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Beds, overlays and mattresses for treating pressure ulcers (Review)

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[Intervention Review]

Beds, overlays and mattresses for treating pressure ulcers

Chunhu Shi[1], Jo C Dumville[1], Nicky Cullum[1], Sarah Rhodes[2], Asmara Jammali-Blasi[3], Victoria Ramsden[4], Elizabeth McInnes[5]

[1]Division of Nursing, Midwifery and Social Work, School of Health Sciences, Faculty of Biology, Medicine and Health, University of Manchester, Manchester Academic Health Science Centre, Manchester, UK. [2]Division of Population Health, Health Services Research & Primary Care, Faculty of Biology, Medicine and Health, University of Manchester, Manchester, UK. [3]Nursing Research Institute, St Vincent's Health Australia (Sydney) and Australian Catholic University (ACU), School of Nursing, Midwifery and Paramedicine, Australian Catholic University, Darlinghurst, Australia. [4]School of Nursing, Faculty of Medicine, University of Notre Dame, Darlinghurst, Australia. [5]Nursing Research Institute, St Vincent's Health Australia Sydney, St Vincent's Hospital Melbourne & Australian Catholic University, Fitzroy, Melbourne, Australia

Contact address: Chunhu Shi, chunhu.shi@manchester.ac.uk.

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ABSTRACT

Background

Pressure ulcers (also known as pressure injuries, pressure sores, decubitus ulcers and bed sores) are localised injuries to the skin or underlying soft tissue, or both, caused by unrelieved pressure, shear or friction. Beds, overlays or mattresses are widely used with the aim of treating pressure ulcers.

Objectives

To assess the effects of beds, overlays and mattresses on pressure ulcer healing in people with pressure ulcers of any stage, in any setting.

Search methods

In November 2019, 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 We also searched clinical trials registries for ongoing and unpublished studies, and scanned reference lists of relevant included studies as well as reviews, meta-analyses and health technology reports to identify additional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 randomised controlled trials that allocated participants of any age to pressure-redistributing beds, overlays or mattresses. Comparators were any beds, overlays or mattresses that were applied for treating pressure ulcers.

Data collection and analysis

At least two review authors independently assessed studies using predetermined inclusion criteria. We carried out data extraction, 'Risk of bias' assessment using the Cochrane 'Risk of bias' tool, and the certainty of the evidence assessment according to Grading of Recommendations, Assessment, Development and Evaluations methodology.

Main results

We included 13 studies (972 participants) in the review. Most studies were small (median study sample size: 72 participants). The average age of participants ranged from 64.0 to 86.5 years (median: 82.7 years) and all studies recruited people with existing pressure ulcers (the baseline ulcer area size ranging from 4.2 to 18.6 cm^2,median 6.6 cm^2). Participants were recruited from acute care settings (six studies) and community and long-term care settings (seven studies). Of the 13 studies, three (224 participants) involved surfaces that were not well described and therefore could not be classified. Additionally, six (46.2%) of the 13 studies presented findings which were considered at high overall risk of bias. We synthesised data for four comparisons in the review: alternating pressure (active) air surfaces versus foam surfaces; reactive air surfaces versus foam surfaces; reactive water surfaces versus foam surfaces, and a comparison between two types of alternating pressure (active) air surfaces. We summarise key findings for these four comparisons below.

(1) Alternating pressure (active) air surfaces versus foam surfaces: we are uncertain if there is a difference between alternating pressure (active) air surfaces and foam surfaces in the proportion of participants whose pressure ulcers completely healed (two studies with 132 participants; the reported risk ratio (RR) in one study was 0.97, 95% confidence interval (CI) 0.26 to 3.58). There is also uncertainty for the outcomes of patient comfort (one study with 83 participants) and adverse events (one study with 49 participants). These outcomes have very low-certainty evidence. Included studies did not report time to complete ulcer healing, health-related quality of life, or cost effectiveness.

(2) Reactive air surfaces versus foam surfaces: it is uncertain if there is a difference in the proportion of participants with completely healed pressure ulcers between reactive air surfaces and foam surfaces (RR 1.32, 95% CI 0.96 to 1.80; I^2 = 0%; 2 studies, 156 participants; low-certainty evidence). When time to complete pressure ulcer healing is considered using a hazard ratio, data from one small study (84 participants) suggests a greater hazard for complete ulcer healing on reactive air surfaces (hazard ratio 2.66, 95% CI 1.34 to 5.17; low-certainty evidence). These results are sensitive to the choice of outcome measure so should be interpreted as uncertain. We are also uncertain whether there is any difference between these surfaces in patient comfort responses (1 study, 72 participants; very low-certainty evidence) and in adverse events (2 studies, 156 participants; low-certainty evidence). There is low-certainty evidence that reactive air surfaces may cost an extra 26 US dollars for every ulcer-free day in the first year of use (1 study, 87 participants). Included studies did not report health-related quality of life.

(3) Reactive water surfaces versus foam surfaces: it is uncertain if there is a difference between reactive water surfaces and foam surfaces in the proportion of participants with healed pressure ulcers (RR 1.07, 95% CI 0.70 to 1.63; 1 study, 101 participants) and in adverse events (1 study, 120 participants). All these have very low-certainty evidence. Included studies did not report time to complete ulcer healing, patient comfort, health-related quality of life, or cost effectiveness.

(4) Comparison between two types of alternating pressure (active) air surfaces: it is uncertain if there is a difference between Nimbus and Pegasus alternating pressure (active) air surfaces in the proportion of participants with healed pressure ulcers, in patient comfort responses and in adverse events: each of these outcomes had four studies (256 participants) but very low-certainty evidence. Included studies did not report time to complete ulcer healing, health-related quality of life, or cost effectiveness.

Authors' conclusions

We are uncertain about the relative effects of most different pressure-redistributing surfaces for pressure ulcer healing (types directly compared are alternating pressure air surfaces versus foam surfaces, reactive air surfaces versus foam surfaces, reactive water surfaces versus foam surfaces, and Nimbus versus Pegasus alternating pressure (active) air surfaces). There is also uncertainty regarding the effects of these different surfaces on the outcomes of comfort and adverse events. However, people using reactive air surfaces may be more likely to have pressure ulcers completely healed than those using foam surfaces over 37.5 days' follow-up, and reactive air surfaces may cost more for each ulcer-free day than foam surfaces.

Future research in this area could consider the evaluation of alternating pressure air surfaces versus foam surfaces as a high priority. Time-to-event outcomes, careful assessment of adverse events and trial-level cost-effectiveness evaluation should be considered in future studies. Further review using network meta-analysis will add to the findings reported here.

PLAIN LANGUAGE SUMMARY

What are the benefits and risks of different types of beds, mattresses and mattress toppers for treating pressure ulcers?

Key messages

Due to a lack of robust evidence, the benefits and risks of most types of beds, mattresses and mattress toppers for treating pressure ulcers are unclear.

Beds with an air-filled surface that apply constant pressure to the skin may be better than mattresses and toppers made of foam for ulcer healing if the evidence on the time needed to completely heal an ulcer is looked at, but may cost more.

Future research in this area should focus on options and effects that are important to decision-makers, such as:

- foam or air-filled surfaces that redistribute pressure under the body; and

- unwanted effects and costs.

What are pressure ulcers?

Pressure ulcers are also known as pressure sores or bed sores. They are wounds to the skin and underlying tissue caused by prolonged pressure or rubbing. They often occur on bony parts of the body, such as heels, elbows, hips and the bottom of the spine. People who have mobility problems or who lie in bed for long periods are at risk of developing pressure ulcers.

What did we want to find out?

There are beds, mattresses and mattress toppers specifically designed for people with pressure ulcers. These can be made from a range of materials (such as foam, air cells or water bags) and are divided into two groups:

- reactive (static) surfaces that apply a constant pressure to the skin, unless a person moves or is repositioned; and

- active (alternating pressure) surfaces that regularly redistribute the pressure under the body.

We wanted to find out if reactive and active surfaces:

- help ulcers to heal;

- are comfortable and improve people's quality of life;

- have health benefits that outweigh their costs; and

- have any unwanted effects.

What did we do?

We searched the medical literature for studies that evaluated the effects of beds, mattresses and mattress toppers. We compared and summarised their results, and rated our confidence in the evidence, based on factors such as study methods and sizes.

What did we find?

We found 13 studies (972 people, average age: 83 years) that lasted between seven days and 18 months (average: 37.5 days).

In general, the studies did not provide sufficiently robust evidence for us to determine the effects of active and reactive surfaces.

Evidence from two studies suggests that, when compared with mattresses and mattress toppers made of foam, beds with a reactive air-filled surface may:

- improve chances of pressure ulcers healing if the data on the time needed to completely heal an ulcer is looked at (1 study, 84 people);

- cost an extra 26 US dollars per person for every ulcer-free day in the first year of use (1 study, 87 people).

The other benefits and risks of these and other surfaces are unclear.

What limited our confidence in the evidence?

Most studies were small (72 people on average) and nearly half of them (six studies) used methods likely to introduce errors in their results.

How up-to-date is this review?

The evidence in this Cochrane Review is current to November 2019.

SUMMARY OF FINDINGS

Summary of findings 1. Alternating pressure (active) air surfaces compared with foam surfaces for treating pressure ulcers

Alternating pressure (active) air surfaces compared with foam surfaces for treating pressure ulcers

Patient or population: people with pressure ulcers
Setting: acute care setting and nursing home
Intervention: alternating pressure (active) air surfaces
Comparison: foam surfaces

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with foam surfaces	Risk with alternating pressure (active) air surfaces				
Proportion of participants with pressure ulcers completely healed Follow-up: range 7 days to 12 weeks	Two studies reported this outcome: Mulder 1994 reported analysable data and the RR was 0.97 (95% CI 0.26 to 3.58). Day 1993 did not report analysable data but stated that the analysis of covariance showed no statistically significant difference in the healing of pressure ulcers between alternating pressure (active) air surfaces and foam surfaces (F[1,78] = 0.35, P value > 0.05).		not estimable	132 (2 RCTs)	⊕⊖⊖⊖ Very low[a,b]	It is uncertain if there is a difference in the proportion of participants with healed pressure ulcers between alternating pressure (active) air surfaces and foam surfaces.
Time to pressure ulcer healing	Included studies did not report this outcome.					
Support surface-associated patient comfort (assessed with the visual analogue scale, ranging from very comfortable at one end of the scale to very uncomfortable at the other end of the scale; however, the range of scores was not specified) Follow-up: 7 days	The mean support surface associated patient comfort was 0	MD 0.4 higher (0.42 lower to 1.22 higher)	-	39 (1 RCT)	⊕⊖⊖⊖ Very low[a,b]	It is uncertain whether there is any difference between alternating pressure (active) air surfaces and foam surfaces in patient comfort responses.
All reported adverse events Follow-up: 12 weeks	Mulder 1994 (49 participants) reported there was no major adverse events that could be attributed to the support surfaces used.		not estimable	49 (1 RCT)	⊕⊖⊖⊖ Very low[a,b]	It is uncertain if there is a difference in adverse events between alternating pres-

					sure (active) air surfaces and foam surfaces.
Health-related quality of life	Included studies did not report this outcome.				
Cost effectiveness	Included studies did not report this outcome.				

*__The risk in the intervention group__ (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; **MD:** Mean difference

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded twice for high risk of detection bias or attrition bias.
[b]Downgraded twice for substantial imprecision due to the small sample size and the reported very wide confidence interval and null effect.

