses six specific domains, namely sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other issues (e.g. extreme baseline imbalance, timing of outcome assessment) (see [Appendix 2](#)) for details of criteria on which the judgement was based). Blinding and completeness of outcome data were assessed for each outcome separately. We completed a 'Risk of bias' table for each eligible study and discussed any disagreement amongst all review authors to achieve a consensus.

We presented assessment of risk of bias using a 'Risk of bias' summary figure, which presents all of the judgements in a cross-tabulation of study by entry. This display of internal validity indicates the weight the reader may give the results of each study.

Measures of treatment effect

Results of dichotomous variables are presented as risk ratio (RR) with 95% confidence intervals (CIs). Risk ratio has been used rather than odds ratios, as event rates are high in these trials, and odds ratios would give an inflated impression of the magnitude of effect (Deeks 1998). Risk ratio is the rate of the event of interest (e.g. pressure ulcers healed in the experimental group divided by the rate of this event in the control group), and indicates the chances of pressure ulcer healing in the experimental treatment compared with the control treatment. As, by definition, the risk of an event occurring in the control group is 1, then the relative risk reduction associated with using an experimental treatment is $1 - \text{RR}$. The risk ratio indicates the relative benefit of a therapy, but not the actual benefit; i.e. it does not take into account the number of people whose pressure ulcer would have healed naturally without treatment.

Continuous outcome variables such as change in wound volume were summarised using the difference in means (MD). All calculations were made using RevMan 5 software. Where insufficient detail was reported in the included studies to permit calculation of the RR or MD, the results reported by study authors have been presented. Data on secondary outcomes such as comfort, durability, reliability and acceptability are presented, where reported, in [Characteristics of included studies](#).

Unit of analysis issues

Studies presented multiple units of analysis including individual pressure ulcer numbers or participant level data (i.e. number of those with one or more pressure ulcers). In rare instances there were study participants with multiple pressure ulcers. We reported results of the studies as they were presented in the original studies.

Dealing with missing data

When a paper provided insufficient information for full data extraction, or if conflicting data were found, we approached study authors for additional information. Where there were losses to follow-up and a treatment effect existed, we undertook a complete case analysis. We included studies published in duplicate only once; we nominated a primary data source, although we reviewed secondary publications for additional data. We have noted the instances when we were unable to obtain the necessary information from the authors of potentially-eligible trials in time for the update in [Characteristics of studies awaiting classification](#) (Mastrangelo 2010; Mayer 2004).

Assessment of heterogeneity

Where there was more than one trial comparing similar devices and using the same outcome measure (though possibly differing lengths of follow-up), statistical heterogeneity was assessed using I^2 (Higgins 2003) and tested for using Chi^2 (with $P < 0.10$ being regarded as statistically significant). In the event we undertook a meta-analysis, we assumed that the RR remained constant for different lengths of follow-up.

Assessment of reporting biases

We assessed publication bias by checking trials registries and contacting the authors of identified studies to ask if they had other

publications or were aware of any other unpublished studies we had missed.

Data synthesis

While we planned to pool trials with similar participants, comparisons and outcomes using the statistical measures described above, the results of the trials were reported narratively because pooling was inappropriate.

Subgroup analysis and investigation of heterogeneity

We were unable to carry out any subgroup analyses due to the paucity of data and the fact that we had not pre-specified any effect modifiers which we planned to investigate.

Sensitivity analysis

Due to clinical heterogeneity observed among the studies, it was decided that no studies would be pooled therefore there was no need for a sensitivity analysis.

GRADE and 'Summary of findings' tables

We created seven 'Summary of findings' tables for different comparisons of support surfaces using healing outcomes as described by study authors. For other comparisons, we presented GRADE assessment without a 'Summary of findings' table. We used the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of evidence as it relates to the studies which contributed data for the prespecified outcomes. We used methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* using GRADEpro GDT software.

The GRADE levels of evidence include (Schünemann 2011):

- high quality: further research is very unlikely to change our confidence in the estimate of effect.
- moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
- low quality: 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.
- very low quality: we are very uncertain about the estimate.

When evaluating the 'Risk of bias' domain, we downgraded the GRADE assessment when we classified a study as being at high risk of bias for one or more domains. We downgraded the GRADE assessment when the 'Risk of bias' assessment for blinding was high. We did not downgrade for unclear 'Risk of bias' assessments in other domains. We also followed GRADE guidance and downgraded twice for imprecision when there were very few events and CIs around effects included both appreciable benefit and appreciable harm.

RESULTS

Description of studies

The results of the searches are shown in a PRISMA diagram (Figure 1).

Figure 1. Study flow diagram.

Nineteen eligible RCTs were identified and included. Fourteen of these involved only those with pressure ulcers, and assessed the treatment efficacy of pressure-relieving support surfaces (Allman 1987; Branom 2001; Caley 1994 [pers comm]; Clark 1998; Day 1993; Devine 1995; Evans 2000; Ferrell 1993; Groen 1999; Mulder 1994; Munro 1989; Russell 2000; Russell 2003; Strauss 1991). A further four trials evaluated surface effects for both prevention and treatment of pressure ulcers in the same trial (Ewing 1964; Keogh 2001; Nixon 2006a; Osterbrink 2005). For this version of the review, one study has been added (Cassino 2013).

The studies included a variety of participants and settings, for example, those in nursing homes and care of the elderly, medical or surgical wards. Most of the included trials were small, and, although nine reported an a priori sample size calculation, 15 of the 19 trials involved 100, or fewer, people. The larger trials (over 100 participants) were: Groen 1999 (120 participants); Russell 2000 (141 participants); Russell 2003 (158 patients); and Nixon 2006a (1971 participants).

Outcomes were measured in various ways and there was little standardisation across studies. Outcome measures included: proportion of pressure ulcers healed; time to healing; rate of healing; size of wound area healed (often not reported clearly); number of pressure ulcers healed; number of participants with healed pressure ulcers and the direction of the effect measured (that is, specifying an increase or decrease in epithelialisation). Measuring the size of wounds was done in a variety of ways including the use of mathematical formulae and computerised photoplanimetry. Some studies presented an absolute change in size by deducting the final size of the wound from the initial size, and some presented the change in size as a percentage change. Some studies used pre- and post-treatment photographs of pressure ulcers to assess whether there had been any improvement in healing. Some studies reported secondary outcomes, such as healthcare resource utilisation or interface pressure, comprehensively, while the healing outcomes were summarised in a form that meant the data could not be entered into RevMan and recalculated (Caley 1994 [pers comm]; Cassino 2013; Munro 1989; Strauss 1991).

Two trials evaluated the use of a cushion as a pressure-relieving device; [Clark 1998](#) compared a dry flotation cushion with an alternating-pressure (AP) cushion, and [Osterbrink 2005](#) evaluated cushions as part of the REPOSE system. One trial assessed the use of sheepskins ([Ewing 1964](#)), and the remaining studies evaluated different mattresses, mattress overlays and beds.

Excluded studies

Sixteen studies were excluded (of which three were newly identified for this update), mainly because they did not report healing data, or were not RCTs ([Bennett 1998](#); [De Roche 2004](#); [Finnegan 2008](#); [Gardner 2008](#); [Hardin 2000](#); [Lazzara 1991](#); [Malbrain 2010](#); [Manzano 2013](#); [Marchand 1993](#); [McGinnis 2017](#); [Meyers 2008](#); [Prebio 2005](#); [Rosenthal 1996](#); [Rosenthal 2003](#); [Stoneberg 1986](#); [Timmons 2008](#)) (see [Characteristics of excluded studies](#)).

Ongoing studies

We identified the published protocol for one large ongoing trial in this update ([Brown 2016](#)).

Studies awaiting classification

We identified five studies (three in this update), which are awaiting classification for various reasons ([Mastrangelo 2010](#); [Mayer 2004](#); [Ozyurek 2015](#); [Park 2017](#); [Sauvage 2017](#)).

Risk of bias in included studies

The methodological quality of the trials was generally poor. Details of the risk of bias of each individual study are included in [Characteristics of included studies](#) and summarised in [Figure 2](#) and [Figure 3](#).

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	ITT Analysis?	Free of other bias? - were groups similar at baseline regarding the most important prognostic factors?	Free of other bias? - was the timing of the outcome assessment similar in all groups?
Allman 1987	+	+	+	+	+	+	-	+
Branom 2001	-	?	?	?	?	-	+	+
Caley 1994 [pers comm]	?	?	-	?	+	?	+	+
Cassino 2013	+	+	-	-	+	-	+	+
Clark 1998	?	+	-	+	+	-	+	+
Day 1993	?	?	?	?	-	-	+	+
Devine 1995	+	+	-	+	+	-	+	+
Evans 2000	?	+	+	+	+	?	+	+
Ewing 1964	?	?	-	?	+	?	?	?
Ferrell 1993	?	+	?	?	+	+	+	+
Groen 1999	?	+	-	?	+	-	+	+
Keogh 2001	?	+	-	-	-	-	-	?

Figure 3. (Continued)

Keogh 2001	?	+	-	-	-	-	-	?
Mulder 1994	?	?	?	+	-	+	?	+
Munro 1989	?	?	-	?	-	?	?	+
Nixon 2006a	+	+	-	+	+	+	+	+
Osterbrink 2005	?	?	?	?	+	+	+	+
Russell 2000	?	?	+	+	+	-	+	+
Russell 2003	+	+	?	?	+	-	+	+
Strauss 1991	+	?	+	?	?	+	+	?

Allocation

Adequate sequence generation using a random component was evident in 6/19 (32%) of the trials (Allman 1987; Cassino 2013; Devine 1995; Nixon 2006a; Russell 2003; Strauss 1991). Methods of randomisation used included random-number tables, automated phone systems and computerised random-number generators. In 12/19 (63%) of the studies, the method of randomisation was unclear and in one it was considered to have a high risk of bias (Branom 2001).

Adequate allocation concealment was evident in 10/19 (53%) of the trials (Allman 1987; Cassino 2013; Clark 1998; Devine 1995; Evans 2000; Ferrell 1993; Groen 1999; Keogh 2001; Nixon 2006a; Russell 2003). Adequate allocation concealment can be defined as the use of central allocation or the use of sequentially-numbered, opaque, sealed envelopes. The method of allocation concealment was unclear in the remainder of the trials.

Blinding

Unfortunately blinded outcome assessment is rarely used in wound care studies, and this was certainly the case in these evaluations of pressure-relieving surfaces. Furthermore, it can be difficult or impossible to disguise from a patient, or outcome assessor, the surface that a participant is on. Nevertheless, some studies minimise bias in outcome assessment by having a second assessor and presenting inter-rater reliability data, or by presenting photographic evidence of pressure area status, which can then be assessed by an assessor blinded to treatment. We could be confident that some form of blinded outcome assessment had been used in only 4/19 (21%) of the trials included in this review (Allman 1987; Evans 2000; Russell 2000; Strauss 1991).

Incomplete outcome data

Assessment of whether incomplete outcome data had been addressed adequately in each study involved examining whether the reasons for attrition or exclusion were reported, whether there was re-inclusion of participants, and whether the completeness of data for each main outcome was described. Of the studies reviewed, 7/19 (37%) addressed incomplete outcome data adequately (Allman 1987; Clark 1998; Devine 1995; Evans 2000; Mulder 1994; Nixon 2006a; Russell 2000), while two studies (Cassino 2013; Keogh 2001) were at high risk of bias; it was unclear, or

unstated, whether they had been addressed adequately in the remaining 10 studies (Branom 2001; Caley 1994 [pers comm]; Day 1993; Ewing 1964; Ferrell 1993; Groen 1999; Munro 1989; Osterbrink 2005; Russell 2003; Strauss 1991). An intention-to-treat (ITT) analysis was performed in 6/19 (32%) of the studies (Allman 1987; Ferrell 1993; Mulder 1994; Nixon 2006a; Osterbrink 2005; Strauss 1991). Nine of the remaining studies did not perform this analysis, and it was unclear whether such analyses took place for four studies (Caley 1994 [pers comm]; Evans 2000; Ewing 1964; Munro 1989).

Selective reporting

For a study to have demonstrated it was free of selective outcome reporting, there would need to have been access to a study protocol with all pre-specified outcomes stated, or, if the study protocol was not available, the report clearly included all expected outcomes (including pre-specified outcomes). Thirteen (68%) of the studies were free of selective outcome reporting (Allman 1987; Caley 1994 [pers comm] Cassino 2013; Clark 1998; Devine 1995; Evans 2000; Ewing 1964; Ferrell 1993; Groen 1999; Nixon 2006a; Osterbrink 2005; Russell 2000; Russell 2003). Four studies were not free from selective outcome reporting as they did not report pre-specified outcomes completely, or reported outcomes that were not pre-specified (Day 1993; Keogh 2001; Mulder 1994; Munro 1989). For two studies, there was insufficient information to classify whether there was or was not selective outcome reporting (Branom 2001; Strauss 1991).