Summary of findings 2. Reactive air surfaces compared with foam surfaces for treating pressure ulcers

Reactive air surfaces compared with foam surfaces for treating pressure ulcers

Patient or population: people with pressure ulcers
Setting: acute care setting and nursing home
Intervention: reactive air surfaces
Comparison: foam surfaces

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with foam surfaces	Risk with reactive air surfaces				
Proportion of participants with pressure ulcers completely healed	Study population		RR 1.32 (0.96 to 1.80)	156 (2 RCTs)	⊕⊕⊖⊖ Low[a]	It is uncertain if there is a difference in the proportion of participants with pressure ulcers completely healed between reactive air surfaces and foam surfaces.
	442 per 1000	583 per 1000 (424 to 795)				

Follow-up: 13.0 days and 37.5 days						
Time to complete pressure ulcer healing Follow-up: 37.5 days	Study population		HR 2.66 (1.34 to 5.17)	84 (1 RCT)	⊕⊕⊖⊖ Low[b]	People using reactive air surfaces may be more likely to have healed pressure ulcers compared with using foam surfaces.
	463 per 1000	809 per 1000 (566 to 960)				
Support surface associated patient comfort Follow-up: 13 days	The only included study (Allman 1987; 72 participants) defined this outcome as the number of participants having changes in comfort from baseline with the level of comfort measured by asking participants: "Which of the following best describes the bed you are using here in the hospital: very comfortable, comfortable, uncomfortable, or very uncomfortable?". Allman 1987 reported 8 participants using reactive air surfaces had increased comfort, 4 without change, and 1 with decreased comfort whilst 3 participants using foam surfaces had increased comfort, 4 had no change and 6 reported decreased comfort (P value = 0.04).		-	72 (1 RCT)	⊕⊖⊖⊖ Very low[b,c]	We are uncertain whether there is any difference between reactive air surfaces and foam surfaces in patient comfort responses.
All reported adverse events Follow-up: range 13.0 days to 37.5 days	Two studies (156 participants) reported this outcome (Allman 1987; Ferrell 1993). We did not pool these data as the definitions of adverse events varied between studies.		-	156 (2 RCTs)	⊕⊕⊖⊖ Low[d,e]	It is uncertain if there is a difference in adverse events between reactive air surfaces and foam surfaces
Health-related quality of life	Included studies did not report this outcome.					
Cost-effectiveness Follow-up: 37.5 days	Ferrell 1995 (87 participants) reported the additional cost due to the use of reactive air surfaces divided by the additional days without an ulcer and suggested that people using reactive air surfaces may cost an extra 26 US dollars for every ulcer-free day in the first year.		-	87 (1 RCT)	⊕⊕⊖⊖ Low[f]	Reactive air surfaces may cost an extra 26 US dollars for every ulcer-free day in the first year

*__The risk in the intervention group__ (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; **HR:** Hazard ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded twice for imprecision as the optimal information size (OIS) was not met and the wide confidence interval crossed RR = 1.25.
[b]Downgraded twice for imprecision due to the very small sample size.
[c]Downgraded twice for high risk of attrition bias for this outcome.
[d]Downgraded once for imprecision due to the small sample size.
[e]Downgraded once for indirectness as the outcome of "all reported adverse events" as a whole was not used in the included studies.
[f]Downgraded twice for imprecision for the time to ulcer healing outcome from which the cost effectiveness was evaluated.

Summary of findings 3. Reactive water surfaces compared with foam surfaces for treating pressure ulcers

Reactive water surfaces compared with foam surfaces for treating pressure ulcers

Patient or population: people with pressure ulcers
Setting: nursing home
Intervention: reactive water surfaces
Comparison: foam surfaces

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with foam surfaces	Risk with **reactive water** surfaces				
Proportion of participants with pressure ulcers completely healed Follow-up: 4 weeks	Study population		RR 1.07 (0.70 to 1.63)	101 (1 RCT)	⊕⊖⊖⊖ Very low[a,b]	It is uncertain if there is a difference in the proportion of participants with healed pressure ulcers between reactive water surfaces and foam surfaces.
	449 per 1000	480 per 1000 (314 to 732)				
Time to complete pressure ulcer healing	Included studies have not reported this outcome.					
Support surface associated patient comfort	Included studies have not reported this outcome.					
All reported adverse events Follow-up: 4 weeks	Groen 1999 (120 participants) reported this outcome, which was defined as the percentages of participants with one or more of the following		-	120 (1 RCT)	⊕⊖⊖⊖ Very low[a,c,d]	It is uncertain if there is any difference in adverse events between reactive water surfaces and foam surfaces.

	types of adverse events: eczema, maceration and pain (Table 1).
Health-related quality of life	Included studies did not report this outcome.
Cost-effectiveness	Included studies did not report this outcome.

*__The risk in the intervention group__ (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 certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded twice for high risk of detection bias in the only study.
[b]Downgraded twice for imprecision as the optimal information size (OIS) was unmet and the very wide confidence interval crossed RRs = 0.75 and 1.25.
[c]Downgraded once for imprecision due to the small sample size.
[d]Downgraded once for indirectness as the study reported specific adverse events rather than all reported adverse events.

BACKGROUND

Description of the condition

Pressure ulcers — also known as pressure injuries, pressure sores, decubitus ulcers and bed sores — are localised injuries to the skin or underlying soft tissue (or both), caused by unrelieved pressure, shear or friction (EPUAP/NPIAP/PPPIA 2019). Pressure ulcer severity is generally classified as follows, using the National Pressure Injury Advisory Panel (NPIAP) system (NPIAP 2016).

- Stage 1: intact skin with a local appearance of non-blanchable erythema
- Stage 2: partial-thickness skin loss with exposed dermis
- Stage 3: full-thickness skin loss
- Stage 4: full-thickness skin and tissue loss with visible fascia, muscle, tendon, ligament, cartilage or bone
- Unstageable pressure injury: full-thickness skin and tissue loss that is obscured by slough or eschar so that the severity of injury cannot be confirmed
- Deep tissue pressure injury: local injury of persistent, non-blanchable deep red, maroon, purple discolouration or epidermal separation revealing a dark wound bed or blood-filled blister

The stages described above are consistent with those described in another commonly used system, the International Classification of Diseases for Mortality and Morbidity Statistics (World Health Organization 2019).

Pressure ulcers are complex wounds that are relatively common, affecting people across different care settings. A systematic review found that prevalence estimates for people affected by pressure ulcers in communities of the UK, USA, Ireland and Sweden ranged from 5.6 to 2300 per 10,000 depending on the nature of the population surveyed (Cullum 2016). A subsequent cross-sectional survey of people receiving community health services in one city in the UK estimated that 1.8 people per 10,000 have a pressure ulcer (Gray 2018). Estimates of pressure ulcer prevalence in hospitals range from 470 to 3210 per 10,000 patients in the UK, USA and Canada (Kaltenthaler 2001).

Pressure ulcers confer a heavy burden in terms of personal impact and use of health-service resources. Having a pressure ulcer may impair physical, social and psychological activities (Gorecki 2009). Ulceration impairs health-related quality of life (Essex 2009); can result in longer institution stays (Graves 2005); and increases the risk of systemic infection (Livesley 2002). There is also substantial impact on health systems: a 2015 systematic review of 14 studies across a range of care settings in Europe and North America showed that costs related to pressure ulcer treatment ranged from EUR 1.71 to EUR 470.49 per person, per day (Demarré 2015). In the UK, the annual average cost to the National Health Service for managing one person with a pressure ulcer in the community was estimated to be GBP 1400 for a Stage 1 pressure ulcer and more than GBP 8500 for more severe stages (2015/2016 prices; Guest 2018). In Australia, the annual cost of treating pressure ulcers was estimated to be AUD 983 million (95% confidence interval (CI) 815 million to 1151 million) at 2012/2013 prices (Nguyen 2015). The serious consequences of pressure ulceration have led to an intensive focus on their prevention.

Description of the intervention

Pressure ulcers are considered treatable. Support surfaces are specialised medical devices designed to relieve or redistribute pressure on the body, or both, in order to prevent and treat pressure ulcers (NPIAP S3I 2007). Support surfaces are widely used for treating pressure ulcers. These include, but are not limited to, integrated bed systems, mattresses and overlays (NPIAP S3I 2007).

The NPIAP Support Surface Standards Initiative (S3I) terms and definitions related to support surfaces can be used to classify types of support surface (NPIAP S3I 2007). According to this system, beds, mattresses and overlays may:

- be powered (i.e. require electrical power to function) or non-powered;
- passively redistribute body weight (i.e. reactive pressure redistribution), or mechanically alternate the pressure on the body (i.e. active pressure redistribution);
- be made of a range of materials, including but not limited to: air cells, foam materials, fibre materials, gel materials, sheepskin for medical use and water bags; and
- be constructed of air-filled cells that have small holes on the surface for blowing out air to dry skin (i.e. low air-loss feature) or have fluid-like characteristics via forcing filtered air through ceramic beads (i.e. air-fluidised feature), or have neither of these features.

Full details of bed, overlay and mattress classifications are listed in Appendix 1. Various types of beds, overlays and mattresses can be used for treating pressure ulcers, including alternating pressure (active) air surfaces, reactive air surfaces, high-specification reactive foam surfaces, and alternative reactive support surfaces that are made of neither foam materials or air cells.

How the intervention might work

The aim of using support surfaces to treat pressure ulceration is to redistribute pressure beneath the body, thereby facilitating blood flow to tissues and preventing distortion of the skin and soft tissue (Wounds International 2010). Active support surfaces achieve pressure redistribution by frequently changing the points of contact between the surface and body, reducing the duration of the pressure applied to each anatomical site (Clark 2011 ; NPIAP S3I 2007). This contrasts with the mode of action of reactive support surfaces, which is more passive and includes immersion (i.e. 'sinking' of the body into a support surface) and envelopment (i.e. conforming of a support surface to the irregularities in the body). These devices distribute the pressure over a greater area, thereby reducing the magnitude of the pressure at specific sites (Clark 2011).

Why it is important to do this review

Beds, overlays and mattresses are the focus of recommendations in international and national guidelines (EPUAP/NPIAP/PPPIA 2019; NICE 2014). Since the publication of the Cochrane Review, 'Support surfaces for treating pressure ulcers' (McInnes 2018), there has been international recognition of the NPIAP S3I terms and definitions related to support surfaces (NPIAP S3I 2007). It is important to update the evidence base to ensure that it is contemporaneous with current guidelines and other reviews in the field.

In this evidence update, we will consider all types of beds and mattresses (instead of including other types of support surfaces such as cushions, as in McInnes 2018) because beds and mattresses are the primary focus in pressure ulcer guidelines (EPUAP/NPIAP/PPPIA 2019; NICE 2014). We have therefore changed the title of this review to 'Beds, overlays and mattresses for treating pressure ulcers' (Differences between protocol and review).

OBJECTIVES

To assess the effects of beds, overlays and mattresses on pressure ulcer healing in people with pressure ulcers of any stage, in any setting.

METHODS

Criteria for considering studies for this review

Types of studies

We included published and unpublished randomised controlled trials (RCTs), including multi-armed studies, cluster-RCTs and cross-over trials, regardless of the language of publication. We excluded studies using quasi-random allocation methods (e.g. alternation).

Types of participants

We included studies in people with a diagnosis of pressure ulcer of any stage (EPUAP/NPIAP/PPPIA 2019), managed in any care setting. We accepted study authors' definitions of pressure ulcer stage. Where study authors used grading scales other than NPIAP, we mapped these to the NPIAP scale (EPUAP/NPIAP/PPPIA 2019).

Types of interventions

We included studies that assessed beds and mattresses (i.e. integrated bed systems, mattresses and overlays) (see Description of the intervention). The types of bed and mattress support surfaces we planned to cover included:

- alternating pressure (active) air surfaces (e.g. alternating pressure air mattress, dynamic low-air-loss mattresses, Softform Premier Active air mattresses);
- foam surfaces;
- reactive air surfaces (e.g. Sofflex static air overlay);
- reactive fibre surfaces (e.g. Silicore fibre overlay);
- reactive gel surfaces (e.g. a gel pad used on an operating table);
- reactive sheepskin surfaces (e.g. Australian Medical Sheepskins overlay); and
- reactive water surfaces.

We planned to include studies where two or more bed and mattress support surfaces were used sequentially over time or in combination, where the beds or mattresses of interest would have been included in one of the study arms. However, we did not identify such studies.

We included studies comparing eligible beds, overlays and mattresses against any comparator defined as a bed, overlay or mattress. Comparators were not limited to any specific type of support surfaces. They could be either different from, or the same type as, the eligible bed, overlay or mattress of interest. We included studies in which co-interventions (e.g. repositioning) were delivered, provided that the co-interventions were the same in all arms of the study (i.e. interventions randomised were the only systematic difference).

Types of outcome measures

Primary outcomes

The primary outcome of this review was complete pressure ulcer healing. We included studies that measured complete pressure ulcer healing. Trialists used a range of different methods for measuring and reporting this outcome. RCTs that reported one or more of the following were considered as providing the most relevant and rigorous measures of ulcer healing.

- **Time to complete pressure ulcer healing** (correctly analysed using survival, time-to-event approaches or median (or mean) time to healing, if it was clear that all ulcers were healed at follow-up).
- **Proportion of participants with pressure ulcers completely healed during follow-up.**

We used the study authors' definitions of complete pressure ulcer healing, and reported these where possible. Where both the complete-healing outcome measures listed above were reported for a study, we considered the proportion of participants with pressure ulcers healed as the primary outcome for this review. Our preferred measure was time to pressure ulcer healing; however, we did not expect it to be reported in many studies. We extracted and analysed time-to-event data but focused on the binary outcome in our conclusions. If an included study had only recruited people with Stage 1 ulcers and reported the outcome of the resolution of Stage 1 ulcers, we planned to term the resolution outcome as complete pressure ulcer healing in this review. We planned to use the same method to consider the resolution outcome where an included study had recruited participants with pressure ulcers of Stage 1 and those with more severe ulcers. However, we did not identify these types of studies.

Note that we recorded any other healing outcome measures reported in the included studies, such as the rate of change in the area or volume of the ulcers. However, we did not consider them as primary outcome measures and these data were not analysed because these measures are more difficult to measure accurately and are less clinically relevant than complete healing.

Secondary outcomes

- **Patient support-surface-associated comfort.** We considered patient comfort outcome data in this review only if the evaluation of patient comfort was pre-planned and was systematically conducted across all participants in the same way in a study. The definition and measurement of this outcome varied from one study to another; for example, the proportion of participants who reported comfort, or comfort measured by a scale with continuous (categorical) numbers. We included these data with different measurements in separate meta-analyses.
- **All reported adverse events** (measured using surveys or questionnaires, other data capture process or visual analogue scale). We included data where study authors specified a clear method for collecting adverse event data. Where available, we extracted data on all serious and all non-serious adverse events as outcomes. We recorded where it was clear that events were reported at the participant level or whether multiple events per person were reported, in which case appropriate adjustments

were required for data clustering (Peryer 2019). We considered the assessment of any event in general defined as adverse by participants, health professionals, or both.

- **Health-related quality of life** (measured using a standardised generic questionnaire such as EQ-5D (Herdman 2011), 36-item Short Form (SF-36; Ware 1992), or pressure ulcer-specific questionnaires such as the PURPOSE Pressure Ulcer Quality of Life (PU-QOL) questionnaire (Gorecki 2013), at noted time points). We did not include ad hoc measures of quality of life because these measures were unlikely to be validated.
- **Cost effectiveness:** within-trial cost-effectiveness analysis comparing mean differences in effects with mean cost differences between the two arms. We extracted data on incremental mean cost per incremental gain in benefit (incremental cost-effectiveness ratio (ICER)). We also considered other measures of relative cost-effectiveness (e.g. net monetary benefit, net health benefit).

Other outcome considerations

If a study did not report any review-relevant outcomes but was otherwise eligible (i.e. eligible study design, participants and interventions), we planned to contact the study authors (where possible) to clarify whether they measured a relevant outcome but did not report it. We did not contact study authors for this purpose, however, because the relevant studies (see Characteristics of excluded studies) appeared to focus on the topic of ulcer prevention. We expected that the study authors did not measure any review-relevant outcomes and excluded these studies.

If a study measured an outcome at multiple time points, we considered outcome measures at three months as of primary interest to this review (Bergstrom 2008), regardless of the time points specified as being of primary interest by the study. If the study did not report three-month outcome measures, we considered those closest to three months.

Where a study only reported a single time point, we considered that time point in this review. Where the study did not specify a time point for their outcome measurement, we assumed this was the final duration of follow-up noted.

Search methods for identification of studies

Electronic searches

We searched the following databases to identify reports of relevant clinical trials:

- the Cochrane Wounds Specialised Register (searched 14 November 2019);
- the Cochrane Central Register of Controlled Trials (CENTRAL; 2019, Issue 10) in the Cochrane Library (searched 14 November 2019);
- MEDLINE Ovid, including In-Process & Other Non-Indexed Citations (1946 to 14 November 2019);
- Embase Ovid (1974 to 14 November 2019);
- EBSCO Cumulative Index to Nursing and Allied Health Literature (CINAHL Plus; 1937 to 14 November 2019).

The search strategies for the Cochrane Wounds Specialised Register, CENTRAL, MEDLINE Ovid, Embase Ovid and EBSCO CINAHL Plus can be found in Appendix 2. We combined the MEDLINE Ovid search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version (2008 revision) (Lefebvre 2019). We combined the Embase search with the Ovid Embase filter developed by the UK Cochrane Centre (Lefebvre 2019). We combined the CINAHL Plus search with the trial filter developed by Glanville 2019. There were no restrictions with respect to language, date of publication or study setting.

We also checked all RCTs included in the Cochrane Review McInnes 2018 against our eligibility criteria.

We also searched the following clinical trials registries:

- US National Institutes of Health Ongoing Trials Register, ClinicalTrials.gov (clinicaltrials.gov) (searched 20 November 2019);
- World Health Organization (WHO) International Clinical Trials Registry Platform (https://www.who.int/clinical-trials-registry-platform) (searched 20 November 2019).

Search strategies for clinical trials registries can be found in Appendix 2.

Searching other resources

For previous versions of McInnes 2018, the review authors of McInnes 2018 contacted experts in the field of wound care to enquire about potentially relevant studies that were ongoing or recently published. In addition, the review authors of McInnes 2018 contacted manufacturers of support surfaces for details of any studies manufacturers were conducting. This approach did not yield any additional studies; therefore, we did not repeat it for this review.

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

We did not perform a separate search for adverse events of interventions used. We considered adverse events described in included studies only.

Data collection and analysis

We carried out data collection and analysis according to the methods stated in the published protocol (Shi 2020), which were based on the *Cochrane Handbook for Systematic Reviews of Interventions* (Li 2019). Changes from the protocol or previous published versions of the review are documented in Differences between protocol and review.

Selection of studies

One review author (CS) re-checked the RCTs included in McInnes 2018 for eligibility. Two review authors (CS and AJB) independently assessed the titles and abstracts of the new search results for relevance using Rayyan (Ouzzani 2016) (Differences between protocol and review), and then independently inspected the full text of all potentially eligible studies. The two review authors resolved disagreements through discussion or by involving a third review author (JCD), if necessary.

Data extraction and management

One review author (CS) checked data from the studies included in McInnes 2018, and extracted additional data where necessary. A second review author or researcher (SR, AJB, VR, EM, Zhenmi Liu, Gill Norman, or Melanie Stephens) checked any new data extracted. For new included studies, one review author (CS) independently extracted data and another review author or researcher (SR, AJB, VR, EM, Zhenmi Liu, Gill Norman, or Melanie Stephens) checked all data (Differences between protocol and review). Any disagreements were resolved through discussion or, if necessary, by involving another review author (JCD). Where necessary, we contacted the authors of included studies (or referred to relevant publications) to clarify data.

We extracted these data using a pre-prepared data extraction form:

- basic characteristics of studies (first author, publication type, publication year and country);
- funding sources;
- care setting;
- characteristics of participants (trial eligibility criteria, average age in each arm or in a study, proportions of participants by gender and the stage of pressure ulcers at baseline);
- bed and mattress support surfaces being compared (including their descriptions);
- details on any co-interventions;
- duration of follow-up;
- the number of participants enrolled;
- the number of participants randomised to each arm;
- the number of participants analysed;
- participant withdrawals, with reasons;
- proportion of participants with pressure ulcers healed;
- data on time to pressure ulcer healing (e.g. Kaplan Meier plot, hazard ratio (HR) and 95% confidence interval (CI));
- comfort/discomfort outcome data;
- adverse event outcome data;
- health-related quality of life outcome data; and
- cost-effectiveness outcome data.

We (CS and NC) classified specific beds and mattresses in the included studies into intervention groups using the NPIAP S3I terms and definitions related to support surfaces (NPIAP S3I 2007). Therefore, to accurately assign specific beds and mattresses to intervention groups, we extracted full descriptions of support surfaces from included studies, and when necessary, supplemented the information with that from external sources, such as other publications about the same support surface, manufacturers' or product websites and expert clinical opinion (Shi 2018b). If we were unable to define any specific support surfaces evaluated in an included study, we extracted available data and reported these as additional data outside the main review results.

Assessment of risk of bias in included studies

Two review authors or researchers (CS and SR, AJB, VR, EM, Zhenmi Liu, Gill Norman, or Melanie Stephens) independently assessed risk of bias of each included study using the Cochrane 'Risk of bias' tool (see Appendix 3). This tool has seven specific domains: sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete data (attrition bias), selective outcome reporting (reporting bias), and other issues (Higgins 2017). We assessed performance bias, detection bias and attrition bias separately for each of the review outcomes (Higgins 2017). We noted that it is often impossible to blind participants and personnel in device trials. In this case, performance bias may be introduced if knowledge of treatment allocation results in deviations from intended interventions, differential use of co-interventions or care between groups not specified in the study protocol that may influence outcomes. We attempted to understand if, and how, included studies compensated for challenges in blinding; for example, by implementing strict protocols to maximise consistency of co-interventions between groups to reduce the risk of performance bias. We also noted that complete pressure ulcer healing is a subjective outcome. Compared with blinded assessment, non-blinded assessment of subjective outcomes tends to be associated with more optimistic effect estimates of experimental interventions in RCTs (Hróbjartsson 2012). Therefore, we judged non-blinded outcome assessment as being at high risk of detection bias. In this review, we included factors such as extreme baseline imbalance and unit of analysis under the domain of 'other issues' (see Appendix 3). For example, unit of analysis issues occurred where a cluster-randomised trial had been undertaken but analysed at the individual level in the study report.

For the studies included in McInnes 2018, one review author (CS) checked the 'Risk of bias' judgements and, where necessary, updated them. A second review author or researcher (SR, AJB, VR, EM, Zhenmi Liu, Gill Norman, or Melanie Stephens) checked any updated judgement. We assigned each 'Risk of bias' domain a judgement of high, low or unclear risk of bias. We resolved any discrepancy through discussion, or by involving another review author (JCD) where necessary. Where possible, useful and feasible, when a lack of reported information resulted in a judgement of unclear risk of bias, we planned to contact study authors for clarification.

We present our assessment of risk of bias using two 'Risk of bias' summary figures: one is a summary of bias for each item across all studies, and the second shows a cross-tabulation of each trial by all of the 'Risk of bias' items. Once judgements had been given for all domains, the overall risk of bias for each study was judged as:

- low risk of bias, if we judged all domains to be at low risk of bias;
- unclear risk of bias, if we judged one or more domains to be at unclear risk of bias but no domain was at high risk of bias; or
- high risk of bias, as long as we judged one or more domains as being at high risk of bias, or all domains had unclear 'Risk of bias' judgements, as this could substantially reduce confidence in the result.

We resolved any discrepancy between review authors through discussion, or by involving another review author (JCD) where necessary. For studies using cluster randomisation, we planned to consider the risk of bias in relation to: recruitment bias, baseline imbalance, loss of clusters, incorrect analysis and comparability with individually randomised studies (Eldridge 2016; Higgins 2019) (Appendix 3). However, we did not include any studies with a cluster design.

Measures of treatment effect

For meta-analysis of data on the proportion of participants with pressure ulcers healed, we present the risk ratio (RR) with its 95% confidence interval (CI). For continuous outcome data (e.g. healing rate in terms of change in the area of the ulcers), we present the mean difference (MD) with 95% CIs for studies that used the same assessment scale. If studies reporting continuous data used different assessment scales, we planned to report the standardised mean difference (SMD) with 95% CIs. However, this was not undertaken in the review.

For time-to-event data (e.g. time to pressure ulcer healing), we present the hazard ratio (HR) with its 95% CI. If included studies reporting time-to-event data did not report an HR, then, when feasible, we estimated this using other reported outcomes, such as numbers of events, through employing available statistical methods (Parmar 1998; Tierney 2007).

Unit of analysis issues

We noted whether studies presented outcomes at the level of the pressure ulcer or at the level of participants. We also recorded whether the same participant was reported as having multiple pressure ulcers. Where studies randomised at the participant level and outcomes were measured at the level of the ulcer, we considered the participant as the unit of analysis if the number of ulcers observed appeared to be equal to the number of participants (e.g. one pressure ulcer per person).

Unit of analysis issues may occur if studies randomise at the participant level but the healing of multiple pressure ulcers is observed and data are presented and analysed at the level of the ulcer (clustered data). We noted whether data regarding multiple ulcers on a participant were (incorrectly) treated as independent within a study, or were analysed using within-participant analysis methods. If clustered data were incorrectly analysed, we recorded this as part of the 'Risk of bias' assessment.

If a cluster-RCT was not correctly analysed, we planned to use the following information (see below) to adjust for clustering ourselves where possible, in accordance with guidance in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019).