Other potential sources of bias

Other potential sources of bias were explored by assessing whether the timing of outcomes under investigation was similar in both groups, and whether the groups under investigation were similar at baseline for the most important prognostic indicators. Quality was not used to weight the studies in the analysis using any statistical technique, however, methodological quality is discussed in relation to the interpretation of the results. Methodological flaws for each study are presented in [Characteristics of included studies](#) (see also [Figure 2](#); [Figure 3](#)).

Baseline comparability

In pressure ulcer treatment trials it is essential to ensure baseline comparability for initial area of ulcers. A change in wound area

is often expressed as the percentage change, which, unlike the absolute change in area, takes into account the initial size of the wound. For two wounds healing at the same linear rate (as measured by diameter reduction), percentage area calculations will show a larger change for a small wound than a big wound. The converse is true when the absolute change in area is measured, since, for any unit reduction in wound radius, a bigger area reduction will occur for a large wound. This has important consequences for the validity of trial results where there is poor comparability in initial wound size at baseline between the treatment groups. For large trials, randomised allocation should ensure that the mean wound size and variance in each group is similar, however, in small trials, random allocation is unlikely to result in an even distribution of wound sizes. In a trial where there is poor comparability between groups for wound size at baseline, and the outcome is based on the change in area, the result can only be considered valid if it is obtained either: against the anticipated direction of the bias for wound size; or where percentage area change and absolute area change are in the same direction. If baseline data are not given, then it is not possible to determine the direction of bias and the validity of the result cannot be determined.

The risk of bias assessed in each study regarding baseline comparability refers to important prognostic factors such as age, sex, continence, reasons for immobility etc. These results are presented in [Figure 3](#). In addition to this, Cochrane review authors have calculated the number of studies that presented data for baseline pressure ulcer area and the number of studies that reported comparability of pressure ulcers between participant groups at the start of the study. This review included 19 trials of beds, mattresses and cushions for treating pressure ulcers, and only nine of these presented data for baseline ulcer area ([Caley 1994 \[pers comm\]](#); [Cassino 2013](#); [Clark 1998](#); [Evans 2000](#); [Ferrell 1993](#); [Groen 1999](#); [Nixon 2006a](#); [Russell 2000](#); [Russell 2003](#)). The remaining 10 studies did not present baseline ulcer area ([Allman 1987](#); [Branom 2001](#); [Day 1993](#); [Devine 1995](#); [Ewing 1964](#); [Keogh 2001](#); [Mulder 1994](#); [Munro 1989](#); [Osterbrink 2005](#); [Strauss 1991](#)). Five trials did not report comparability of pressure ulcer size or grade at baseline ([Branom 2001](#); [Cassino 2013](#); [Ewing 1964](#); [Mulder 1994](#); [Strauss 1991](#)), and one trial reported more severe ulcers in the air-suspension group ([Day 1993](#)). The remaining 13 studies reported comparability of pressure ulcer size and/or grade at baseline ([Allman 1987](#); [Caley 1994 \[pers comm\]](#); [Clark 1998](#); [Devine 1995](#); [Evans 2000](#); [Ferrell 1993](#); [Groen 1999](#); [Keogh 2001](#); [Munro 1989](#); [Nixon 2006a](#); [Osterbrink 2005](#); [Russell 2000](#); [Russell 2003](#)). Fourteen of the 19 studies (74%) reported that participants were comparable at baseline regarding other prognostic factors e.g. age, sex, continence, reasons for immobility etc ([Branom 2001](#); [Caley 1994 \[pers comm\]](#); [Cassino 2013](#); [Clark 1998](#); [Day 1993](#); [Devine 1995](#); [Evans 2000](#); [Ferrell 1993](#); [Groen 1999](#); [Nixon 2006a](#); [Osterbrink 2005](#); [Russell 2000](#); [Russell 2003](#); [Strauss 1991](#)). Of the remaining five studies, three had insufficient information ([Ewing 1964](#); [Mulder 1994](#); [Munro 1989](#)) and two did not have comparable groups ([Allman 1987](#); [Keogh 2001](#)) ([Figure 3](#)).

Timing of outcome assessment

Overall, the included studies followed up participants for varying lengths of time, from four days to 18 months. Sixteen (84%) of the studies reported similar timing of outcomes in both groups ([Allman 1987](#); [Branom 2001](#); [Caley 1994 \[pers comm\]](#); [Cassino 2013](#); [Clark 1998](#); [Day 1993](#); [Devine 1995](#); [Evans 2000](#); [Ferrell 1993](#); [Groen 1999](#);

[Mulder 1994](#); [Munro 1989](#); [Nixon 2006a](#); [Osterbrink 2005](#); [Russell 2000](#); [Russell 2003](#)).

Effects of interventions

See: [Summary of findings for the main comparison](#) Profiling bed with foam mattress compared with hospital bed with foam mattress; [Summary of findings 2](#) Water mattress overlay compared with low-tech mattress; [Summary of findings 3](#) Low-air-loss bed compared with low-tech mattress overlay; [Summary of findings 4](#) Alternating pressure mattresses; [Summary of findings 5](#) Alternating-pressure mattress compared with alternating-pressure mattress overlay; [Summary of findings 6](#) Alternating-pressure mattress compared with air-filled devices; [Summary of findings 7](#) Alternating-pressure cushion compared with dry flotation cushion

Low-tech constant pressure support surfaces

This section considers comparisons of low specification (low-tech), constant low-pressure (CLP) supports which are usually not powered. The following interventions are classified as continuous low-pressure, low-technology supports (CLP): static air-filled supports; water-filled supports; contoured or textured foam supports; gel-filled supports; sheepskins; bead-filled supports; silicone-filled supports.

Comparison 1: Profiling bed with foam mattress versus hospital bed with foam mattress (1 study with 100 participants including 14 participants with pressure ulcers)

Outcome: Proportion of healed Grade 1 ulcers.

[Keogh 2001](#) compared a bed that enabled individual profiling (Contour 880) and a foam mattress (Pentaflex) with a flat-based hospital standard bed and a pressure-relieving mattress. Both groups also had a pressure-reducing foam mattress or cushion. Study participants, were expected to stay in bed for at least 12 hours a day, and had a Waterlow score of 15 to 25 (high risk to very high risk) on initial assessment. Fourteen of the 100 randomised participants from both medical and surgical hospital wards had existing pressure ulcers at the start of the study and these participants were not evenly distributed between treatment groups. The study authors reported that healing occurred in all four of the experimental group participants, and in two of the 10 control group participants. Only 70 of the 100 participants were included in the analyses. No analyses were performed by the study authors to examine the statistical significance of these findings. It is very uncertain whether profiling beds improve the proportion of pressure ulcers which heal because the certainty of the evidence is very low (risk ratio (RR) 3.96, 95% confidence interval (CI) 1.28 to 12.24; [Analysis 1.1](#)) (downgraded twice due to risk of bias, twice due to imprecision and once due to imprecision) ([Summary of findings for the main comparison](#)).

Comparison 2: Polyester overlays versus gel overlays (1 study with 72 participants)

Outcome: Pressure ulcer healing

[Cassino 2013](#) investigated wound healing in 72 long-term care residents by randomising participants to either a 3D polyester overlay (Aiartex) or a gel polyurethane overlay (Akton). The primary outcome measure, pressure ulcer healing, was reported as unchanged/worsened, unreliable, improved or resolved. Results

were presented per participant rather than per wound with no raw extractable data available for further analysis. Other secondary outcomes included participant comfort, formation of new ulcers and ease of nursing assistance. We were unable to carry out further analysis.

Comparison 3: Non-powered mattress versus low-air-loss mattress (1 study with 20 participants)

Outcome: Pressure ulcer healing

Branom 2001 randomised 20 people from long-term and subacute care centres to either a PressureGuard non-powered mattress or a low-air-loss mattress (LAL) (each facility enrolled in the study used the brand most familiar to them) and two different LAL mattresses were used in this study. Participants were bedridden and had Grade 3 or worse pressure ulcers on the trunk or pelvis. There were insufficient data (no variance data reported) available from the study to calculate the difference in mean rates of pressure ulcer healing between the two interventions and it was not clear how many ulcers were healed. The study authors reported that the rate of wound healing at the end of the study for those on the PressureGuard mattress was 9% compared with 5% for those on the LAL mattress. We were unable to carry out further analysis. It is uncertain whether the use of a non-powered mattress improves the proportion of pressure ulcers which heal compared with using low-air loss mattresses because the certainty of the evidence is low. The evidence was downgraded due to risk of bias and imprecision.

Comparison 4: Water filled supports versus foam replacement mattress (1 study with 120 participants)

Outcome: Pressure ulcer healing

Groen 1999 conducted a trial of 120 nursing-home residents, 60 years of age and above, with Grade 3-4 ulcers. The trial investigated the effect of a foam replacement mattress compared with a Secutex water mattress overlay on the proportion of participants with healed pressure ulcers at the four-week follow-up. It is uncertain whether water filled supports improves the proportion of pressure ulcers which heal because the certainty of the evidence is low (RR 0.93, 95% CI 0.63 to 1.37) ([Analysis 2.1](#)), (downgraded due to risk of bias and imprecision) ([Summary of findings 2](#)).

Comparison 5: Standard hospital mattress with sheepskin overlay versus standard hospital mattress (1 study with 36 participants)

Outcome: Pressure ulcer healing

One small trial at high risk of bias, involving 36 participants in an elderly care setting, compared standard hospital mattresses with, and without, sheepskin overlays (**Ewing 1964**). There were 8 events in the control group compared with none in the intervention group (RR 0.06, 95% CI 0.00 to 0.95). The reported results should be regarded with caution due the age of the study, insufficient data and the poor definitions used to classify pressure ulcers. It should also be noted that since the publication of this study in the 1960s, the hospital "standard" mattress has changed. The certainty of the evidence is very low (downgraded once for risk of bias and twice for imprecision).

High-tech pressure supports

High-tech support surfaces include:

- Alternating-pressure (AP) mattresses/overlays: air-filled sacs that inflate and deflate sequentially to relieve pressure at different anatomical sites for short periods; these may incorporate a pressure sensor.
- Air-fluidised beds: warmed air circulates through fine ceramic beads covered by a permeable sheet; allowing support over a larger contact area (CLP).
- Low-air-loss beds: a series of air sacs through which warmed air passes (CLP) supports the person.

Low-air-loss (LAL)

Comparison 1: Low-air-loss beds versus low tech mattress overlays (3 studies with 210 participants) *No pooling was undertaken due to the different way in which outcomes were measured.

Outcome: Pressure ulcers completely healed

The study by **Ferrell 1993** compared a LAL bed (KINAIR) with a foam overlay placed on top of a standard mattress in a group of 84 nursing-home residents. The trial reported on change in pressure ulcer surface area in participants randomised to the LAL bed compared with participants on the foam overlay (reported $P = 0.0002$), and change in surface area for this group (reported $P = 0.004$) was reported. However no further analyses were conducted. From analyses performed for the purpose of this review, however, it is uncertain whether LAL beds reduce pressure ulcer size because there is no clear difference between trial arms. The certainty of the evidence is low (RR 1.30, 95% CI 0.87 to 1.96), downgraded due to risk of bias and imprecision ([Analysis 3.1](#)) [Summary of findings 3](#).

The hospital-based study by **Day 1993** examined the change in mean ulcer size in 77 participants allocated to either an air suspension bed (Therapulse) or a foam mattress overlay (Geomatt). It included participants with pressure ulcers Grade 2 to 4, whose activity was limited to a chair or bed during hospitalisation. Analysis of covariance (to remove possible bias from the difference in the initial ulcer size between the two groups, which were significantly different at baseline) to assess the difference in the healing of pressure ulcers in the two groups was done (reported $P > 0.05$). There were insufficient data to carry out further analysis. It is uncertain whether air suspension beds improve pressure ulcer healing compared with low tech mattress overlays because the certainty of the evidence is low. The evidence was downgraded due to risk of bias, indirectness and imprecision.

The study by **Mulder 1994** examined pressure ulcer healing using pressure ulcer volume and surface area in 49 nursing-home residents from 25 nursing homes. Participants were randomised to either an air suspension bed (Therapulse), or a convoluted foam mattress overlay (Geomatt), and all participants were turned every two hours. Change in pressure ulcer size (initial entry area minus exit area) in participants randomised to the LAL bed was reported (reported $P = 0.042$) by the study authors however there were insufficient data (no variance data) available to calculate the mean difference between the two interventions. We assessed this as very low evidence (downgraded due to risk of bias, indirectness and imprecision).

Comparison 2: Different low-air-loss surfaces (1 study with 93 participants)

Outcome: Changes in pressure ulcer size

Only one trial compared different types of LAL support surfaces (Caley 1994 [pers comm]), i.e. an LAL bed (Monarch) and an LAL overlay (SPR Plus), in 93 hospital patients. This study examined changes in pressure ulcer surface area, healing progress over time, and the relative costs of each device. The study reported on changes in surface area (reported $P = .060$), and average perimeter of the pressure ulcers (reported $P = 0.171$). The median changes in pressure ulcer surface area using overlay therapy and bed therapy were 3.9 cm² and 1.9 cm² respectively, and the mean changes in pressure ulcer surface area were 10.2 cm² and 3.8 cm² respectively. There were insufficient data available from the study to carry out further analysis. It is very uncertain whether the use of an LAL bed results in a change in pressure ulcer size compared with the use of an LAL overlay because the certainty of the evidence is very low. The evidence was downgraded due to risk of bias and imprecision.

Alternating-pressure (AP) support surfaces

A variety of alternating-pressure (AP) supports (mattresses and overlays) is used in hospitals and in the community and these are commonly grouped as 'high-tech' devices. Depth of air cells and mechanical robustness can vary between devices and these factors may be important in determining effectiveness. It is worth emphasising that most of the trials of AP supports did not describe the equipment being evaluated adequately, and did not specify the size of the air cells.

Comparison 1: Different AP mattress (2 studies with 182 participants)

*no pooling was undertaken due to the different way in which outcomes were measured.

Outcome: Pressure ulcers completely healed and decrease in pressure ulcer size

Devine 1995 reported a comparison of the Nimbus I DFS (composed of rows of figure-of-eight-shaped cells) and the Pegasus Airwave for the treatment of existing pressure ulcers in 41 hospital patients. Participants had pressure ulcers that were Grade 2 and above. Specifically, this study looked at the rate of complete healing/reduction in pressure ulcer size at four weeks, participant comfort and the median rate of reduction in pressure ulcer area (cm²/day). It is uncertain which intervention under investigation is better at improving the proportion of pressure ulcers which healed as the certainty of the evidence is low (RR 0.57, 95% CI 0.26 to 1.27) (Analysis 4.1), as is the evidence pertaining to the intervention effect on reducing pressure ulcer size (RR 0.58, CI 95% 0.21 to 1.65) (Analysis 4.2). Low-certainty evidence (downgraded due to risk of bias and imprecision) (Summary of findings 4).

A larger, more recent trial, of 141 geriatric patients with pressure ulcers Grade 2 and above (Russell 2000), also found that there is no clear difference in pressure ulcer healing and improvement between two newer AP devices, namely the Nimbus 3 (combined with four-hourly turning and use of an Aura cushion) and the Pegasus Cairwave therapy system (combined with eight-hourly turning and use of a Proactive 2 Seating cushion) (RR 0.99, CI 95% 0.90 to 1.09) (Analysis 4.3). The certainty of evidence was rated low, downgraded due to risk of bias and imprecision (Summary of findings 4).

Comparison 2: AP mattress versus AP mattress overlay (3 studies with 2161 participants) * pooled analysis was not possible due to differences in the devices evaluated, insufficient raw data to enter

into RevMan for analysis, the co-interventions used, and different techniques for measuring outcomes.

Outcomes: Pressure ulcer healing and pressure ulcer improvement

A study by Evans 2000, conducted in hospital and nursing home settings, compared an AP mattress replacement system (Huntleigh Nimbus 3) with either an AP mattress overlay (AlphaXcell/Quattro), or another AP mattress replacement system (Pegasus Biwave/Pegasus Airwave/AlphaXcell/Pegasus Cairwave). Thirty-two participants were recruited; 20 from a nursing home (Huntleigh Nimbus 3, $n = 10$; AlphaXcell, $n = 9$; Quattro, $n = 1$), and 12 from a hospital (Huntleigh Nimbus 3, $n = 7$; Pegasus Biwave, $n = 1$; Pegasus Airwave, $n = 1$; AlphaXcell, $n = 1$; Pegasus Cairwave, $n = 2$). This study aimed to investigate the change in wound surface area as well as participant comfort. The study author reported no differences between the hospital-based group and the nursing home group for the outcomes under investigation. There were insufficient data available in the study report to calculate the mean difference between the two interventions. It is uncertain whether the use of an AP mattress improves the healing of pressure ulcers compared with the use of an AP mattress overlay because the certainty of the evidence is low, downgraded due to risk of bias and imprecision.

The large Russell 2003 trial (158 hospital-based patients) also compared an AP mattress (Nimbus 3) with a static fluid overlay mattress (RIK ® static). Patients with pressure ulcers of all grades were included. It is uncertain which intervention under investigation is better at improving the proportion of pressure ulcers which healed as the certainty of the evidence is low (RR 0.97, 95% CI 0.80 to 1.17) (Analysis 5.1). However, in this trial the co-intervention of re-positioning frequency was not standardised, and participants could request additional turning. It is, therefore, difficult to discern whether the lack of treatment effect was due to the non-effect of the experimental device or the effect of the differential co-intervention, or both. The evidence was downgraded due to risk of bias and imprecision (Summary of findings 5).

Another study evaluated the differences between an AP overlay and an AP mattress on pressure ulcer development and healing (as measured by complete epithelialisation and time to healing) in a hospital setting with 1971 participants with Grade 2 or above pressure ulcers (Nixon 2006a). This was a large study with over 11 different sites and was of high-methodological quality. It was reported that of the 113 participants with existing pressure ulcers at randomisation, 20/59 in the overlay group and 19/54 in the mattress group, had complete pressure ulcer healing by the end of the study. The use of an AP overlay may lead to no clear difference in pressure ulcer healing compared with the use of an AP mattress (RR 0.96, 95% CI 0.58 to 1.60) (Analysis 5.2). Low-certainty evidence downgraded due to risk of bias and imprecision (Summary of findings 5).

Comparison 3: AP mattresses versus air-filled devices (1 study with 50 participants)

Outcome: Proportion of participants with pressure ulcers healed

One study investigated the healing success of existing pressure ulcers (at least Grade 2) in a group of 50 patients from one hospital (care of the elderly, neurological or surgical wards) and eight nursing homes (Osterbrink 2005). These participants were

randomised to either the air-filled device (REPOSE system) or to the AP device (either small-cell or large-cell) on which they were being nursed at the time of recruitment. The air-filled device consisted of a range of air-filled products, including a mattress overlay, foot protectors and a wedge pillow. The small-cell AP mattresses were grouped with the large-cell AP mattresses during the calculation of the effect size and were treated as the control group. It is uncertain which intervention under investigation is better at improving the proportion of pressure ulcers which healed as the certainty of the evidence is low (RR 5.50, 95% CI 0.73 to 41.44) ([Analysis 6.1](#)). The evidence was downgraded due to risk of bias and imprecision ([Summary of findings 6](#)).

Comparison 4: AP cushion versus dry flotation cushion (1 study with 25 participants)

Outcome: Pressure ulcers completely healed

One study involving 25 participants from hospitals and nursing homes with pressure ulcers Grade 2 and above ([Clark 1998](#)), found no difference between a dry flotation cushion (ROHO Quadtro) and an alternating-pressure cushion (Pegasus) in the number of ulcers completely healed. These participants had pressure ulcers on the sacrum or ischial tuberosities with a surface area of between 2 cm² and 15 cm². The authors of the study reported that the mean reduction in pressure ulcer area (cm²/day) in the 14 participants assigned to the AP cushion was 0.13, and 0.27 for the 11 participants assigned to the dry flotation cushion. The reduction in volume of pressure ulcers (cm³/day) was also reported for the cohort as being 0.56, and 0.49 for the AP cushion and dry flotation cushion respectively. The authors did not state whether either set of results were statistically significant. Overall, three pressure ulcers in the AP cushion group, and five in the dry flotation group, healed completely, i.e. had restoration of complete epithelial cover. However, it is uncertain which intervention under investigation is better at improving the proportion of pressure ulcers which healed or the size of pressure ulcers as the certainty of the evidence is low (RR 0.47, 95% CI 0.14 to 1.56) ([Analysis 7.1](#)). The evidence was downgraded due to risk of bias and imprecision ([Summary of findings 7](#)).

Comparison 5: Air-fluidised therapy versus with standard/conventional therapy (3 studies with 202 participants) *pooling of data was inappropriate due to the different methods of outcome measurement and incomplete reporting of data (for example, no variance data).

Outcome: Change in pressure ulcer size

[Allman 1987](#) included 65 surgical patients with pressure ulcers of all stages on the sacrum, buttocks, trochanters or back, with mobilisation limited to a bed or chair for at least one week and life expectancy of at least one week, and no skin graft or flap planned for the pressure ulcer within one week. Participants were randomised to either conventional treatment (including two-hourly turns, heel and elbow protectors and AP mattress) or to the air-fluidised therapy (CLINITRON). There was a high rate of dropouts in those allocated the AF intervention (32%), which was higher than in those allocated to conventional treatment (24%). Wound healing was defined as 'healed', 'much improved' or 'a little improved'. Median change in pressure ulcer surface area and improvement in the pressure ulcer healing was measured on the basis of assessment by photographs. There were insufficient

data available from the study to calculate the difference in effects between the two interventions using RevMan. It is very uncertain whether air-fluidised therapy leads to a change in pressure ulcer size compared with standard therapy because the certainty of the evidence is very low. The evidence was downgraded due to risk of bias and imprecision).

The air-fluidised therapy was also investigated by [Munro 1989](#) in a group of 40 male hospital patients with grade 2 or 3 pressure ulcers expected to stay in hospital for at least 15 days. The air-fluidised bed (Clinitron) was compared with standard hospital care, defined as positioning or massage as well as sheepskins or gel pads placed under the pressure ulcers. Change in mean pressure ulcer area, nursing time per shift, participant satisfaction and self-perceived pain were investigated. Standard deviations were not given for mean changes in pressure ulcer area. However, the study authors presented results on the mean size of pressure ulcers in the air-fluidised therapy group compared with pressure ulcer size in the standard care group (reported $P = 0.05$). The only raw data presented in the study were the mean ulcer sizes for days one, two, eight and 15. There were insufficient variance data available from the study to calculate the mean difference between the two interventions. It is very uncertain whether air-fluidised therapy leads to a difference in pressure ulcer size compared with standard therapy because the certainty of the evidence is very low. The evidence was downgraded due to imprecision.

[Strauss 1991](#) examined pressure ulcer improvement in 97 participants retrospectively by means of photographs evaluated by blinded assessors who made a judgement on whether the ulcer was improved (progressed to a lower stage, smaller surface area, reduced inflammation or reduced eschar), unchanged, or worse, on the basis of descriptions in the medical records. The study was home-based, and participants had at least one grade 3 or 4 pressure ulcer. Home air-fluidised therapy (CLINITRON) was compared with conventional therapy (prescribed, patient-specific devices including mattresses and pads). Study authors reported that a higher proportion of participants randomised to the air-fluidised therapy had pressure ulcers classified as "improved". The reporting of results and tabular representation of the results was poor and it was not clear whether all those enrolled in the study were included in the analysis. In addition, there were insufficient data available from the study to calculate the mean difference between the two interventions. The certainty of the evidence is very low downgraded due to risk of bias and imprecision.

DISCUSSION

Despite the frequency of pressure ulcer incidence and the myriad of types of support surfaces that have been evaluated, there is a paucity of good-quality evidence to guide current clinical practice with respect to the most effective support surfaces for treating existing pressure ulcers.

Other shortcomings in this group of trials were the variety of outcome measures used, which prohibited the pooling of studies, even when similar interventions were evaluated. Subjective outcome assessments that relied on retrospective assessment of outcomes and judgements of "better, worse, unsure" are unreliable and of questionable validity when complete healing is the goal. There is a need for those involved in wound care research to set standards for outcome reporting. Furthermore, we were concerned, after critical appraisal of many of the studies, that

important variables such as number of ulcers healed or mean change in size of ulcers were often inadequately reported. For example, failure to report both the numerator and denominator; only wound surface area rather than a more clinically significant volume measure; standard deviation alongside the mean; or selective reporting of significance tests for some outcomes (comfort, healthcare resource utilisation), but not for healing outcomes. Pressure ulcers of different stages were included in some studies, and it was not possible to separate out results that included grade 1 pressure ulcers from all other grades. In addition, the number of pressure ulcers healed was included in some studies as the outcome, while in others the number of participants with healed pressure ulcers was the outcome and unit of analysis. This complicated comparison of results across studies.

In conclusion, the quality of most of the evidence is poor and the results unclear. We are unable to provide decision makers and patients with a clear message regarding the relative effects of alternative support surfaces for the treatment of pressure ulcers.

Summary of main results

Nineteen randomised trials of support surfaces for pressure ulcer treatment were identified.