- The number of clusters randomly assigned to each intervention, or the average (mean) number of participants per cluster.
- Outcome data ignoring the cluster design for the total number of participants.
- Estimate of the intra-cluster (or intra-class) correlation coefficient (ICC).

However, we did not identify any cluster-RCTs in this review.

Cross-over trials

For cross-over trials, we only considered outcome data at the first intervention phase (i.e. prior to cross-over) as eligible.

Studies with multiple treatment groups

If a study had more than two eligible study groups, where appropriate we combined results across these arms to make single pair-wise comparisons (Higgins 2019).

Dealing with missing data

Data are commonly missing from study reports. Reasons for missing data could be the exclusion of participants after randomisation, withdrawal of participants from a study, or loss to follow-up. The exclusion of these data from analysis may break the randomisation and potentially introduce bias.

Where there were missing data and where relevant, we contacted study authors to pose specific queries about these data. In the absence of other information, for the proportion of participants with pressure ulcers healed we assumed that participants with missing data had ulcers healed for the main analysis (i.e. we added missing data to the denominator but not the numerator). We examined the impact of this assumption through undertaking a sensitivity analysis (see Sensitivity analysis). Where a study did not specify the number of randomised participants prior to dropout, we used the available number of participants as the number randomised.

Assessment of heterogeneity

Assessing heterogeneity can be a complex, multifaceted process. Firstly, we considered clinical and methodological heterogeneity; that is, the extent to which the included studies varied in terms of participant, intervention, outcome and other characteristics, including duration of follow-up, clinical settings and overall study-level 'Risk of bias' judgement (Deeks 2019). In terms of the duration of follow-up, in order to assess the relevant heterogeneity, we recorded and categorised assessment of outcome measures as follows:

- up to eight weeks (short-term);
- more than eight weeks to 24 weeks (medium-term); and
- more than 24 weeks (long-term).

We supplemented this assessment of clinical and methodological heterogeneity with information regarding statistical heterogeneity assessed using the Chi^2 test. We considered a P value less than 0.10 to indicate statistically significant heterogeneity given that the Chi^2 test has low power, particularly in the case where studies included in a meta-analysis have small sample sizes. We carried out this statistical assessment in conjunction with the I^2 statistic (Higgins 2003), and the use of prediction intervals for random-effects meta-analyses (Borenstein 2017; Riley 2011).

The I^2 statistic is the percentage of total variation across studies due to heterogeneity rather than chance (Higgins 2003). Very broadly, we considered that I^2 values of 25% or less may indicate a low level of heterogeneity and values of 75% or more may indicate very high heterogeneity (Higgins 2003). For random-effects models where the meta-analysis had more than 10 included studies and no clear funnel plot asymmetry, we also planned to present 95% prediction intervals (Deeks 2019). We planned to calculate prediction intervals following methods proposed by Borenstein 2017.

Random-effects analyses produce an average treatment effect, with 95% confidence intervals indicating where the true population average value is likely to lie. Prediction intervals quantify variation away from this average due to between-study heterogeneity. The interval conveys where a future study treatment effect estimate is likely to fall based on the data analysed to date (Riley 2011).

Prediction intervals are always wider than confidence intervals (Riley 2011).

It is important to note that prediction intervals will reflect heterogeneity of any source, including from methodological issues as well as clinical variation. For this reason, some authors have suggested that prediction intervals are best calculated for studies at low risk of bias to ensure intervals that have meaningful clinical interpretation (Riley 2011). We had planned to calculate prediction intervals for all analyses to assess heterogeneity and then to explore the impact of risk of bias in subgroup analysis stratified by study risk of bias assessment as detailed below. However, we did not calculate any prediction intervals because all conducted meta-analyses contained fewer than 10 studies.

Assessment of reporting biases

We followed the systematic framework recommended by Page 2019 to assess risk of bias due to missing results (non-reporting bias) in the meta-analysis of data on the proportion of participants with pressure ulcers healed. To make an overall judgement about risk of bias due to missing results, we:

- identified whether the missing outcome data were unavailable by comparing the details of outcomes in trials registers, protocols or statistical analysis plans (if available) with reported results. If the above information sources were unavailable, we compared outcomes in the conference abstracts or in the methods section of the publication, or both, with the reported results. If we found non-reporting of study results, we then judged whether the non-reporting was associated with the nature of findings by using the 'Outcome Reporting Bias In Trials' (ORBIT) system (Kirkham 2018).
- assessed the influence of definitely missing outcome data on meta-analysis.
- assessed the likelihood of bias where a study had been conducted but not reported in any form. For this assessment, we considered whether the literature search was comprehensive and planned to produce a funnel plot for meta-analysis for seeking more evidence about the extent of missing results, provided there were at least 10 included studies (Peters 2008; Salanti 2014).

However, we did not produce a funnel plot for any meta-analysis because all analyses in this review had fewer than 10 included studies.

Data synthesis

We summarised the included studies narratively and synthesised included data by using meta-analysis where applicable. We structured comparisons according to type of comparator and then by outcomes, ordered by follow-up period.

We considered clinical and methodological heterogeneity and undertook pooling when studies appeared appropriately similar in terms of participants, beds and mattresses and outcome type. Where statistical synthesis of data from more than one study was not possible or considered inappropriate, we conducted a narrative review of eligible studies.

Once the decision to pool was made, we used a random-effects model, which estimated an underlying average treatment effect from studies. Conducting meta-analysis with a fixed-effect model in the presence of even minor heterogeneity may provide overly narrow confidence intervals. We used the Chi^2 test and I^2 statistic to quantify heterogeneity but not to guide choice of model for meta-analysis (Borenstein 2009). We exercised caution when meta-analysed data were at risk of small-study effects because use of a random-effects model may be unsuitable in this situation. In this case, or where there were other reasons to question the choice of a fixed-effect or random-effects model, we assessed the impact of the approach using sensitivity analyses to compare results from alternate models (Thompson 1999).

We performed meta-analyses largely using Review Manager 5.4 (Review Manager 2020). We presented data using forest plots where possible. For dichotomous outcomes, we presented the summary estimate as a RR with 95% CI. Where continuous outcomes were measured, we presented the MD with 95% CIs; we planned to report SMD estimates where studies measured the same outcome using different methods. For time-to-event data, we presented the summary estimates as HRs with 95% CIs.

Subgroup analysis and investigation of heterogeneity

Investigation of heterogeneity

When important heterogeneity occurred, we planned to follow steps proposed by Cipriani 2013 and Deeks 2019 to investigate further:

- check the data extraction and data entry for errors and possible outlying studies;
- if outliers exist, perform sensitivity analysis by removing them; and
- if heterogeneity was still present, we planned to perform subgroup analyses for study-level characteristics (see below) in order to explain heterogeneity as far as possible. However, we did not undertake any subgroup analysis because meta-analyses in this review included fewer than 10 studies.

Subgroup analysis

We investigated heterogeneity using the methods described in Section 10.11 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2019). We planned to perform subgroup analyses to determine whether the size of treatment effects was influenced by these two study-level characteristics:

- risk of bias (binary: low or unclear risk of bias; and high risk of bias (Schulz 1995)); and
- settings (categorical: acute care and other hospital settings; long-term care settings; operating theatre setting; and intensive care unit).

We planned to compare subgroup findings using the 'Test for Subgroup Differences' in Review Manager 5.4 (Review Manager 2020). We did not perform subgroup analysis when the number of studies included in the meta-analysis was not reasonable (i.e. fewer than 10).

Sensitivity analysis

We conducted sensitivity analyses for the following factors, to assess the robustness of meta-analysis of data on the proportion of participants with pressure ulcers healed.

- Impact of the selection of healing outcome measure. The proportion of pressure ulcers completely healed was the primary outcome measure for this review but we also analysed time to pressure ulcer healing, where data were available.
- Impact of missing data. The primary analysis assumed that the ulcers of participants with missing data had healed; we also analysed healing by only including data for the participants for whom we had endpoint data (complete cases).
- Impact of altering the effects model used. We used a random-effects model for the main analysis followed by a fixed-effect analysis.

Summary of findings and assessment of the certainty of the evidence

We presented the main, pooled results of the review in 'Summary of findings' tables, which we created using GRADEpro GDT software. These tables present key information concerning the certainty of evidence, the magnitude of the effects of the interventions examined and the sum of available data for the main outcomes (Schünemann 2019). The tables also include an overall grading of the certainty of the evidence associated with each of the main outcomes that we assessed using the GRADE approach. The GRADE approach defines the certainty of a body of evidence as the extent to which one can be confident that an estimate of effect or association is close to the true quantity of specific interest.

The GRADE assessment involves consideration of five factors: within-trial risk of bias, directness of evidence, heterogeneity, precision of effect estimates, and risk of publication bias (Schünemann 2019). The certainty of evidence can be assessed as being: high, moderate, low or very low. RCT evidence has the potential to be high-certainty. We did not downgrade the certainty of evidence for the risk of bias factor in a specific circumstance. That is, if the blinding of participants and personnel was the only domain resulting in our judgement of overall high risk of bias for the included studies; however, for these studies, it was impossible to blind participants and personnel.

When downgrading for imprecision, we followed the methods described in Guyatt 2011: either considering both the optimal information size (OIS) and the 95% CI of each meta-analysis if they were estimable; or considering the sample size, the number of events and other effectiveness indicators if the calculation of OIS and undertaking a meta-analysis were not applicable. Where necessary, we used the GRADE 'default' minimum important difference values (RR = 1.25 and 0.75 for binary outcome data) as the thresholds to judge if a 95% CI was wide (imprecise) so as to include the possibility of clinically important harm and benefit (Guyatt 2011).

We presented a separate 'Summary of findings' table for all but one comparison evaluated in this review. The exception was the comparison of alternating pressure (active) air surfaces versus the another type of alternating pressure (active) air surfaces (Differences between protocol and review). We presented these outcomes in the 'Summary of findings' tables:

- proportion of participants with pressure ulcers healed;
- time to pressure ulcer healing;
- patient support-surface-associated comfort;
- all reported adverse events;
- health-related quality of life; and
- cost effectiveness.

We prioritised the time points and method of outcome measurement specified in Types of outcome measures for presentation in ‘Summary of findings’ tables. Where we did not pool data for some outcomes within a comparison, we conducted a GRADE assessment for each of these outcomes and presented these assessments in a narrative format in 'Summary of findings' tables (Differences between protocol and review).

RESULTS

Description of studies

See Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification; and Characteristics of ongoing studies.

Results of the search

The electronic searches identified 1624 records, including 1164 from electronic databases and 460 from trials registries. We excluded 218 duplicate records and screened 1406 records, of which 233 were identified as potentially eligible and obtained as full-text. Following full-text screening, we considered 13 records of 11 studies eligible for inclusion in this review (Allman 1987; Cassino 2013a; Day 1993; Devine 1995; Evans 2000a; Evans 2000b; Ferrell 1993; Ferrell 1995; Groen 1999; Russell 2000a; Strauss 1991).

From other resources, we identified eight potentially eligible records by scanning reference lists of the 14 systematic reviews or meta-analyses that were identified from electronic searches (Chou 2013; Huang 2013; McGinnis 2011; McInnes 2015; McInnes 2018; Mistiaen 2010a; De Oliveira 2017; Rae 2018; Reddy 2006; Reddy 2008; Serraes 2018; Shi 2018a; Smith 2013; Yao 2018), as well as clinical practice guidelines listed in Searching other resources. Following full-text screening of three full-text reports, we considered two studies (Mulder 1994; Munro 1989) eligible for inclusion in this review.

In total we included 13 studies (15 publications) in the review, of which two separate studies were reported in the same publication (Evans 2000a; Evans 2000b). See Figure 1.