Five studies analysed 318 participants and compared low-tech CLP support surfaces. It is uncertain whether there is a difference in ulcer healing between different low-tech CLP support surfaces because the quality of evidence is low or very low. The evidence was downgraded for risk of bias and imprecision due to small sample sizes from single-study outcome results, which we were unable to pool. Fourteen studies analysing 2923 participants compared different high-tech support surfaces. It is uncertain whether there is a difference in ulcer healing.

In this updated version of the review, one study was added that examined a polyester overlay compared with a gel overlay among long-term care patients. The included studies provided little valid or reliable evidence for any differential effects of alternative support surfaces in improving healing rates. The relevant studies, however, were small and with methodological limitations that need to be addressed before firm conclusions can be made. The lack of evaluations of seat cushions is surprising given their widespread use by wheelchair users and others. There is no conclusive evidence to suggest that alternating-pressure devices, low-air-loss therapy or continuous low-pressure supports are more effective than alternatives in the treatment of existing pressure ulcers.

Overall completeness and applicability of evidence

Most of the included trials were under-powered and, therefore, bring the great risk of failing to detect that clinically significant differences are statistically significant. The evidence is generally applicable to hospital and community settings. In many studies, participants with existing pressure ulcers constituted a small subgroup of the larger trial population under investigation and, therefore, this subgroup was underpowered. In addition, the age of some trials (some being 20 years old), means that other technologies may have superseded those investigated.

Quality of the evidence

Thirty-seven per cent of studies reported clear evidence of adequate random sequence generation and fifty-three per cent

reported clear evidence of adequate allocation concealment. This is a slight increase on the previous update in terms of the percentage of studies reporting these elements. Intention-to-treat analysis was reported as undertaken by only 37% of trials.

The confidence with which firm conclusions could be drawn from the studies and meta-analyses performed was greatly tempered by: (a) the poor quality of many of the trials, including incomplete reporting of data; and (b) the heterogeneity of the sample populations, interventions, outcome measurements and study settings reported amongst the studies. Reporting of results was inadequate in some studies (for example, failure to report P values, numerators and denominators, and statistical information such as standard deviations), which hampered data pooling. The results were from single-study outcomes with very small sample sizes. Of the studies included in the 'Summary of Findings' tables, the above methodological flaws significantly contributed to studies being graded as low- or very low-certainty evidence.

Potential biases in the review process

The strengths of this review included the systematic searches that were conducted to identify all relevant trials. Nonetheless, it is accepted that no search strategy is infallible and, consequently, we may not have identified all unpublished eligible trials. This means that the effect of publication bias on this review should not be discounted.

Agreements and disagreements with other studies or reviews

We identified a systematic review that evaluated support surfaces for treating pressure ulcers ([Reddy 2008](#)). This reported on 12 randomised controlled trials (RCTs); the authors found no clear evidence to favour one support surface over another in the treatment of pressure ulcers. Readers are also referred to other Cochrane Reviews relating to the healing of pressure ulcers ([Choo 2014](#); [Dumville 2015a](#); [Dumville 2015b](#); [Langer 2014](#); [Moore 2016](#); [Moore 2015b](#); [Moore 2015c](#); [Naing 2017](#); [Norman 2016](#); [Walker 2017](#); [Westby 2017](#)). These reviews also found the evidence regarding the relative effects of these treatments wanting due to the poor quality or small size of the available evidence (where trials existed).

AUTHORS' CONCLUSIONS

Implications for practice

There is no conclusive or reliable evidence to suggest that alternating-pressure devices, low-air-loss therapy, continuous low-pressure supports, profiling beds or sheepskins are more effective than other surfaces in the treatment of existing pressure ulcers. There is limited evidence for the effectiveness of air-fluidised and some "low-tech" devices in the treatment of existing pressure ulcers, however, this body of evidence is not robust and mainly of low quality.

Implications for research

Independent, well-designed, multi-centred, randomised, controlled trials are needed to compare the clinical and cost-effectiveness of different types of pressure-relieving devices to treat existing pressure ulcers for participants at different levels of risk, in a variety of settings. In particular, this research should aim to compare:

- alternating-pressure devices with other "high-tech" equipment (such as low-air-loss therapy and air-fluidised beds);
- alternating-pressure mattresses with less costly alternating-pressure overlays; and
- alternating-pressure devices with "lower-tech" alternatives (such as different types of foam mattresses).

Future research must address the methodological deficiencies associated with much of the research described in this review. Participants should be truly randomised (with concealed allocation), trials should be of sufficient size to detect clinically important differences, and have clear criteria for measuring outcomes - which ideally should be assessed without knowledge of the intervention received (blinded). Researchers should be encouraged to develop measures to assess participants' experiences of pressure-relieving equipment, e.g. comfort and acceptability. In addition, secondary outcomes such as reliability and durability of the devices should be measured. The studies should also have adequate follow-up, and stratify their results by pressure ulcer size (i.e. make clear whether grade 1 pressure ulcers are included, and report separate analyses for pressure ulcers of grade 2 and above). Evaluations of the cost-benefit trade-off of

pressure ulcer treatment alternatives should also be undertaken. Validated measures of pressure ulcer healing are also required.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Allman 1987

Methods	RCT with a mean of 13 days follow-up (range 4-77 days).
Participants	Surgical patients aged 18 or over, with pressure ulcers of all stages included (Shea classification). Patients expected to be limited to bed/chair and in hospital for a minimum of 1 week. Groups appeared to be well matched at baseline, including for baseline ulcer area. Study set in the USA.
Interventions	<ul style="list-style-type: none"> Air-fluidised therapy (CLINITRON) (n = 31) repositioned every 4 hours. Conventional treatment (including 2-hourly turns, heel and elbow protectors, alternating-pressure mattresses) (n = 34).
Outcomes	<p>Median change in total surface area of ulcers.</p> <p>Improvement in condition of pressure ulcer judged from photographs by blinded assessors.</p> <p>Pain response.</p> <p>No variance data.</p>
Notes	A priori sample size calculation. 90% follow-up. Four participants withdrew because of difficulty transferring in and out of the air-fluidised bed. Support surfaces provided by pharmaceutical company.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The randomisation sequence was determined using a table of random numbers".
Allocation concealment (selection bias)	Low risk	Quote: "Treatment allocations were placed in envelopes sealed and numbered sequentially".
Blinding (performance bias and detection bias) All outcomes	Low risk	Quote: "The masked assessment included review of serial photographs of all pressure sores".
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data.
Selective reporting (reporting bias)	Low risk	All of the study's pre-specified outcomes were reported.
ITT Analysis?	Low risk	Specified in study report.

Support surfaces for treating pressure ulcers (Review)

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Allman 1987 (Continued)

Free of other bias? - were groups similar at baseline regarding the most important prognostic factors?	High risk	Quote: "Patients on air-fluidized beds had a more limited activity level". Size of baseline ulcers not measured.
Free of other bias? - was the timing of the outcome assessment similar in all groups?	Low risk	Data collected weekly.

Branom 2001

Methods	RCT with an 8-week follow-up.	
Participants	Inpatients from long-term and subacute care centre specialising in ventilator-dependent patients and those with extensive wound care needs. Bedridden patients had a pressure ulcer at Grade 3 or 4 on trunk or pelvis (staging system not specified). Two groups were matched in age, nutritional deficiency and use of g-tubes.	
Interventions	<ul style="list-style-type: none"> PressureGuard CFT (Constant Force Therapy) (non-powered mattress) (n = 10). LAL mattress (n = 10). 	
Outcomes	Meeting the goals of wound treatment as determined by medical team (including wound closure, maintenance of condition and preparation for flap). The rate of wound healing over eight weeks No variance data.	
Notes	Each facility used the LAL mattress brand most familiar to them.	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "Patients who met the inclusion criteria were randomly assigned to one of the two groups, the study mattress or the LAL, in an alternating pattern as they were admitted".
Allocation concealment (selection bias)	Unclear risk	Inadequate information given.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Unstated.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unstated.
Selective reporting (reporting bias)	Unclear risk	Data tables incompletely labelled.
ITT Analysis?	High risk	Not specified in study report.
Free of other bias? - were groups similar at baseline	Low risk	However, baseline comparability for initial ulcer size not reported.

Support surfaces for treating pressure ulcers (Review)

Branom 2001 (Continued)

regarding the most important prognostic factors?

Free of other bias? - was the timing of the outcome assessment similar in all groups?	Low risk	Wound measurements taken at 3 weeks.
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Caley 1994 [pers comm]

Methods	RCT with average 24-day follow-up.	
Participants	Acute care patients with existing pressure ulcers, for whom an Enterostomal Therapy Nurse had recommended low-air-loss therapy. 60% female, 40% male; aged 42-98 years (mean 76 years); average length of stay 23.9 days; 87% Caucasian; average Norton Score of 10. Baseline ulcer areas NOT presented. Grades of existing pressure ulcers not specified.	
Interventions	<ul style="list-style-type: none"> LAL bed (Monarch, Mediscus) (n = 23). LAL overlay (SPR Plus, Gaymar) (n = 32). 	
Outcomes	Median change in ulcer area measured by multiplying ulcer length by ulcer width. Healing progress over time.	
Notes	Very little data provided (median change in area and range). Unclear (and unlikely) that outcome assessment was blind to treatment group. No description of co-interventions, except that routine skin care protocol applied to both groups. NB: only 55/93 (59%) of randomised participants completed the study for reasons that are not completely clear (those discharged before 3rd week of study were not included in analysis (i.e. those who improved quickest)). ⁷²	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not stated. Authors state "subjects were randomised to either the low-air-loss bed or the low-air-loss overlay".
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not stated.
Blinding (performance bias and detection bias) All outcomes	High risk	No blinding.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of attrition/exclusions.
Selective reporting (reporting bias)	Low risk	All of the study's pre-specified outcomes were reported.
ITT Analysis?	Unclear risk	Unclear.
Free of other bias? - were groups similar at baseline regarding the most important prognostic factors?	Low risk	Baseline comparability for initial area of ulcer also reported.

Caley 1994 [pers comm] (Continued)

Free of other bias? - was the timing of the outcome assessment similar in all groups?	Low risk	Pressure ulcers measured every week for 1 month, or until discharge.
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Cassino 2013

Methods	RCT with 12-week follow-up.
Participants	Quote: "Patients enrolled at eight long-term care Italian centres", 72 patients, 86 lesions, 76% female, mean age 85.4 years. Groups well balanced for age, weight, BMI, gender, Norton score, Braden score. Study set in Italy.
Interventions	<ul style="list-style-type: none"> Intervention group with 3D overlay (Aiartex): 9mm thick, polyester, two layers. Control group with gel overlay (Akton): 15.9 mm thick, polyurethane.
Outcomes	Healing of existing pressure ulcer: unchanged/worsened, unreliable, improved, resolved. Area of wound (presented graphically as absolute change and percentage change, nil raw data available). Patient comfort: poor, fair, good, excellent. Ease of assistance of nursing: poor, fair, good, excellent. Avoidance of new ulcers.
Notes	Wound outcomes presented graphically with no raw data extractable, outcomes presented by patient rather than by wound, outcomes not presented by grade. High suspension rate secondary to "worsening of the lesions".

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomised using closed envelopes", "ratio 1:1".
Allocation concealment (selection bias)	Low risk	Quote: "Closed envelopes which were opened at the moment of assignment".
Blinding (performance bias and detection bias) All outcomes	High risk	No blinding.
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "High percentage of suspension", "majority of suspensions caused by worsening of the lesions". Rate of loss 18/35 (treatment, aiartex), 26/37 (control, Akton).
Selective reporting (reporting bias)	Low risk	All outcomes listed in the introduction were reported on: (1) reduction of ulcer, (2) healing, (3) avoidance of new ulcers, (4) comfort and safety.
ITT Analysis?	High risk	Not specified.

Cassino 2013 (Continued)

Free of other bias? - were groups similar at baseline regarding the most important prognostic factors?	Low risk	Yes, quote: "groups proved homogeneous" (for age, weight, BMI), "P=NS" (for gender, age, Norton, Braden)".
Free of other bias? - was the timing of the outcome assessment similar in all groups?	Low risk	Yes, quote: "patients were followed for an overall period of 12 weeks".

Clark 1998

Methods	RCT. Allocation using sequential, sealed, opaque envelopes. Patients remained in the study for an average of 58.6 days (ProActive) and 43.73 days (ROHO).	
Participants	Elderly patients in two acute care hospitals and two nursing homes; predicted to remain in the trial for at least 7 days; with established pressure ulcers Grade 2 or above (grading system not specified). Groups well matched at baseline for important variables such as Waterlow score, mobility, nutritional status, continence.	
Interventions	<ul style="list-style-type: none"> ProActive 2 cushion (Pegasus) (n = 14). Cushion for day chairs and wheelchairs. Seating automatically adjusts to patient's weight. Cycle time 12 minutes. <ul style="list-style-type: none"> ROHO cushion (n = 11). Dry flotation system. All participants had a Pegasus Airwave System in bed.	
Outcomes	Number of ulcers healed completely. Rate of healing (cm ² /day). Rate of healing (cm ³ /day).	
Notes	Although priori sample size calculation was done, projected sample size not achieved.	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "All eligible subjects were allocated to a cushion according to a pre-determined randomisation protocol".
Allocation concealment (selection bias)	Low risk	Quote: "On entry to the study, an opaque envelope was opened to identify the cushion to be allocated".
Blinding (performance bias and detection bias) All outcomes	High risk	Quote: "A single unblinded observer collected all data".
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data (see Table 3 in original study report).
Selective reporting (reporting bias)	Low risk	All of the study's pre-specified outcomes were reported (see Table 2 in original study report).

Support surfaces for treating pressure ulcers (Review)

Clark 1998 (Continued)

ITT Analysis?	High risk	Quote: "Data analysis was based on the remaining 25 subjects".
Free of other bias? - were groups similar at baseline regarding the most important prognostic factors?	Low risk	Baseline comparability for initial area of ulcer also reported.
Free of other bias? - was the timing of the outcome assessment similar in all groups?	Low risk	Participants assessed at weekly intervals.

Day 1993

Methods	RCT with minimum 7-day follow-up. Allocation by sealed envelopes.	
Participants	Hospitalised, adult patients with existing Grade 2-4 pressure ulcer (NPUAP grading system). Study set in the USA.	
Interventions	<ul style="list-style-type: none"> Air suspension bed (Therapulse, Kinetic concepts) (n = 44). Foam mattress overlay (Geomatt, SpanAmerica) (n = 39). Wound care standardised for both groups.	
Outcomes	Mean ulcer size (initial minus end) divided into Grade 2 and Grade 3/4 ulcers. Mean comfort scores.	
Notes	No P values given, but all analyses reported as not statistically significantly different. Comfort score results only completed by half the participants (Group 1, n = 20; Group 2, n = 21).	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Only information given: quote: "patients were randomised to either the air-suspension bed or the foam mattress overlay".
Allocation concealment (selection bias)	Unclear risk	Not stated.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not stated.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of attrition/exclusions.
Selective reporting (reporting bias)	High risk	Not all of the study's pre-specified outcomes were reported.
ITT Analysis?	High risk	Not specified in study report.
Free of other bias? - were groups similar at baseline	Low risk	Baseline comparability for initial ulcer size not reported.

Day 1993 (Continued)

regarding the most important prognostic factors?

Free of other bias? - was the timing of the outcome assessment similar in all groups?	Low risk	Patient assessment flow sheet completed daily by nursing staff. Nutrition and comfort assessed weekly by staff. Ulcer measurements taken weekly.
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Devine 1995

Methods	RCT with 4-week follow-up. Allocation by random number list kept separate from trial co-ordinator.	
Participants	Elderly patients in hospital admitted with ulcers of Grade 2 or above (grading system not specified). Mean age 82.5 years (69-98 years). More people incontinent of urine in Nimbus group; more people catheterised in Airwave group.	
Interventions	<ul style="list-style-type: none"> Alternating-pressure mattress (Nimbus I) (n = 22). Modular, with rows of figure-of-eight shaped cells. Two sets of cells are inflated and deflated over 10-minute cycle. <ul style="list-style-type: none"> Alternating-pressure mattress (Pegasus Airwave) (n = 19). Double-layer mattress with a 3-cell alternating cycle lasting 7.5 minutes. All participants were subject to the standard hospital protocol for wound dressings; details of this were not provided.	
Outcomes	Complete healing at four weeks. Comfort. Median rate of reduction in area (cm ² / day). Withdrawal rates by group and reasons for withdrawal.	
Notes	Withdrawal rates by group and reasons for withdrawal stated. 11 participants (24%) died or moved to other hospitals.	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Allocation to each group was achieved using a computer-generated list of random numbers kept separately from the trial co-ordinator".
Allocation concealment (selection bias)	Low risk	See above.
Blinding (performance bias and detection bias) All outcomes	High risk	No blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	See Table 2 in original study report.
Selective reporting (reporting bias)	Low risk	All of the study's pre-specified outcomes were reported.
ITT Analysis?	High risk	Not specified in study report.

Devine 1995 (Continued)

Free of other bias? - were groups similar at baseline regarding the most important prognostic factors?	Low risk	However, baseline comparability for initial ulcer size not reported.
Free of other bias? - was the timing of the outcome assessment similar in all groups?	Low risk	Timing of outcome assessment only stated for grading of pressure sore, quote: "at 3 day intervals..."

Evans 2000

Methods	RCT with two-week follow-up period. Allocation by sequential, labelled, sealed envelopes.	
Participants	12 hospital and 20 nursing patients, over 65 years with either Grade 2 or 3 ulcer, or grade 2 ulcer and one or more of the following: difficult to reposition in bed, unable to tolerate 30 degree tilt, unable to move in bed, in bed for > 20 hour/24 hours, >108 kg and bed-bound, undergone spinal anaesthetic. Grading system not specified. Study set in the UK.	
Interventions	<ul style="list-style-type: none"> Alternating-pressure mattress replacement system (APMRS) (Nimbus 3) (n = 17). Alternating-pressure mattress replacement system (APMRS) for hospital participants (P.Biwave, P.Airwave. P.Cairwave or AlphaXCell) or alternating-pressure mattress overlay (AlphaXCell or Quattro) for nursing home participants (n = 15). <p>Turning and wound care standardised for 2 groups.</p>	
Outcomes	Absolute and relative reduction in wound surface area, calculated twice weekly by planimetry. Comfort.	
Notes	Large proportion of participants did not complete follow-up (11 / 20 in nursing home group, 75% in hospital group). Funding provided by Huntleigh Health.	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not stated.
Allocation concealment (selection bias)	Low risk	Quote: "Treatments were randomly allocated to sequentially-labelled sealed envelopes".
Blinding (performance bias and detection bias) All outcomes	Low risk	Quote: "Two research team members, blind to the surface used, carried out the WSA measurements".
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data.
Selective reporting (reporting bias)	Low risk	All of the study's pre-specified outcomes were reported.
ITT Analysis?	Unclear risk	Unclear.

Evans 2000 (Continued)

Free of other bias? - were groups similar at baseline regarding the most important prognostic factors?	Low risk	Baseline comparability for initial area of ulcer also reported.
Free of other bias? - was the timing of the outcome assessment similar in all groups?	Low risk	Primary outcome (ulcer site, size and grade) measured twice weekly, secondary outcome measure (patient comfort) measured weekly.

Ewing 1964

Methods	RCT (trial report stated that there was "random selection"), with 6-month follow-up.	
Participants	Elderly patients, average age 72.5 years, confined to bed, with reduced mobility in the legs due to neurological disorder, or fixed joints, peripheral vascular disease. No baseline data given and baseline comparability not described. Study set in Australia.	
Interventions	<ul style="list-style-type: none"> Sheepskin under both legs (n = 18). No sheepskin (n = 18). Both groups received 4-hourly washing, drying, powdering of the skin, light massage of pressure points, bed cradle.	
Outcomes	Relief of redness and pressure ulcer healing. Comfort.	
Notes	Small, poorly reported study.	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Mode of allocation unclear, only stated as "random selection".
Allocation concealment (selection bias)	Unclear risk	Not stated.
Blinding (performance bias and detection bias) All outcomes	High risk	No blinding.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear
Selective reporting (reporting bias)	Low risk	All of the study's pre-specified outcomes were reported (no tables).
ITT Analysis?	Unclear risk	Unclear.
Free of other bias? - were groups similar at baseline	Unclear risk	Not stated.

Ewing 1964 (Continued)
regarding the most important prognostic factors?

Free of other bias? - was the timing of the outcome assessment similar in all groups?	Unclear risk	Not stated.
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Ferrell 1993

Methods	RCT with median follow-up of 33 days (LAL group) and 40 days (foam mattress). Randomisation in blocks of 10; 5 to each treatment. Assignments were sealed in individual envelopes and opened sequentially.
Participants	Elderly nursing home residents with multiple medical problems, and with trunk or trochanter pressure ulcers (Shea Grade 2 or greater). Where patient had multiple ulcers, largest ulcer chosen as index ulcer. Patients excluded if: expected to survive less than one month; had already participated in the study; surgery to the ulcer was planned. Groups appeared to be well matched at baseline, including ulcer area; except that patients in LAL bed group had significantly lower serum albumin.
Interventions	<ul style="list-style-type: none"> LAL bed (KINAIR) (n = 43). 10 cm convoluted foam overlay on top of standard foam mattress (n = 41). <p>Both groups had similar co-interventions as per standard care i.e. mobilisation as much as possible; two-hourly turning during waking hours; avoidance of head-of-bed elevation; avoidance of dragging participants on sheets; nutritional support; infection control.</p>
Outcomes	Rate of healing. Wound surface area was traced twice/week on plastic film, and area measured using planimetry. Ulcers completely healed (covered with epithelium).
Notes	A priori sample size calculation; study terminated at interim analysis as difference much larger than expected.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation unclear.
Allocation concealment (selection bias)	Low risk	Quote: "Assignments were sealed in individual envelopes and opened sequentially on establishment of study criteria".
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Unclear.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of attrition/exclusions
Selective reporting (reporting bias)	Low risk	All of the study's pre-specified outcomes were reported.
ITT Analysis?	Low risk	Specified in study report.

Ferrell 1993 (Continued)

Free of other bias? - were groups similar at baseline regarding the most important prognostic factors?	Low risk	Baseline comparability for initial area of ulcer also reported.
Free of other bias? - was the timing of the outcome assessment similar in all groups?	Low risk	Healing assessed twice weekly.

Groen 1999

Methods	RCT with 4-week follow-up. Allocation by sealed envelopes.	
Participants	Nursing home patients, > 59 years old with pressure ulcer on trunk of Grade 3 (superficial cutaneous or subcutaneous necrotic) or Grade 4 (deep subcutaneous necrotic). The grading system of the ulcers was not specified. Study set in Holland.	
Interventions	<ul style="list-style-type: none"> Foam replacement mattress: 3 layers of polyurethane foam designated as comfort, load-distributing and support layers (n = 60). Secutex water mattress: placed on top of standard hospital mattress, three PVC sections holding 26 L water each, with heating element (n = 60). Standard turning protocol (every 2 to 3 hours) for both groups.	
Outcomes	Proportion with healed ulcers at four weeks. Mean pressure ulcer severity score at four weeks.	
Notes	Withdrawals: 11 from Group 1, eight from Group 2, but not stated at which time points withdrawals occurred. Reasons for withdrawals included severe illness and discharge.	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not stated.
Allocation concealment (selection bias)	Low risk	Quote: "Subjects were randomly divided into two groups of 60 by selection of sealed envelopes".
Blinding (performance bias and detection bias) All outcomes	High risk	No blinding.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of attrition/exclusions.
Selective reporting (reporting bias)	Low risk	All of the study's pre-specified outcomes were reported.
ITT Analysis?	High risk	Not specified in study report.
Free of other bias? - were groups similar at baseline	Low risk	Baseline comparability for initial area of ulcer also reported.

Support surfaces for treating pressure ulcers (Review)

Groen 1999 (Continued)
regarding the most important prognostic factors?

Free of other bias? - was the timing of the outcome assessment similar in all groups?	Low risk	Pressure ulcer severity measured once a week.
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Keogh 2001

Methods	RCT with 5-10 days' follow-up. Computer-generated randomisation sequence, block design. Allocation by sealed, sequentially-numbered, opaque envelopes. Blinding of treatment allocation up to point of randomisation only. Also some influence of PU status on allocation of control intervention.
Participants	Patients from two surgical and two medical wards: >18 years old; Waterlow score of 15-25; tissue damage no greater than Grade 1 (EPUAP grading system). Study set in the UK.
Interventions	<ul style="list-style-type: none"> Profiling bed with a pressure reducing foam mattress/cushion (n = 35). Flat-based bed with a pressure relieving/redistributing mattress/cushion (n = 35). <p>30 participants were not included in the analysis - it was unclear if they were randomised.</p>
Outcomes	Proportion with healed Grade 1 ulcers.
Notes	The extent of follow-up was difficult to ascertain. A priori sample size calculation done. Funding provided by Huntleigh Health.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The block design randomisation code was computer generated by an independent statistician using blocks of 8"; however the participants PU status influenced allocation.
Allocation concealment (selection bias)	Low risk	Quote: "The allocation for each patient was placed in sealed, opaque envelopes that were numbered sequentially".
Blinding (performance bias and detection bias) All outcomes	High risk	Study states patients and researcher were not aware of bed allocation until after recruitment; suggest therefore this should be high risk: patients were shown how to operate the profiling bed**.
Incomplete outcome data (attrition bias) All outcomes	High risk	Insufficient reporting of attrition/exclusions. Many participants were not included in the final analysis as they did not complete the required duration in the study.
Selective reporting (reporting bias)	High risk	Not all of the study's pre-specified outcomes were reported.
ITT Analysis?	High risk	Only data from 70 patients who remained in the study for five days or more and who completed the patient questionnaire were analysed for secondary outcomes; focus should be on those with existing PUs at start of study.
Free of other bias? - were groups similar at baseline	High risk	However, baseline comparability for initial ulcer size not reported. Pressure ulcers not equally distributed between groups.