Figure 1. Study flow diagram

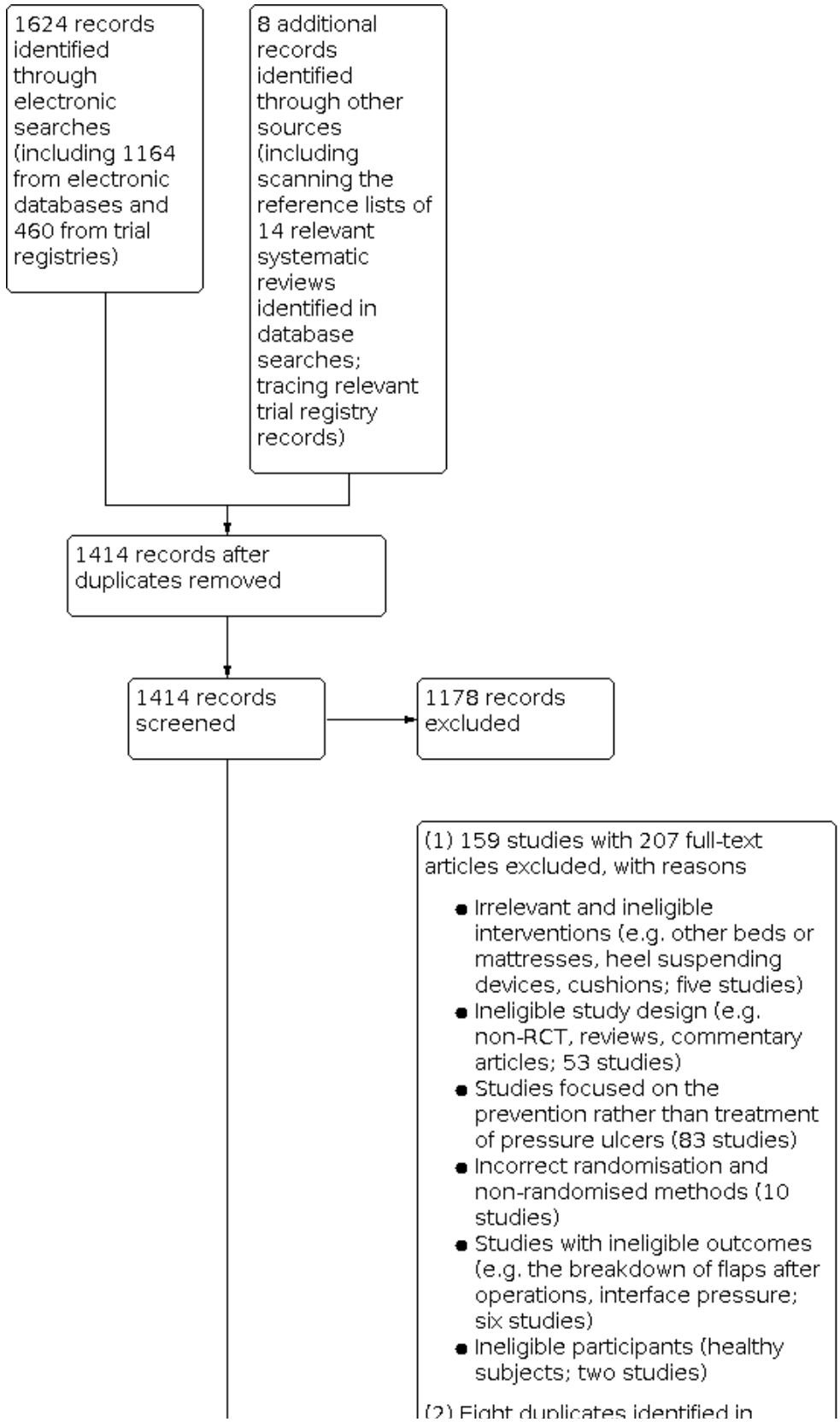
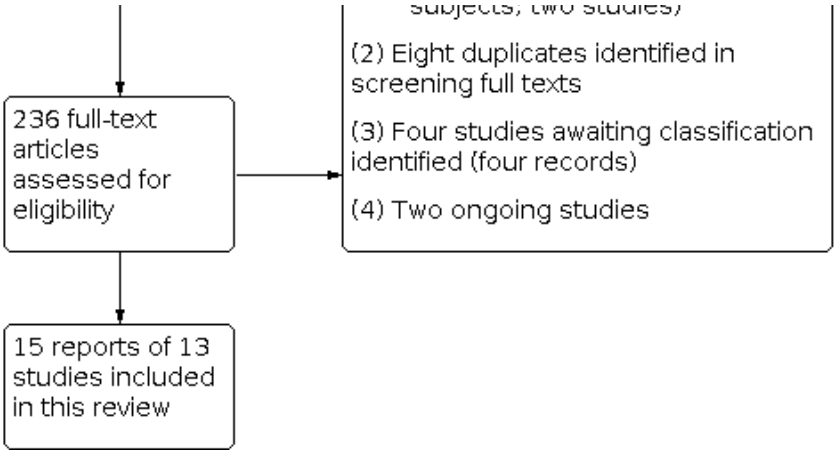


Figure 1. (Continued)



Included studies

Types of studies

Of the 13 included studies, 12 were two-armed RCTs using a parallel group design, and one (Ferrell 1995) was a trial-based economic evaluation associated with Ferrell 1993.

Of all included studies, five were conducted at more than one research site (Cassino 2013a; Ferrell 1993; Ferrell 1995; Groen 1999; Strauss 1991). All of the included studies were conducted in high-income and upper-middle-income economies in the regions of Europe and North America, including: Italy (Cassino 2013a), the Netherlands (Groen 1999), the UK (Devine 1995; Evans 2000a; Evans 2000b; Russell 2000a), and the USA (Allman 1987; Day 1993; Ferrell 1993; Ferrell 1995; Mulder 1994; Munro 1989; Strauss 1991).

In the 13 studies, the median duration of follow-up was 37.5 days (range: 7 days to 18 months).

Types of participants

Age and sex at baseline

The 13 studies enrolled a total of 972 participants (median study sample size: 72 participants; range: 12 to 183). The average participant age was specified for 11 studies and ranged from 64.0 to 86.5 years (median: 82.7 years). Sex was specified for 10 studies; and within these 284 (46.3%) of participants were male and 329 (53.7%) were female.

Pressure ulcer characteristics at baseline

All 13 studies (972 participants) recruited people with existing pressure ulcers, of which Cassino 2013a recruited people with ulcers of stage I to IV; six recruited those with ulcers of stage II to IV or stage III to IV (Day 1993; Devine 1995; Evans 2000a; Evans 2000b; Mulder 1994; Strauss 1991); but five did not specify the stage of ulcers included (Allman 1987; Ferrell 1993; Ferrell 1995; Groen 1999; Russell 2000a). Six studies specified the pressure ulcer stage systems used, including the Shea criteria (Allman 1987; Ferrell 1993; Strauss 1991), the Torrance criteria (Russell 2000a), and the early versions of the EPUPA/NPUAP stage system (Cassino 2013a; Day 1993).

The average size of pressure ulcers at baseline was specified for seven studies (353 participants; Allman 1987; Devine 1995; Evans 2000a; Evans 2000b; Ferrell 1993; Ferrell 1995; Munro 1989) and ranged from 4.2 to 18.6 cm^2 (median: 6.6 cm^2). Six studies did not specify the average pressure ulcer size at baseline (Cassino 2013a; Day 1993; Groen 1999; Mulder 1994; Russell 2000a; Strauss 1991).

Care settings

Participants were from two types of settings, including:

- acute care settings (including hospitals in general) (Allman 1987; Day 1993; Devine 1995; Evans 2000a; Munro 1989; Russell 2000a); and
- community and long-term care settings (including community, nursing homes, long-term facilities, geriatric units) (Cassino 2013a; Ferrell 1993; Ferrell 1995; Evans 2000b; Groen 1999; Mulder 1994; Strauss 1991).

Types of interventions

Beds and mattresses evaluated in included studies are summarised in Appendix 4. The studies investigated a wide range of support surfaces, including alternating pressure (active) air surfaces, reactive air surfaces, foam surfaces, reactive gel surfaces, reactive water surfaces and a type of reactive surface that we could not define using NPIAP S3I 2007 support surface terms.

In terms of comparator surfaces, 10 of the 13 studies used surfaces that could be classified using the NPIAP S3I support surfaces terms and definitions. The following control surfaces could not be classified further:

- the 'standard bed' evaluated in Munro 1989 (40 participants) as the control surface was not specified;
- the 'conventional therapy' evaluated in Strauss 1991 (112 participants) as the control surface was one of many options from *'alternating pressure pads, air support mattresses, water mattresses, and high-density foam pads*"; and
- the Aiartex® overlay evaluated in one study (72 participants; Cassino 2013a) as the surface did not match any of the NPIAP S3I support surfaces terms.

We defined the control surfaces used in Munro 1989 and Strauss 1991 as 'standard hospital surfaces'.

Nine studies specified co-interventions (e.g. repositioning, cushions) (Allman 1987; Devine 1995; Evans 2000a; Evans 2000b; Ferrell 1993; Groen 1999; Mulder 1994; Russell 2000a; Strauss 1991); all stated or indicated that the same co-interventions were applied in all study groups.

Funding sources

All but one of the 13 included studies specified the details of funding sources. All of these 12 studies were completely or partly funded by industry or received mattresses under evaluation from industries (Allman 1987; Cassino 2013a; Day 1993; Devine 1995; Evans 2000a; Evans 2000b; Ferrell 1993; Ferrell 1995; Mulder 1994; Munro 1989; Russell 2000a; Strauss 1991).

Excluded studies

We excluded 159 studies (with 207 records). The main reasons for these 159 exclusions were: irrelevant and ineligible interventions (five studies); ineligible study design (e.g. non-RCT, reviews, commentary articles; 53 studies); studies focused on the prevention rather than treatment of pressure ulcers (83 studies); incorrect randomisation and non-randomised methods (10 studies); studies with ineligible outcomes (six studies); and ineligible participants (healthy subjects; two studies). We also identified eight duplicates in screening full texts (see Figure 1).

Ongoing studies

We identified two ongoing studies from the trials registry search (ACTRN12618000319279; JPRN-UMIN000029680). The two studies randomised participants who had existing pressure ulcers into two study arms using different support surfaces. They both measured pressure ulcer healing outcomes and other outcomes (e.g. participant support-surface-associated comfort).

Studies awaiting classification

There were four studies (four records) about which we could not make eligibility decisions because we were unable to obtain them in full text despite extensive efforts (in part due to more limited access to intra-library loans during the COVID-19 period) (Chaloner 2000b; Henn 2004; Knight 1999; Melland 1998).

Risk of bias in included studies

We summarise 'Risk of bias' assessments for the primary outcome of this review in Figure 2 and Figure 3.