Keogh 2001 (Continued)
regarding the most important prognostic factors?

Free of other bias? - was the timing of the outcome assessment similar in all groups?	Unclear risk	Unclear.
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Mulder 1994

Methods	RCT with maximum 12 week follow-up, or until ulcers healed, whichever occurred first. Method of allocation not stated.	
Participants	49 nursing home patients with Grade 3-4 pressure ulcers (International Association of Enterostomal Therapists staging system). Single-centre trial.	
Interventions	<ul style="list-style-type: none"> Air suspension bed (Therapulse, Kinetic concepts): a pulsating air suspension therapy (cushions alternately inflate and deflate but classed as LAL rather than AP) (n = 31). Convuluted foam mattress overlay (Geomatt, SpanAmerica) (n = 18). <p>Wound care and repositioning standardised for both groups.</p>	
Outcomes	<p>Wound closure. Pressure ulcer improvement (pressure ulcer reduced by one grade or more, including healed completely). Wound surface area assessed by photoplanimetry. Ulcer volume = ulcer length x width x depth (of deepest ulcer point).</p> <p>No variance data.</p>	
Notes	Enrolled 49: 10 "dropped from study" (no reasons given), 8 died, 1 lost to follow-up, 1 protocol violation. No information about groups from which withdrawals came. No explanation of why the stated 1:1 randomisation ratio resulted in such disproportionate groups.	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not stated. Quote: "this was a single center study conducted as a randomised controlled trial".
Allocation concealment (selection bias)	Unclear risk	Unclear.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Unclear.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data.
Selective reporting (reporting bias)	High risk	Not all of the study's pre-specified outcomes were reported.
ITT Analysis?	Low risk	Specified in study report.
Free of other bias? - were groups similar at baseline	Unclear risk	However, baseline comparability for initial ulcer size not reported.

Support surfaces for treating pressure ulcers (Review)

Mulder 1994 (Continued)
regarding the most important prognostic factors?

Free of other bias? - was the timing of the outcome assessment similar in all groups?	Low risk	Wounds assessed weekly.
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Munro 1989

Methods	RCT with 15-day follow-up. Method of randomisation not described.
Participants	Included male patients with Grade 2 or 3 pressure ulcers, expected to remain in hospital for at least 15 days. Excluded patients with grade 4 ulcers; patients weighing > 250 lb; patients at less than 70% of ideal body weight; patients with serum albumin < 2.1 g/100 mL. Groups described as comparable for age, diagnosis, size of ulcer, pain, and Gosnell score at baseline, but data not presented by group. Staging systems used to classify the pressure ulcers not specified.
Interventions	<ul style="list-style-type: none"> Air-fluidised bed (Clinitron) (n = 20). Standard care (n = 20). <p>The bed/mattress in the standard care group was not described. Sheepskins or gel pads were placed beneath ulcer areas. Standard care involved positioning and massage.</p>
Outcomes	Change in mean ulcer area (mm ²) measured on 1st, 3rd, 8th, 15th days, but provided only mean values and no data regarding the spread of results. Final area presented as % of initial nursing time in minutes per 8-hour shift. participants' perception of pain. Patient satisfaction. No variance data
Notes	No information regarding sample size calculations, blinding, baseline characteristics or extent of follow-up. No raw data presented in the paper.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not stated. Quote: "Eligible, consenting patients...were randomly assigned to the Clinitron bed (experimental group) or to a standard hospital bed (control group)".
Allocation concealment (selection bias)	Unclear risk	Unclear.
Blinding (performance bias and detection bias) All outcomes	High risk	No blinding.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of attrition/exclusions.
Selective reporting (reporting bias)	High risk	Not all of the study's pre-specified outcomes were reported.
ITT Analysis?	Unclear risk	Unclear.

Munro 1989 (Continued)

Free of other bias? - were groups similar at baseline regarding the most important prognostic factors?	Unclear risk	However, baseline comparability for initial ulcer size not reported.
Free of other bias? - was the timing of the outcome assessment similar in all groups?	Low risk	Ulcer size/patient pain/administration of modified Gosnell scale measured on days 1, 3, 8, and 15. Nursing time measured on day 8. Not mentioned when patient satisfaction measured.

Nixon 2006a

Methods	RCT with 30-day follow-up. Randomisation by independent, automated telephone system.	
Participants	Patients at least 55 years old, from vascular, orthopaedic, medical or care of the elderly wards with an expected length of stay at least 7 days and Braden Score of 1 or 2, or an existing Grade 2 pressure ulcer (grading system not specified). Study set in the UK.	
Interventions	<ul style="list-style-type: none"> Alternating-pressure overlay within 24 hours of admission (n = 59 with existing pressure ulcers of the 989 randomised to this group) Alternating-pressure mattress within 24 hours of admission (n = 54 with existing pressure ulcers of the 982 randomised to this group). 	
Outcomes	Proportion of participants developing a new pressure ulcer of Grade 2 or worse. Time to development of new pressure ulcers. Proportion of participant developing a new pressure ulcer within 30 days. Healing of existing pressure ulcers. Patient acceptability.	
Notes	Study funded by HTA.	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomisation was through an independent, secure, 24 hour randomisation automated telephone system".
Allocation concealment (selection bias)	Low risk	Quote: "Randomisation was through an independent, secure, 24 hour randomisation automated telephone system, ensuring allocation concealment".
Blinding (performance bias and detection bias) All outcomes	High risk	No blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data (flow chart on page 3 of study report).
Selective reporting (reporting bias)	Low risk	All of the study's pre-specified outcomes were reported.
ITT Analysis?	Low risk	Specified in study report.
Free of other bias? - were groups similar at baseline	Low risk	Baseline comparability for initial area of ulcer also reported.

Support surfaces for treating pressure ulcers (Review)

Nixon 2006a (Continued)

regarding the most important prognostic factors?

Free of other bias? - was the timing of the outcome assessment similar in all groups?	Low risk	Skin status assessed twice weekly for 30 days and then once weekly for 60 days.
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Osterbrink 2005

Methods	RCT with follow-up time stated as being for as long as clinical circumstances allowed (maximum duration 42 days).	
Participants	Participants recruited from aged-care facility, acute care hospitals and home care setting. Participants were > 18 years old with at least one Grade 2 pressure ulcer at any bony prominence. If recruited from hospital, must have been nursed on care of the elderly, neurological or surgical units. EPUAP classification system used to grade the pressure ulcers.	
Interventions	<ul style="list-style-type: none"> • Repose device (n = 28). • Small cell AP (n = 12). • Large cell AP (n = 10). 	
Outcomes	Wound healing success. Weekly changes in wounds (ulcer size, grade, wound bed, edge appearance and local wound treatment).	
Notes	There was no standardisation of pressure ulcer care across the participating centres.	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Unclear.
Allocation concealment (selection bias)	Unclear risk	Unclear.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Unstated.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of attrition/exclusions.
Selective reporting (reporting bias)	Low risk	All of the study's pre-specified outcomes were reported.
ITT Analysis?	Low risk	Specified in study report.
Free of other bias? - were groups similar at baseline regarding the most important prognostic factors?	Low risk	However, baseline comparability for initial ulcer size not reported.

Osterbrink 2005 (Continued)

Free of other bias? - was the timing of the outcome assessment similar in all groups?	Low risk	Weekly assessment of patient vulnerability to developing a new pressure ulcer and changes in pressure ulcers assessed weekly.
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Russell 2000

Methods	RCT with 18-month follow-up. Method of random allocation not described.	
Participants	141 patients from care of the elderly units with pressure ulcer of > Grade 2 (Torrance classification system). Enrolled over 18 months during 1997 to 1998. Average age 83.9 and 84.6 years in the two groups. NB. Patients excluded if randomised equipment unavailable (not stated how often this occurred). Study set in the UK.	
Interventions	Two types of alternating cell mattress systems with pressure-relieving cushions. <ul style="list-style-type: none"> Huntleigh Numbus 3 with Aura cushion and 4-hourly turning (n = 70). Pegasus Cairwave Therapy System with Proactive 2 seating cushion and 8-hourly turning (n = 71). Length of intervention period unclear.	
Outcomes	Ulcer healing: all types, and divided into heel and sacral ulcers, at 12 and 18 months.	
Notes	No differential difference in losses to follow-up between the groups: 13/70 in Group 1, 16/71 in Group 2. Insufficient information on outcome measurements. Ulcer healing was recorded by weekly camera and nurse gradings - called "improvement factor". No information provided regarding randomisation processes or allocation concealment. No control group used.	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "On admission to the study, subjects were randomly allocated to trial equipment". Method of randomisation not described.
Allocation concealment (selection bias)	Unclear risk	Unclear.
Blinding (performance bias and detection bias) All outcomes	Low risk	Quote: "Images [of the pressure ulcers] were stored on compact discs, using codes that ensured image analysis could be carried out 'blind' to treatment group".
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data.
Selective reporting (reporting bias)	Low risk	All of the study's pre-specified outcomes were reported.
ITT Analysis?	High risk	Not specified in study report.
Free of other bias? - were groups similar at baseline regarding the most important prognostic factors?	Low risk	Baseline comparability for initial area of ulcer also reported.

Russell 2000 (Continued)

Free of other bias? - was the timing of the outcome assessment similar in all groups?	Low risk	Ulcers photographed weekly and participants surveyed at seven days after trial entry. Not stated when comfort was assessed.
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Russell 2003

Methods	RCT. Allocation using sealed envelopes and computer-generated randomisation sequence. Length of follow-up unclear, but presumably until discharge from enrolment hospital.	
Participants	158 patients with Grade 1 or 2 pressure ulcers (EPUAP classification) admitted to hospital between April 2001 to April 2002. Mean age 80 years. Baseline Waterlow scores = 21.8 and 21.3 in Groups 1 and 2, respectively and baseline Burton scores = 14.6 and 14.2 in groups 1 and 2, respectively. Exclusions included patients previously enrolled in the trial, obese patients (> 25 stone), those with > Grade 3 ulcers. Patients well matched at baseline. Study set in the UK.	
Interventions	<ul style="list-style-type: none"> Alternating-pressure, multicell mattress with 10-minute cycle time (Nimbus 3) (n = 83). Fluid overlay mattress (RIK® static) (n = 75). <p>All participants had standard 4-hourly re-positioning, but could have additional turning at the patient's request - the effect of this co-intervention on treatment effect is unclear.</p>	
Outcomes	Improved ulcer response, length of hospital stay.	
Notes	Power calculations stated. No blinding of treatment allocation to participants or clinicians described. Blinded photographic assessment of ulcer grading. Enrolled 199 participants, excluded 41 from analysis as discharged before more than one outcome assessment could be made. Trial funded by makers of Nimbus 3 mattress. No information on reliability, specificity or sensitivity for identification and/or classification of ulcers.	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Allocations were made using a random number generator in Excel 97".
Allocation concealment (selection bias)	Low risk	Quote: "Allocation was by selection of a sealed envelope in which a trial number and bed allocation was enclosed".
Blinding (performance bias and detection bias) All outcomes	Unclear risk	States 'blinding' occurred.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of attrition/exclusions.
Selective reporting (reporting bias)	Low risk	All of the study's pre-specified outcomes were reported.
ITT Analysis?	High risk	Not specified in study report.
Free of other bias? - were groups similar at baseline	Low risk	Baseline comparability for initial area of ulcer also reported.

Russell 2003 (Continued)

regarding the most important prognostic factors?

Free of other bias? - was the timing of the outcome assessment similar in all groups?	Low risk	Participants assessed daily and full assessment performed weekly.
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Strauss 1991

Methods	RCT, though method of randomisation not stated. 36-week follow-up.	
Participants	<p>People: with at least one Grade 3 or 4 pressure ulcer (Shea classification); who would probably require future hospitalisation for the pressure ulcer; with severely limited mobility; for whom home air-fluidised therapy was a practical option; likely to comply; live at least one year; aged 16 years or over.</p> <p>NB. Whilst baseline data were presented by group for many variables, baseline ulcer area was not presented or discussed.</p>	
Interventions	<ul style="list-style-type: none"> Home air-fluidised therapy (CLINITRON) when Grade 3 or 4 ulcers present, plus the consultative and technical services of a visiting nurse specialist (n = 47). Conventional or standard therapy, patient specific and as prescribed (n = 50), but included alternating -pressure pads, air-filled mattresses, water-filled mattresses, high-density foam pads. 	
Outcomes	<p>Pressure ulcers classified by blinded observers as improved; unchanged; worse; or not assessable.</p> <p>Pressure ulcer-related hospitalisations and costs/patient.</p> <p>Pressure ulcer-related hospital days/patient.</p> <p>No variance data.</p>	
Notes	Seven AF participants and 17 standard therapy participants had missing or uninterpretable pressure ulcer photographs/nurse notes and could not be reviewed for improvement by the blinded nurse assessors (73% follow-up).	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation took place, quote: "using forms created by a computerized random-number-generating system".
Allocation concealment (selection bias)	Unclear risk	Unclear.
Blinding (performance bias and detection bias) All outcomes	Low risk	Quote: "The study assessed clinical outcomes through reviews by two independent nurses who were experts in the care of pressure sores and who were blinded to treatment category".
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient reporting of attrition/exclusions.
Selective reporting (reporting bias)	Unclear risk	All pre-specified outcomes reported.
ITT Analysis?	Low risk	Specified in study report.

Strauss 1991 (Continued)

Free of other bias? - were groups similar at baseline regarding the most important prognostic factors?	Low risk	However, baseline comparability for initial ulcer size not reported.
Free of other bias? - was the timing of the outcome assessment similar in all groups?	Unclear risk	Unclear.

Abbreviations

> = more than

< = less than

AF = Air-fluidised

AP = alternating pressure

BMI: body mass index

L = litre(s)

lb = pounds (imperial weight measure)

LAL = low-air-loss

PVC = polyvinylchloride

RCT = randomised controlled trial

WSA = wound surface area

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Bennett 1998	Authors did not report treatment data: quote: "too few patients with existing pressure ulcers were treated for too short a period of time to assess the effect of low-air-loss hydrotherapy on pressure sore healing".
De Roche 2004	Ulcers had been surgically closed and, therefore, were post-surgical wounds.
Finnegan 2008	Ulcers had been surgically closed and, therefore, were post-surgical wounds.
Gardner 2008	Not investigating pressure ulcer treatment. Outcome measure of interface pressure reported.
Hardin 2000	Not an RCT, measured interface pressure and included a retrospective chart audit.
Lazzara 1991	Participants did not have existing pressure ulcers.
Malbrain 2010	Does not meet inclusion criteria
Manzano 2013	Not an RCT
Marchand 1993	Retrospective chart audit.
McGinnis 2017	Does not meet inclusion criteria
Meyers 2008	Study did not investigate the treatment of pressure ulcers.
Prebio 2005	Unclear of baseline number of pre-existing pressure ulcers.
Rosenthal 1996	Study investigated interface pressures.

Study	Reason for exclusion
Rosenthal 2003	Treatment outcomes were inadequately reported. Process of randomisation may have introduced bias.
Stoneberg 1986	Participants did not have existing pressure ulcers.
Timmons 2008	Not an RCT, but a product review.

RCT = randomised controlled trial

Characteristics of studies awaiting assessment *[ordered by study ID]*

[Mastrangelo 2010](#)

Methods	Participants randomised to standard anti-decubitus ulcer treatment and to the newly-introduced treatment. Ulcerative area classified according to Wagner scale, photographed and objectively assessed using doppler. Sites assessed at days 0, 15, 30, 60 and 90.
Participants	13 participants with a total of 15 lesions. 11 patients with multi-localised vascular pathology and 2 with senile dementia. Group A: 4 patients with sacral ulcers (3 male, 1 female). Age 67-93 years. Total of 4 lesions (size range: 3 cm to 8.5 cm). Group B: 3 patients with calcaneal ulcers (2 male, 1 female). Age 70-87 years. Total of 5 lesions (size range 1.5 cm to 4.5 cm). Group C: 6 patients with pre-ulcerous sacral lesions (3 male, 3 female). Age 62-81 years. Total of 6 lesions.
Interventions	Standard treatment vs mattress cover: AIARTREX TEXSIVE
Outcomes	1. Impact of new fabric on therapy and prevention of pressure ulcers. 2. Reduction of the time for the pressure ulcer to become 50% of its original size and of the erythematous and peri-lesional surface. 3. Reduction of the quantity of exudate and improvement of the microenvironment of the lesion.
Notes	Awaiting English translation.

[Mayer 2004](#)

Methods	RCT (three arms)
Participants	51 participants with 70 wounds
Interventions	Thevo-Activ System (foam mattress with vibrating understructure) Microcellular alternating pressure systems Macrocellular alternating pressure systems.
Outcomes	Complete wound healing
Notes	Author contacted for further information about the study. Report in German with some English information

Ozyurek 2015

Methods	RCT
Participants	105 participants admitted to an intensive care unit
Interventions	Viscoelastic foam 1 Viscoelastic foam 2 support surface
Outcomes	Unclear if relevant secondary outcomes (primary outcome appearance of pressure ulcers)
Notes	

Park 2017

Methods	RCT
Participants	122 participants who were 19 years or older, had a Braden Scale for Pressure Sore Risk score of 16 or less, and were cared for on a neurology, oncology, or pulmonology inpatient care unit.
Interventions	Viscoelastic foam overlay (VEFO) Standard hospital mattress
Outcomes	Unclear if relevant secondary outcomes (primary outcome appearance of pressure ulcers)
Notes	

Sauvage 2017

Methods	RCT with survival analysis
Participants	76 participants aged 70 or over bedridden for at least 15 hours per day, with reduced mobility due to medical problems (such as malnutrition, low blood pressure, urinary incontinence, neurological diseases and sensory disorders), a low to zero positioning capability, a Karnofsky score $\leq 40\%$ and a planned period of hospitalisation of at least two weeks.
Interventions	Alternating pressure air mattress (APAM) Viscoelastic foam mattress (VFM)
Outcomes	Quality of life (primary outcome appearance of pressure ulcers)
Notes	

RCT = randomised controlled trial

Characteristics of ongoing studies [ordered by study ID]

Brown 2016

Trial name or title	Pressure RELieving Support SURfaces: a Randomised Evaluation 2 (PRESSURE 2)
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Support surfaces for treating pressure ulcers (Review)

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Brown 2016 (Continued)

Methods	RCT (double triangular, group sequential design)
Participants	Maximum of 2954 'high-risk' patients with evidence of acute illness. Participants can, but are not required to, have an existing pressure ulcer up to category 2)
Interventions	High-specification foam mattress or alternating-pressure mattress in conjunction with an electric profiling bed frame
Outcomes	Time to healing of pre-existing Category 2 pressure ulcers, health-related quality of life, cost-effectiveness, incidence of mattress change and safety (all secondary outcomes; primary outcomes relate to development of new pressure ulcers)
Starting date	The first patient was randomised on 14 August 2013. As of 13 April 2016, 1501 patients have been randomised
Contact information	Sarah Brown, Clinical Trials Research Unit, Leeds Institute of Clinical Trials Research, University of Leeds, Leeds LS2 9JT, UK
Notes	Funded by National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme (Project: 11/36/33)

RCT = randomised controlled trial

DATA AND ANALYSES

Comparison 1. Low-tech bed versus foam mattress (Hospital standard)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer healing	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Profiling bed	1	14	Risk Ratio (M-H, Fixed, 95% CI)	3.96 [1.28, 12.24]
1.2 Sheepskin bed	1	36	Risk Ratio (M-H, Fixed, 95% CI)	0.06 [0.00, 0.95]

Analysis 1.1. Comparison 1 Low-tech bed versus foam mattress (Hospital standard), Outcome 1 Pressure ulcer healing.

Comparison 2. Water filled support versus foam replacement mattress

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer healing	1	120	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.63, 1.37]

Analysis 2.1. Comparison 2 Water filled support versus foam replacement mattress, Outcome 1 Pressure ulcer healing.

Comparison 3. Low-air-loss versus low-tech overlay

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcers completely healed	1	84	Risk Ratio (M-H, Fixed, 95% CI)	1.30 [0.87, 1.96]

Analysis 3.1. Comparison 3 Low-air-loss versus low-tech overlay, Outcome 1 Pressure ulcers completely healed.

Comparison 4. Different alternating pressure mattresses

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Pressure ulcers completely healed	1	30	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.26, 1.27]
2 Decrease in pressure ulcer size	1	30	Risk Ratio (M-H, Fixed, 95% CI)	0.58 [0.21, 1.65]
3 Pressure ulcers completely healed	1	141	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.90, 1.09]

Analysis 4.1. Comparison 4 Different alternating pressure mattresses, Outcome 1 Pressure ulcers completely healed.

Analysis 4.2. Comparison 4 Different alternating pressure mattresses, Outcome 2 Decrease in pressure ulcer size.

Analysis 4.3. Comparison 4 Different alternating pressure mattresses, Outcome 3 Pressure ulcers completely healed.

Comparison 5. Alternating-pressure mattress versus alternating-pressure mattress overlay

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer improvement	1	158	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.80, 1.17]
2 Pressure ulcer healing	1	113	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.58, 1.60]

Analysis 5.1. Comparison 5 Alternating-pressure mattress versus alternating-pressure mattress overlay, Outcome 1 Pressure ulcer improvement.

Analysis 5.2. Comparison 5 Alternating-pressure mattress versus alternating-pressure mattress overlay, Outcome 2 Pressure ulcer healing.

Comparison 6. Alternating-pressure mattress versus air-filled devices

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Proportion of patients with healed pressure ulcer	1	50	Risk Ratio (M-H, Fixed, 95% CI)	5.5 [0.73, 41.44]

Analysis 6.1. Comparison 6 Alternating-pressure mattress versus air-filled devices, Outcome 1 Proportion of patients with healed pressure ulcer.

Comparison 7. Alternating-pressure cushion versus dry flotation cushion

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcers completely healed	1	25	Risk Ratio (M-H, Fixed, 95% CI)	0.47 [0.14, 1.56]

Analysis 7.1. Comparison 7 Alternating-pressure cushion versus dry flotation cushion, Outcome 1 Pressure ulcers completely healed.

APPENDICES

Appendix 1. Search strategies

Cochrane Wounds Specialised Register

- 1 MESH DESCRIPTOR beds EXPLODE ALL AND INREGISTER
- 2 mattress* AND INREGISTER
- 3 cushion* AND INREGISTER
- 4 (foam or transfoam) AND INREGISTER
- 5 overlay* AND INREGISTER
- 6 (pad or pads) AND INREGISTER
- 7 gel AND INREGISTER
- 8 (pressure NEXT relie*) AND INREGISTER
- 9 (pressure NEXT reduc*) AND INREGISTER
- 10 (pressure NEXT alleviat*) AND INREGISTER
- 11 ("low pressure" near2 device*) AND INREGISTER
- 12 ("low pressure" near2 support) AND INREGISTER
- 13 (constant near2 pressure) AND INREGISTER
- 14 "static air" AND INREGISTER
- 15 (alternat* next pressure) AND INREGISTER
- 16 (air next suspension*) AND INREGISTER
- 17 (air next bag*) AND INREGISTER
- 18 (water next suspension*) AND INREGISTER
- 19 (elevation near2 device*) AND INREGISTER
- 20 (clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or "foot waffle" or silicore or pegasus or cairwave) AND INREGISTER
- 21 (turn* or tilt*) next (bed* or frame*) AND INREGISTER
- 22 kinetic next (therapy or table*) AND INREGISTER
- 23 (net next bed*) AND INREGISTER
- 24 (positioning or repositioning) AND INREGISTER
- 25 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 AND INREGISTER
- 26 MESH DESCRIPTOR Pressure Ulcer EXPLODE ALL AND INREGISTER
- 27 (pressure next (ulcer* or sore* or injur*)) AND INREGISTER
- 28 (decubitus next (ulcer* or sore*)) AND INREGISTER
- 29 ((bed next sore*) or bedsore*) AND INREGISTER
- 30 #26 OR #27 OR #28 OR #29 AND INREGISTER
- 31 #25 AND #30 AND INREGISTER

The Cochrane Central Register of Controlled Clinical Trials (CENTRAL)

- #1 MeSH descriptor: [Beds] explode all trees
- #2 mattress*:ti,ab,kw
- #3 cushion*:ti,ab,kw
- #4 (foam or transfoam):ti,ab,kw
- #5 overlay*:ti,ab,kw
- #6 "pad" or "pads":ti,ab,kw
- #7 "gel":ti,ab,kw
- #8 (pressure next relie*):ti,ab,kw