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study

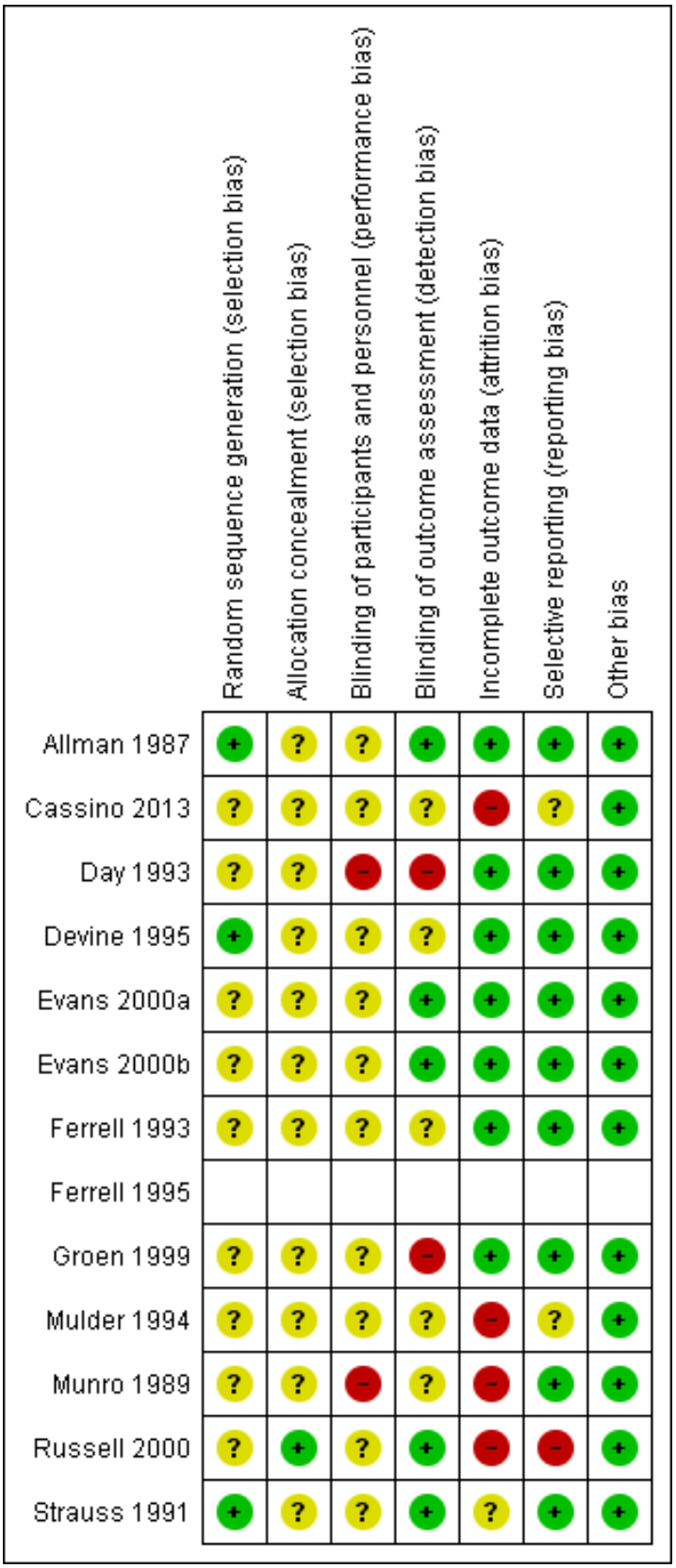
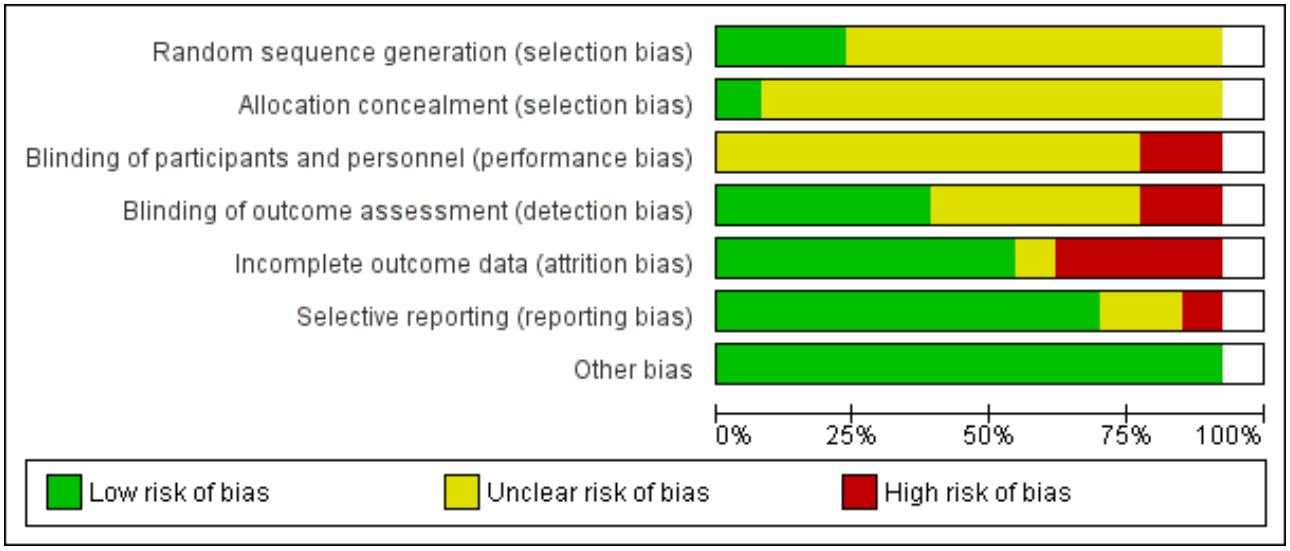


Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies



We judged six of the 12 RCTs (of the 13 studies) as having unclear overall risk of bias for the primary outcome (Allman 1987; Devine 1995; Evans 2000a; Evans 2000b; Ferrell 1993; Strauss 1991). We judged another six studies as being at high overall risk of bias as they had one or more domains with high risk of bias judgement (Cassino 2013a; Day 1993; Groen 1999; Mulder 1994; Munro 1989; Russell 2000a). Of these six studies, three had high risk of bias judgement for the primary outcome in domains of blinding of participants and personnel, blinding of outcome assessment, or both (Day 1993; Groen 1999; Munro 1989).

Publication bias

We ran a comprehensive search and were able to locate two eligible studies from other resources. We considered the risk of having missed published reports to be low. We were unable to assess for the risk of non-publication of studies with negative findings as we could not present funnel plots given the small number of included studies in each analysis.

Effects of interventions

See: **Summary of findings 1** Alternating pressure (active) air surfaces compared with foam surfaces for treating pressure ulcers; **Summary of findings 2** Reactive air surfaces compared with foam surfaces for treating pressure ulcers; **Summary of findings 3** Reactive water surfaces compared with foam surfaces for treating pressure ulcers

See Summary of findings 1; Summary of findings 2; Summary of findings 3.

Unless otherwise stated, random-effects analysis was used throughout. Each pooled result presented is an average effect, rather than a common effect, and should be interpreted as such.

We have not reported data from the three studies with surfaces that were not classified in the main body of the results (Cassino 2013a; Munro 1989; Strauss 1991). For completeness, we summarise the results of these studies in Appendix 5 and Appendix 6.

We performed data analyses for the following comparisons and outcomes.

Comparison 1: Alternating pressure (active) air surfaces versus foam surfaces (two studies, 132 participants)

Two studies compared alternating pressure (active) air surfaces with foam surfaces (Day 1993; Mulder 1994).

Primary outcomes

Proportion of participants with pressure ulcers completely healed (follow-up duration 7 days and 12 weeks)

Both studies (132 participants) reported this outcome. It is uncertain if there is a difference in the proportion of participants with healed pressure ulcers between alternating pressure (active) air surfaces and foam surfaces. Of the two studies, Mulder 1994 (49 participants) reported analysable data and the RR is 0.97 (95% CI 0.26 to 3.58; Analysis 1.1). Day 1993 (83 participants) did not report analysable data but stated that an analysis of covariance showed no statistically significant difference in the healing of pressure ulcers between alternating pressure (active) air surfaces versus foam surfaces ($F[1,78] = 0.35$, P value > 0.05). Evidence is of very low certainty, downgraded twice for high risk of detection or attrition bias in the two included studies, and twice for imprecision due to the small sample sizes and the wide confidence interval reported in one study and the null effect reported in another study.

Subgroup analysis

We considered the studies included for this outcome heterogeneous in terms of care settings and follow-up durations. Because Analysis 1.1 included only one study, however, we did not undertake a subgroup analysis.

Sensitivity analyses

We did not perform any pre-specified sensitivity analyses because Analysis 1.1 included only one study with available data. In addition, the included studies did not report data on time to pressure ulcer healing.

Secondary outcomes

Support-surface-associated patient comfort (follow-up duration 7 days)

It is uncertain whether there is any difference between alternating pressure (active) air surfaces and foam surfaces in patient comfort responses. Only Day 1993 (83 participants) reported this outcome, defined as the participant self-rated perception of comfort using a visual analogue scale ranging from 'Very comfortable' to 'Very uncomfortable'. There were only outcome data for 39 participants: the MD is 0.40 (95% CI -0.42 to 1.22; Analysis 1.2). Evidence is of very low certainty, downgraded twice for high risk of attrition bias for this outcome, and twice for substantial imprecision due to the small sample size and very wide confidence interval.

All reported adverse events (follow-up duration 12 weeks)

It is uncertain if there is a difference in adverse events between alternating pressure (active) air surfaces and foam surfaces. Only Mulder 1994 (49 participants) reported this outcome but stated there were no major adverse events that could be attributed to the support surfaces used. Evidence is of very low certainty, downgraded twice for high risk of attrition bias, and twice for imprecision due to the small sample sizes.

Health-related quality of life

Not reported.

Cost effectiveness

Not reported.

Comparison 2: Reactive air surfaces versus foam surfaces (three studies, 156 participants)

Three studies (156 participants) compared reactive air surfaces with foam surfaces (Allman 1987; Ferrell 1993; Ferrell 1995). Ferrell 1995 was an economic evaluation based on the trial of Ferrell 1993.

Primary outcomes

Proportion of participants with pressure ulcers completely healed (follow-up duration 13 days and 37.5 days)

Two studies (156 participants) reported data for this outcome that were pooled (Allman 1987; Ferrell 1993). It is uncertain if there is a difference in the proportion of participants with completely healed pressure ulcers between reactive air surfaces (46/79 (58.2%)) and foam surfaces (34/77 (44.2%)). The RR is 1.32 (95% CI 0.96 to 1.80; I^2 = 0%; Analysis 2.1). Evidence is of low certainty, downgraded twice for imprecision due to the OIS being unmet and the wide confidence interval that crossed RR = 1.25.

Subgroup analysis

We considered the studies included in Analysis 2.1 heterogeneous in terms of care settings. As noted in Subgroup analysis and investigation of heterogeneity, because there were fewer than 10 studies, however, a subgroup analysis was not undertaken.

Sensitivity analyses

- ***Sensitivity analysis with fixed-effect (rather than random-effects) model*** . The use of fixed-effect model resulted in the same RR of 1.32 (95% CI 0.96 to 1.80; I^2 = 0%). This remained consistent with the main analysis.
- ***Sensitivity analysis with time to complete pressure ulcer healing as the primary outcome (follow-up duration of 37.5 days)*** . One study (84 participants) reported this outcome measure (Ferrell 1993). The reported hazard ratio from the Cox regression (adjusted for fecal continence) is 2.66 (95% CI 1.34 to 5.17). Low-certainty evidence suggests that people using reactive air surfaces may be more likely to have healed pressure ulcers compared with those on foam surfaces. Evidence certainty was downgraded twice for imprecision due to the very small sample size. These results are sensitive to the choice of format for the primary outcome measure so the results of Analysis 2.1 should be interpreted cautiously.

Secondary outcomes

Support-surface-associated patient comfort (follow-up duration 13 days)

We are uncertain whether there is any difference between reactive air surfaces and foam surfaces in patient comfort responses. Only Allman 1987 (72 participants) reported this outcome, defined by the study authors as the number of participants having changes in comfort from baseline, with the level of comfort measured by asking participants: “Which of the following best describes the bed you are using here in the hospital: very comfortable, comfortable, uncomfortable, or very uncomfortable?” Allman 1987 reported eight participants using reactive air surfaces had increased comfort, four without change, and one with decreased comfort whilst three participants using foam surfaces had increased comfort, four had no change and six reported decreased comfort (P value = 0.04). Evidence is of very low certainty, downgraded twice for high risk of attrition bias for this outcome, and twice for imprecision due to the very small sample size.

All reported adverse events (follow-up duration 13.0 and 37.5 days)

Two studies (156 participants) reported this outcome (Allman 1987; Ferrell 1993). We did not pool these data as the definitions of adverse events varied between studies (Table 1). It is uncertain if there is a difference in adverse events between reactive air surfaces and foam surfaces (low-certainty evidence). Evidence certainty was downgraded once for indirectness as the outcome of "all reported adverse events" as a whole was not used in the included studies, and once for imprecision due to the small sample sizes of both studies.

Health-related quality of life

Not reported.

Cost effectiveness (follow-up duration 37.5 days)

Only Ferrell 1995 (87 participants) reported this outcome, which considered standard care costs, support surfaces cost and additional nursing time for pressure ulcer care in base-case cost-effectiveness analysis. Ferrell 1995 reported the additional cost due to the use of reactive air surfaces divided by the additional days without an ulcer. Low-certainty evidence suggests that reactive air surfaces may cost an extra 26 US dollars for every ulcer-free day in the first year of use. Evidence certainty was downgraded twice for imprecision for the time to ulcer healing outcome from which the cost effectiveness was evaluated.

Comparison 3: Reactive water surfaces versus foam surfaces (one study, 120 participants)

Primary outcomes

Proportion of participants with pressure ulcers completely healed (follow-up duration four weeks)

Groen 1999 (101 participants) reported this outcome. It is uncertain if there is a difference in the proportion of participants with completely healed pressure ulcers between reactive water surfaces (25/52 (48.1%)) and foam surfaces (22/49 (44.9%)). The RR is 1.07 (95% CI 0.70 to 1.63; Analysis 3.1). The evidence is of very low certainty, downgraded twice for high risk of detection bias and twice for imprecision due to the OIS being unmet and a very wide confidence interval that crossed RRs = 0.75 and 1.25.

Sensitivity analyses

We did not perform any pre-specified sensitivity analyses because Analysis 3.1 included only one study with available data. In addition, the included study did not report data on time to pressure ulcer healing.

Secondary outcomes

Support-surface-associated patient comfort

Not reported.

All reported adverse events (follow-up duration four weeks)

Groen 1999 (120 participants) reported this outcome, defined as the percentage of participants with one or more of the following adverse events: eczema, maceration and pain (Table 1). It is uncertain if there is any difference in adverse events between reactive water surfaces and foam surfaces. Evidence is of very low certainty, downgraded twice for high risk of detection bias, once for indirectness as the study reported specific adverse events rather than all reported adverse events, and once for imprecision due to the small sample size (120 participants).

Health-related quality of life

Not reported.

Cost effectiveness

Not reported.

Comparison 4: Comparison between two types of alternating pressure (active) air surface (four studies, 256 participants)

We included four studies (256 participants) comparing different types of alternating pressure (active) air surfaces: all used distinct Nimbus alternating pressure air systems in one study arm and different Pegasus systems in the other study arm (Devine 1995; Evans 2000a; Evans 2000b; Russell 2000a).

We did not pool data from the four studies but instead summarised study findings narratively below with outcome data presented in Table 1, Table 2, and Table 3.

Primary outcomes

Proportion of participants with pressure ulcers completely healed (follow-up period minimum 20.5 days maximum 18.0 months)

Four studies (256 participants) reported data for this outcome (Devine 1995; Evans 2000a; Evans 2000b; Russell 2000a). It is uncertain if there is a difference in the proportion of participants with completely healed pressure ulcers between Nimbus alternating pressure (active) air surfaces (38/88 (43.2%)) and Pegasus alternating pressure (active) air surfaces (27/87 (31.0%)). See Table 2. Evidence is of very low certainty, downgraded once for risk of bias (one large study was at high risk of attrition and reporting bias and three small studies were at unclear risk of bias), twice for imprecision due to small sample size, and once for inconsistency.

The included studies did not report data on time to pressure ulcer healing.

Secondary outcomes

Support-surface-associated patient comfort (follow-up duration minimum 20.5 days maximum 18.0 months)

Four studies (256 participants) reported this outcome (Devine 1995; Evans 2000a; Evans 2000b; Russell 2000a). It is uncertain if there is a difference in patient comfort responses between different types of alternating pressure (active) air surface. The studies reported a range of different outcome measurement methods (see Table 3): two small studies reported greater comfort with the Nimbus system whilst two larger studies found no difference. Evidence is of very low certainty, downgraded once for risk of bias (one large study was at high risk of attrition and reporting bias and three small studies were at unclear risk of bias), once for inconsistency, and once for imprecision due to small sample sizes.

All reported adverse events (follow-up duration minimum 20.5 days maximum 18.0 months)

Four studies (256 participants) reported this outcome (Devine 1995; Evans 2000a; Evans 2000b; Russell 2000a). We are uncertain if there is a difference in adverse events between different types of alternating pressure (active) air surfaces. The studies largely report death data but did not state if there were other adverse events (see Table 1). Evidence is of very low certainty, downgraded once for risk of bias (one large study was at high risk of attrition and reporting bias and three small studies were at unclear risk of bias), once for indirectness as the study reported specific adverse events rather than all reported adverse events, and once for imprecision due to small sample sizes.

Health-related quality of life

Not reported.

Cost effectiveness

Not reported.

DISCUSSION

Summary of main results

We report evidence from 13 RCTs on the effects of a range of beds, overlays and mattresses on the healing of pressure ulcers in any setting and population. We did not analyse data reported in the three studies with surfaces that we could not classify. We synthesised evidence for the following four comparisons and summarise their key findings below.

- **Alternating pressure air surfaces versus foam surfaces**: it is uncertain if there is a difference between alternating pressure (active) air surfaces and foam surfaces in the proportion

of participants with healed pressure ulcers (two studies with 132 participants), in patient comfort (one study with 83 participants), or in adverse events (one study with 49 participants).

- **Reactive air surfaces versus foam surfaces**: it is uncertain if there is a difference in the proportion of participants with pressure ulcers completely healed between reactive air surfaces and foam surfaces (two studies with 156 participants, low-certainty evidence). However, this should be interpreted cautiously because there is low-certainty evidence that people using reactive air surfaces may be more likely to have an ulcer heal over 37.5 days' follow-up when the time to complete pressure ulcer healing is considered using a hazard ratio (one study with 84 participants). We are uncertain whether there is any difference between reactive air surfaces and foam surfaces in patient comfort (one study with 72 participants; very low-certainty evidence) and in the risk of adverse events (two studies with 156 participants, low-certainty evidence). Reactive air surfaces may cost an extra 26 US dollars for every ulcer-free day in the first year of use (one study with 87 participants, low-certainty evidence).
- **Reactive water surfaces versus foam surfaces**: it is uncertain if there is a difference in pressure ulcer healing between reactive water surfaces and foam surfaces (one study with 101 participants) and in adverse events (one study with 120 participants).
- **Alternating pressure (active) air surfaces (Nimbus systems) compared with the another type of alternating pressure (active) air surfaces (Pegasus systems)**: it is uncertain if there is a difference between Nimbus systems and Pegasus systems in pressure ulcer healing, in patient comfort and in adverse events: each of the outcomes included four studies (256 participants) but very low-certainty evidence.

Overall completeness and applicability of evidence

As detailed in Search methods for identification of studies, we ran a comprehensive set of literature searches to maximise the relevant research included here.

Whilst use of support surfaces is relevant to adults and children, all participants in the included studies were adults (with the reported average age ranging from 64.0 to 86.5 years, median of 82.7 years). Across the included studies, more than half (53.7%) of enrolled participants were female. All of the studies enrolled people with existing pressure ulcers: seven studies (353 participants) reported the average size of pressure ulcers ranging from 4.2 to 18.6 cm^2 (median: 6.6 cm^2).

Most of the included studies were small (half had fewer than 72 participants) whilst only three studies enrolled more than 100 participants (Groen 1999; Russell 2000a; Strauss 1991). The geographical scope of the included studies was limited, and all the studies were from Europe and North America.

Included studies recruited participants from two types of care settings: acute care settings (six studies); and community and long-term care settings (seven studies). There were no specific data for operating rooms or intensive care units. Whilst two of the four comparisons included studies from these two different care settings, due to the limited number of included studies for these comparisons, we could not perform pre-specified subgroup analysis by different care settings. Thus, for these two comparisons, we are unable to drawn conclusions about potential modification of treatment effects in different care settings.

Included studies compared a wide range of support surfaces, including alternating pressure (active) air surfaces, reactive air surfaces, foam surfaces, reactive water surfaces and reactive gel surfaces. However, there were no data for reactive fibre surfaces or reactive sheepskin surfaces.

In this review, we considered all specific types of alternating pressure air surfaces (e.g. alternating pressure air overlays, and "hybrid" air mattresses like Nimbus 3) in the broad term of "alternating pressure (active) air surfaces". This is because all these specific air surfaces have the same underlying mechanism of redistributing pressure activity (i.e. mechanically alternating pressure). Some health professionals have expressed an interest in the effectiveness of air-filled support surfaces defined as "hybrid", based on having a mixed composition of alternating pressure mode and reactive mode as opposed to only alternating pressure mode. Exploring the evidence on “hybrid” surfaces and alternating pressure air surfaces separately may be important for future work if deemed a clinical priority.

We included three studies which had surfaces that could not be classified. We did not perform any analysis for these studies. However, for completeness of all relevant evidence, we reported the data from these studies in Appendix 5 and Appendix 6.

Another limitation in the included studies was the large variation in durations of follow-up (ranging from seven days to 18 months, median of 37.5 days). This variation arises partly because different durations of follow-up are appropriate in different care settings. For example, participants in acute care settings are more likely to be discharged after a short-term hospital stay whilst those staying at community and long-term care settings are often available for longer-term follow-up. The short median duration of follow-up may contribute to an under-estimation of pressure ulcer healing across study groups of the included studies because the median healing time for all ulcers could be 63 days (Öien 2013). Some healed pressure ulcers may have been missed in these studies.

Quality of the evidence

We implemented the GRADE approach for assessing the certainty of the evidence and found that most included evidence from our 13 meta-analyses or syntheses across the four comparisons was of low or very low certainty: downgrading of evidence was largely due to the high risk of bias of findings and imprecision due to small study sizes. There was also some indirectness for adverse event outcomes.

Limitations in study design

We downgraded once or twice for study limitations for evidence in nine syntheses. We assessed risk of bias according to seven domains: sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, selective outcome reporting, incomplete follow-up, and other potential biases. Of the 13 studies, one was an economic evaluation and we judged six of the remaining 12 studies as being at high overall risk of bias and only six at unclear overall risk of bias. The prevalence of high overall risk of bias is partly due to incomplete outcome data for most of the comparisons. Two

studies had high risk of performance bias (Day 1993; Munro 1989), and were related to two comparisons: alternating pressure (active) air surfaces versus foam surfaces, and reactive air surfaces versus standard hospital surfaces. We acknowledged that the blinding of participants and personnel was impractical for these two comparisons. Therefore, we did not downgrade certainty of evidence for studies at high overall risk of bias that was solely due to the possible presence of performance bias.

Two studies were also at high risk of bias due to unblinded outcome assessment (Day 1993; Groen 1999). Unblinded assessment has been found to exaggerate odds ratios (from subjective binary outcomes) by, on average, 36% (Hróbjartsson 2012). The outcome assessment of complete pressure ulcer healing relies on the subjective judgement of investigators, and blinded assessment - whilst operationally challenging - can be undertaken (e.g. masked adjudication of photographs of pressure areas) (Baumgarten 2009). Therefore, we considered unblinded pressure ulcer healing assessment could substantially bias effect estimates in the included studies and downgraded the certainty of evidence for detection bias on a study by study basis.

Indirectness of evidence

We downgraded for indirectness for three pieces of adverse events evidence. This was because we considered that the reported adverse event outcomes (e.g. deaths) in the included studies could not directly represent all reported adverse events (i.e. the outcome of interest for this review).

Inconsistency of results and unexplained heterogeneity

Statistical heterogeneity was low for all but two syntheses we performed and we did not downgrade for inconsistency for this evidence. The low statistical heterogeneity was partly because seven of the 13 syntheses included only one study. The exceptions are the outcomes 'pressure ulcer incidence' and 'support-surface-associated patient comfort' for the comparison of alternating pressure (active) air surfaces (Nimbus systems) versus another type of alternating pressure (active) air surfaces (Pegasus systems). This is because results of included studies were inconsistent for the pressure ulcer incidence and comfort outcomes for this comparison.

We have to note that although we planned to calculate prediction intervals to understand the implications of heterogeneity, none of these analyses included more than 10 studies so further analysis was not possible.

Imprecision of results

We downgraded once or twice for imprecision for evidence in all 13 syntheses. Study sample sizes were mainly small (median sample size: 72; range: 12 to 183) with small numbers of events and wide confidence intervals. Confidence intervals often crossed the line of null effect and/or RRs = 0.75 and 1.25 so we could not discern whether the true population effect was likely to be beneficial or harmful.

Publication bias

We did not downgrade the certainty of evidence for publication bias because (1) we have confidence in the comprehensiveness of our literature searches; and (2) we did not find any clear evidence of non-reporting bias of study results. Although we planned to perform funnel plots for meta-analysis to visually inspect for publication bias, there was no analysis including more than 10 studies.

Potential biases in the review process

We followed pre-specified methods to review evidence in order to prevent potential bias in the review process. For example, we ran comprehensive electronic searches, searched trials registries and checked references of systematic reviews identified in electronic searches.

This review also has limitations. Firstly, some included studies may have considered co-interventions as 'usual care' but did not fully describe them. We assumed that all studies had provided co-interventions equally to participants in their study groups if there was nothing to indicate that this was not the case. Secondly, we did not implement pre-specified subgroup analyses as we mentioned above, mainly because no analysis included more than 10 studies. Thirdly, we were not able to pre-specify the comparisons included in this review. This is because specific support surfaces applied could only be known and defined once eligible studies were included. However, we used the NPIAP S3I 2007 support surface terms and definitions to define specific support surfaces as we pre-planned in order to avoid any potential bias. Finally, we included three studies that evaluated surfaces we could not classify (Cassino 2013a; Munro 1989; Strauss 1991). Future classification of these surfaces using the NPIAP S3I support surfaces terms may change the evidence base.

Agreements and disagreements with other studies or reviews

To our knowledge, among the systematic reviews or meta-analyses we identified in electronic searches of this review (McGinnis 2011; McInnes 2018; Rae 2018; Reddy 2008; Smith 2013), the Cochrane Review 'Support surfaces for treating pressure ulcers' (McInnes 2018) is the most recent comprehensive review.

This review is different from McInnes 2018 in eligibility criteria. In this review, we considered studies enrolling and randomising participants with existing pressure ulcers as eligible whilst McInnes 2018 included some studies that randomised participants at risk of having a new pressure ulcer and simultaneously measured ulcer healing outcome (Ewing 1964; Keogh 2001; Nixon 2006).