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```
#9 (pressure next reduc*):ti,ab,kw
#10 (pressure next alleviat*):ti,ab,kw
#11 ("low pressure" near/2 device*):ti,ab,kw
#12 ("low pressure" near/2 support):ti,ab,kw
#13 (constant near/2 pressure):ti,ab,kw
#14 "static air":ti,ab,kw
#15 (alternat* next pressure):ti,ab,kw
#16 (air next suspension*):ti,ab,kw
#17 (air next bag*):ti,ab,kw
#18 (water next suspension*):ti,ab,kw
#19 (elevation near/2 device*):ti,ab,kw
#20 (clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or "foot waffle" or silicore or pegasus or cairwave):ti,ab,kw
#21 (turn* or tilt*) next (bed* or frame*):ti,ab,kw
#22 kinetic next (therapy or table*):ti,ab,kw
#23 (net next bed*):ti,ab,kw
#24 (positioning or repositioning):ti,ab,kw
#25 {or #1-#24}
#26 MeSH descriptor: [Pressure Ulcer] explode all trees
#27 (pressure next (ulcer* or sore* or injur*)):ti,ab,kw
#28 (decubitus next (ulcer* or sore*)):ti,ab,kw
#29 ((bed next sore*) or bedsore*):ti,ab,kw
#30 {or #26-#29}
#31 {and #25, #30} in Trials
```

Ovid MEDLINE

```
1 exp Beds/
2 mattress*.mp.
3 cushion*.mp.
4 (foam or transfoam).mp.
5 overlay*.mp.
6 (pad or pads).ti,ab.
7 gel.ti,ab.
8 pressure relie*.mp.
9 pressure reduc*.mp.
10 pressure alleviat*.mp.
11 (low pressure adj2 device*).mp.
12 (low pressure adj2 support).mp.
13 (constant adj2 pressure).mp.
14 static air.mp.
15 (alternat* adj pressure).mp.
16 air suspension*.mp.
17 air bag*.mp.
18 water suspension*.mp.
19 (elevation adj2 device*).mp.
20 (clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or foot waffle or silicore or pegasus or cairwave).mp.
21 ((turn* or tilt*) adj (bed* or frame*)).mp.
22 (kinetic adj (therapy or table*)).mp.
23 net bed*.mp.
24 (positioning or repositioning).mp.
25 or/1-24
26 exp Pressure Ulcer/
27 (pressure adj (ulcer* or sore*)).mp.
28 (decubitus adj (ulcer* or sore*)).mp.
29 (bed adj (ulcer* or sore*)).mp.
30 or/26-29
31 and/25,30
32 randomized controlled trial.pt.
33 controlled clinical trial.pt.
34 randomi?ed.ab.
35 placebo.ab.
```

36 clinical trials as topic.sh.
37 randomly.ab.
38 trial.ti.
39 or/32-38
40 exp animals/ not humans.sh.
41 39 not 40
42 31 and 41

Ovid Embase

1 exp Bed/
2 mattress*.mp.
3 cushion*.mp.
4 (foam or transfoam).mp.
5 overlay*.mp.
6 (pad or pads).ti,ab.
7 gel.ti,ab.
8 pressure relie*.mp.
9 pressure reduc*.mp.
10 pressure alleviat*.mp.
11 (low pressure adj2 device*).mp.
12 (low pressure adj2 support).mp.
13 (constant adj2 pressure).mp.
14 static air.mp.
15 (alternat* adj pressure).mp.
16 air suspension*.mp.
17 air bag*.mp.
18 water suspension*.mp.
19 (elevation adj2 device*).mp.
20 (clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or foot waffle or silicore or pegasus or cairwave).mp.
21 ((turn* or tilt*) adj (bed* or frame*)).mp.
22 (kinetic adj (therapy or table*)).mp.
23 net bed*.mp.
24 (positioning or repositioning).mp.
25 or/1-24
26 exp Decubitus/
27 (pressure adj (ulcer* or sore*)).mp.
28 (decubitus adj (ulcer* or sore*)).mp.
29 (bed adj (ulcer* or sore*)).mp.
30 or/26-29
31 and/25,30
32 Randomized controlled trials/
33 Single-Blind Method/
34 Double-Blind Method/
35 Crossover Procedure/
36 (random* or factorial* or crossover* or cross over* or cross-over* or placebo* or assign* or allocat* or volunteer*).ti,ab.
37 (doubl* adj blind*).ti,ab.
38 (singl* adj blind*).ti,ab.
39 or/32-38
40 exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/
41 human/ or human cell/
42 and/40-41
43 40 not 42
44 39 not 43
45 31 and 44

EBSCO CINAHL Plus

S43 S29 AND S42
S42 S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41
S41 TI allocat* random* or AB allocat* random*

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S40 MH "Quantitative Studies"
 S39 TI placebo* or AB placebo*
 S38 MH "Placebos"
 S37 TI random* allocat* or AB random* allocat*
 S36 MH "Random Assignment"
 S35 TI randomi?ed control* trial* or AB randomi?ed control* trial*
 S34 AB (singl* or doubl* or trebl* or tripl*) and AB (blind* or mask*)
 S33 TI (singl* or doubl* or trebl* or tripl*) and TI (blind* or mask*)
 S32 TI clinic* N1 trial* or AB clinic* N1 trial*
 S31 PT Clinical trial
 S30 MH "Clinical Trials+"
 S29 S23 and S28
 S28 S24 or S25 or S26 or S27
 S27 TI decubitus or AB decubitus
 S26 TI (bed sore* or bedsore*) or AB (bed sore* or bedsore*)
 S25 TI (pressure ulcer* or pressure sore*) or AB (pressure ulcer* or pressure sore*)
 S24 (MH "Pressure Ulcer")
 S23 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22
 S22 TI (positioning or repositioning) or AB (positioning or repositioning)
 S21 TI net bed* or AB net bed*
 S20 TI (kinetic therapy or kinetic table*) or AB (kinetic therapy or kinetic table*)
 S19 TI (turn* bed* or tilt* bed*) or AB (turn* frame* or tilt* frame*)
 S18 TI (clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or foot waffle or silicore or pegasus or cairwave) or AB (clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or foot waffle or silicore or pegasus or cairwave)
 S17 TI elevation N2 device* or AB elevation N2 device*
 S16 TI water suspension or AB water suspension
 S15 TI air bag* or AB air bag*
 S14 TI air suspension or AB air suspension
 S13 TI alternat* pressure or AB alternat* pressure
 S12 TI static air or AB static air
 S11 TI constant N2 pressure or AB constant N2 pressure
 S10 TI low pressure N2 support or AB low pressure N2 support
 S9 TI low pressure N2 device* or AB low pressure N2 device*
 S8 TI pressure alleviat* or AB pressure alleviat*
 S7 TI pressure reduc* or AB pressure reduc*
 S6 TI pressure relie* or AB pressure relie*
 S5 TI (overlay* or pad or pads or gel) or AB (overlay* or pad or pads or gel)
 S4 TI (foam or transfoam) or AB (foam or transfoam)
 S3 TI (mattress* or cushion*) or AB (mattress* or cushion*)
 S2 (MH "Pillows and Cushions")
 S1 (MH "Beds and Mattresses+")

Appendix 2. Risk of bias criteria

1. Was the allocation sequence randomly generated?

Low risk of bias

The investigators describe a random component in the sequence generation process such as: referring to a random number table; using a computer random number generator; coin tossing; shuffling cards or envelopes; throwing dice; drawing of lots.

High risk of bias

The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: sequence generated by odd or even date of birth; sequence generated by some rule based on date (or day) of admission; sequence generated by some rule based on hospital or clinic record number.

Unclear

Insufficient information about the sequence generation process to permit judgement of low or high risk of bias.

2. Was the treatment allocation adequately concealed?

Low risk of bias

Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone, web-based and pharmacy-controlled randomisation); sequentially-numbered drug containers of identical appearance; sequentially-numbered, opaque, sealed envelopes.

High risk of bias

Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: using an open random allocation schedule (e.g. a list of random numbers); use of assignment envelopes were used without appropriate safeguards (e.g. envelopes were unsealed, non-opaque or not sequentially numbered); alternation or rotation; date of birth; case record number; any other explicitly unconcealed procedure.

Unclear

Insufficient information to permit judgement of low or high risk of bias. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement, for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.

3. Blinding - was knowledge of the allocated interventions adequately prevented during the study?

Low risk of bias

Any one of the following.

- No blinding, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding.
- Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others unlikely to introduce bias.

High risk of bias

Any one of the following.

- No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding.
- Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.

Unclear

Either of the following.

- Insufficient information to permit judgement of low or high risk of bias.
- The study did not address this outcome.

4. Were incomplete outcome data adequately addressed?

Low risk of bias

Any one of the following.

- No missing outcome data.
- Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias).
- Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate.
- For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size.
- Missing data have been imputed using appropriate methods.

High risk of bias

Any one of the following.

- Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate.
- For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size.
- 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation.
- Potentially inappropriate application of simple imputation.

Unclear

Either of the following.

- Insufficient reporting of attrition/exclusions to permit judgement of low or high risk of bias (e.g. number randomised not stated, no reasons for missing data provided).
- The study did not address this outcome.

5. Are reports of the study free of suggestion of selective outcome reporting?

Low risk of bias

Either of the following:

- The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
- The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon)

High risk of bias

Any one of the following.

- Not all of the study's pre-specified primary outcomes have been reported.
- One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified.
- One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect).
- One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis.
- The study report fails to include results for a key outcome that would be expected to have been reported for such a study.

Unclear

Insufficient information to permit judgement of low or high risk of bias. It is likely that the majority of studies will fall into this category.

6. Other sources of potential bias

Low risk of bias

The study appears to be free of other sources of bias.

High risk of bias

There is at least one important risk of bias. For example, the study:

- had a potential source of bias related to the specific study design used; or
- had extreme baseline imbalance; or
- has been claimed to have been fraudulent; or
- had some other problem.

Unclear

There may be a risk of bias, but there is either:

- insufficient information to assess whether an important risk of bias exists; or
- insufficient rationale or evidence that an identified problem will introduce bias.

WHAT'S NEW

Date	Event	Description
3 October 2018	New citation required but conclusions have not changed	No change to conclusions
3 October 2018	New search has been performed	Second update of review, new searches undertaken. One new trial included. Methods updated including addition of GRADE assessment of the certainty of evidence and addition of 'Summary of findings' tables.

HISTORY

Review first published: Issue 12, 2011

Date	Event	Description
1 December 2009	Amended	Converted to new review format
20 May 2004	New citation required and conclusions have changed	First update (substantive amendment) published 2004. This review included only trials which consider interventions which aimed to prevent pressure ulcers. The title of the review has been changed to more accurately reflect the scope of the review. The original review: Beds, mattresses and cushions for preventing and treating pressure ulcers. Cullum N, Deeks J, Sheldon TA, Song F, Fletcher AW, has been substantially updated and now forms the basis of a prevention review and a separate treatment review.

CONTRIBUTIONS OF AUTHORS

For this second update of the review, the titles and abstracts of the papers identified by the search were independently assessed for relevance by at two review authors (AJ-B, VL), full-text copies of all potentially-relevant studies were obtained. Decisions on final inclusion were then made by one review author (VL) and checked by a second review author (AJ-B); disagreements were resolved by discussion with a third review author (EMcI). Rejected studies were checked by a third review author (EMcI). In addition, EMcI assisted in the sifting of identified citations, data extraction, quality assessment and author follow-up, co-ordinated and reviewed the analysis, and was responsible for the editing and writing of the final report. AJ-B assisted in the sifting of identified citations, follow-up of pending assessments, undertook the new 'Risk of bias' assessment for all included trials, undertook analyses and reporting of the included studies, and updated the supporting literature review for the [Background](#) section.

Contributions of the editorial base

Nicky Cullum (Co-ordinating Editor): edited the update; advised on methodology, interpretation and content; approved the final update prior to publication.

Gill Rizzello (Managing Editor): co-ordinated the editorial process; advised on content; edited the update.

Naomi Shaw and Ruth Foxlee (Information Specialists): edited the search strategy, ran the searches and edited the search methods section for this update and the previous update respectively.

Ursula Gonthier (Editorial Assistant): edited the Plain language summary and the reference section.

DECLARATIONS OF INTEREST

Elizabeth McInnes: none known.

Asmara Jammali-Blasi: none known.

Sally Bell-Syer: none known.

Vannessa Leung: none known.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Originally, this review was combined with Cochrane Review *Support surfaces for prevention of pressure ulcers* ([McInnes 2015](#)) and published as *Beds, mattresses and cushions for preventing and treating pressure ulcers* ([Cullum 2000](#)). The current authors were not involved in this publication.

Differences between current review and previous version

One more study has been included. The conclusions are unchanged. This version includes GRADE assessment of the certainty of the evidence.

INDEX TERMS

Medical Subject Headings (MeSH)

Bedding and Linens [*standards]; Beds [*standards]; Equipment Design; Pressure Ulcer [*therapy]; Randomized Controlled Trials as Topic; Surface Properties; Wound Healing

MeSH check words

Humans