We included studies that reported the measure of ulcer healing but excluded studies that measured intermediate outcomes (e.g. the change in ulcer sizes), whilst McInnes 2018 included some studies with intermediate outcomes. As a result, we excluded five studies (Branom 2001; Caley 1994; Clark 1998; Osterbrink 2005; Russell 2003a) that were included in McInnes 2018. Evans 2000a and Evans 2000b were considered as one study in McInnes 2018 because they were both reported in a single publication; however, we considered them as two separate studies. We added a new study: Ferrell 1995.

The Cochrane Review McInnes 2018 followed the terms of support surfaces used in original studies. This review used the NPIAP S3I terms to define the specific support surfaces included. McInnes 2018 grouped some interventions under the term 'standard/conventional therapy' or 'standard hospital mattress' but acknowledged that the types of surfaces labelled in this way varied over time. In this review, we made great efforts to define surfaces, where these surfaces were described as a 'standard

hospital surface' in the included studies, to ensure they were placed in the correct comparisons. We defined those 'standard hospital mattresses' used in the included studies as undefined surfaces if we could not collect sufficient information to accurately define them.

This review is inconsistent with McInnes 2018 in terms of the methods used for assessing risk of bias in the included studies. We applied seven risk of bias domains and the criteria of Higgins 2017 to assess the risk of bias whilst McInnes 2018 used the Cochrane tool for assessing risk of bias (Higgins 2011).

Both this review and McInnes 2018 consistently suggest that there is some uncertain evidence with the use of pairwise meta-analysis methods. Further planned review work using network meta-analysis will add to the findings reported here.

AUTHORS' CONCLUSIONS

Implications for practice

Current evidence is uncertain about the relative effects of alternating pressure (active) air surfaces versus foam surfaces, reactive water surfaces versus foam surfaces, or Nimbus versus Pegasus alternating pressure (active) air surfaces in complete pressure ulcer healing, adverse events and patient comfort responses. For people in acute care or long-term care settings, those using reactive air surfaces may be more likely to have pressure ulcers completely healed than those using foam surfaces up to 37.5 days' follow-up. However, people using reactive air surfaces may cost more for each ulcer-free day than people using foam surfaces.

Implications for research

Given the large number of different support surfaces available, future studies should prioritise which support surfaces to evaluate on the basis of the priorities of decision-makers; for example, alternating pressure air surfaces versus foam surfaces could be a high priority for evaluation. All interventions used should be clearly described using the current classification system, and researchers should clearly specify the surfaces evaluated (avoiding use of generic terms such as 'standard hospital mattress'). Limitations in included studies are largely due to small sample size and sub-optimal RCT design. Under-recruitment or over-estimation of event rates that then fail to occur, or both, can lead to imprecision and less robust effect estimates.

Future studies should also consider carefully the choice of outcomes they report; time to pressure ulcer complete healing data should be used in studies. Careful and consistent assessment and reporting of adverse events needs to be undertaken to generate meaningful data that can be compared between studies. Likewise, patient comfort is an important outcome but it is poorly defined and reported, and this needs to be considered in future research studies. Further studies should aim to collect and report health-related quality of life using validated measures. Finally, future studies should nest cost-effectiveness analysis in their conduct where possible.

Any future studies must be undertaken to the highest standard possible. Whilst it is challenging to avoid the risk of performance bias in trials of support surfaces as blinding of participants and personnel is seldom possible, stringent protocols - for example, in terms of encouraging consistent care and blinded decision-making - can help to minimise risk. It is also important to fully describe co-interventions (e.g. repositioning) and ensure protocols mandate balanced use of these co-interventions across trial arms. The risk of detection bias can also be minimised with the use of digital photography and adjudicators of the photographs being masked to support surfaces (Baumgarten 2009). Follow-up periods should be for as long as possible and clinically relevant in different settings. Where possible and useful, data collection after discharge from acute settings may be considered.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Allman 1987

Study characteristics	
Methods	**Study objective**: to compare the effectiveness and adverse effects of air-fluidised beds and conventional therapy for patients with pressure sores. **Study design including the number of centres**: randomised controlled trial, single centre. **Study grouping**: parallel group **Duration of follow-up**: median 13 days **Number of arms**: 2 **Study start date and end date**: recruited between October 1984 and March 1986. **Care setting**: urban, academic referral, and primary care medical centre.
Participants	**Baseline characteristics** **Inclusion criteria**: age greater than 18 years old; presence of a pressure sore on the sacrum, buttocks, trochanters, or back; activity expected to be limited to bed or chair in the hospital for at least 1 week; patient expected to live at least 1 week; informed consent obtained. **Exclusion criteria**: had been in the trial previously or a skin graft or flap planned for the pressure sore within 1 week. **Sex (M/F)**: 27/38 overall. 11/20 in air-fluidised bed; 16/18 in conventional therapy. **Age (years)**: mean 65.5 (SD 15.6) in air-fluidised bed, 67.6 (18.3) in conventional therapy; estimated overall 66.6 (17.0). **The stage of pressure ulcers at baseline**: using Shea criteria; 16 superficial and 15 deep ulcers on air-fluidised bed; 20 superficial and 14 deep ulcers on conventional therapy. Median total surface area 7.8 cm^2 (range 0.3 to 83.2) on air-fluidised bed, 10.8 cm^2 (0.4 to 180.3) on conventional therapy. **Group difference**: no difference

Allman 1987 *(Continued)*

Total number of participants: 140 patients met inclusion criteria, 72 patients consent and randomised (65 completed the study).

Unit of analysis: individuals

Unit of randomisation (per patient): individuals

Interventions	**Intervention characteristics** Air-fluidised bed • **Description of interventions**: air-fluidised bed (Clinitron Therapy, Support Systems International, Inc.) … contain ceramic beads … warm, pressurized air is forced up through the beads, on the characteristics of a fluid. • **NPIAP S3I classification**: non-powered, reactive air surfaces; air-fluidised bed. • **Number of participants randomised**: not given • **Number of participants analysed**: 31 • **Co-intervention**s: repositioning every 4 hours without use of other antipressure devices. Conventional therapy • **Description of interventions**: used a vinyl alternating air-mattress covered by a 19 mm thick foam pad (Lapidus Air Float System, American Pharmaceal Company) on a regular bed. • **NPIAP S3I classification**: non-powered, reactive foam surfaces; powered, alternating pressure (active) air surfaces. • **Number of participants randomised**: not given • **Number of participants analysed**: 34 • **Co-intervention**s: repositioning every 2 hours and elbow or heel pads as needed.
Outcomes	*Proportion of participants with pressure ulcers healed* • **Outcome type**: binary • **Time points**: median 13 days • **Reporting**: fully reported • **Definition and measurement method (e.g. scale, self-reporting)**: sore surface areas determined by tracking the borders of all pressure sores on clear, plastic transparencies. Photos taken and read by independent assessors. • **Dropouts and reasons**: 7 withdrew prior to follow-up and excluded from analysis (6 died, 1 withdrew due to nausea and dislike of the air-fluidised bed). • **Data and results**: 20 patients on air-fluidised bed therapy had 1 or more sores healed compared with 15 on conventional therapy (P = 0.10). • **Notes (e.g. other results reported)**: pressure sore surface areas not extracted for this review. *Time to pressure ulcer healing* • **Not reported** *Support-surface-associated patient comfort* • **Outcome type**: categorical • **Time points**: median 13 days • **Reporting**: partially reported • **Definition and measurement method (e.g. scale, self-reporting)**: patients with change in comfort from baseline. level of comfort assessed by asking the patient to respond to a second question scored from 1 to 4: “Which of the following best describes the bed you are using here in the hospital: very comfortable, comfortable, uncomfortable, or very uncomfortable?” • **Dropouts and reasons**: 7 withdrew prior to follow-up and excluded from analysis (6 died, 1 withdrew due to nausea and dislike of the air-fluidised bed).

Allman 1987 *(Continued)*

- **Data and results**: 8 comfort increased, 4 no change and 1 decreased on air-fluidised bed; 3 increased, 4 no change and 6 decreased on conventional therapy (P = 0.04).
- **Notes (e.g. other results reported)**:

All reported adverse events

- **Outcome type**: binary
- **Time points**: median 13 days
- **Reporting**: partially reported
- **Definition and measurement method (e.g. scale, self-reporting)**: patients developing complications.
- **Dropouts and reasons**: 7 withdrew prior to follow-up and excluded from analysis (6 died, 1 withdrew due to nausea and dislike of the air-fluidised bed).
- **Data and results**: 8 died, 2 pneumonia, 10 urinary tract infections, 6 hypotension, 5 hypernatraemia, 5 oliguria, 7 sepsis, 16 fever, and 3 heart failure on air-fluidised bed; 7 died, 4 pneumonia, 7 urinary tract infections, 7 hypotension, 5 hypernatraemia, 8 oliguria, 6 sepsis, 22 fever, and 6 heart failure on conventional therapy.
- **Notes (e.g. other results reported)**: some patients appeared to have multiple adverse events.

Health-related quality of life (HRQOL)

- **Not reported**

Cost-effectiveness

- **Not reported**

Outcomes that are not considered in this review but reported in trials:

- Change in total surface area
- Patients improved
- 50% reduction in total surface area
- Pain response
- New skin breakdown (9 on air-fluidised beds vs 15 on conventional therapy, P = 0.24)

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomly allocated to treatment groups in two strata in balanced blocks of six with stratification … The randomization sequence was determined using a table of random numbers …" Comment: low risk of bias due to the use of a proper randomisation method.
Allocation concealment (selection bias)	Unclear risk	Quote: "… treatment allocations were placed in envelopes sealed and numbered sequentially. After establishing eligibility, one of the investigators selected the unopened envelope with the lowest number in the appropriate strata and allocated the patient to the treatment indicated on the enclosed card" Comment: unclear risk of bias because information is still insufficient to ensure if concealment is performed properly.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided.

Allman 1987 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Low risk	***Outcome group: ulcer healing*** Quote: "The masked assessment included review of serial photographs of all pressure sores present …" Comment: low risk of bias. ***Outcome group: comfort*** Comment: high risk of bias because patients self-rated comfort.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: all outcomes*** Comment: low risk of bias because of the low rate of attrition (7/72, 9.7%).
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Cassino 2013a

Study characteristics	
Methods	**Study objective**: to evaluate the performance and effectiveness of an anti-bedsore, three-dimensional overlay (Aiartex®, Herniamesh) compared with a commonly-used gel overlay (Akton® Overlay). **Study design including the number of centres**: randomised controlled trial, open label, multi-sites. **Study grouping**: parallel group **Duration of follow-up**: observation period of 12 weeks and subsequent follow-up at 28 (+/- 3) days. **Number of arms**: 2 **Study start date and end date**: patients recruited between May and July 2012. **Care setting**: long-term care wards
Participants	**Baseline characteristics** **Inclusion criteria**: informed consent; age > 18 years; Braden score between 6 and 14; Norton Score between 5 and 12; patients with EPUAP-NPUAP Stages I to IV decubitus; BMI > 16 and < 40; absence of infection. **Exclusion criteria**: patients without decubitus; terminal patients; immunosuppressive or antiblastic therapies; pregnant women; patients who need different aids; allergies to overlay materials; AIDS, HCV; patients enrolled in other studies in the 3 preceding months. **Sex (M/F)**: 17:55 overall; 7:28 in Aiartex and 10:27 in Akton gel overlay. **Age (years)**: mean 84.9 (SD 9.1) in Aiartex and 85.9 (9.1) in Akton; estimated overall 85.4 (9.0). **The stage of pressure ulcers at baseline**: all with EPUAP-NPUAP Stages I to IV decubitus; mean Norton score 9.4 (SD 1.9) in Aiartex and 10.1 (1.7) in Akton gel overlay. Braden Q score 12 (SD 1.5) Aiartex and 12.5 (SD 1.5) in Akton gel overlay. **Group difference**: no difference

Cassino 2013a *(Continued)*

Total number of participants: 72 patients, 86 lesions with a mean 1.19 lesions per patient and a range of 1-3.

Unit of analysis: individuals

Unit of randomisation (per patient): individuals

Interventions	**Intervention characteristics** Aiartex® • **Description of interventions**: the three-dimensional overlay (Aiartex®, Herniamesh srl) is of three-dimensional macro-porous material, 9 mm thick, made completely of polyester and weighing approximately 800 grams … behaves functionally as an air chamber that cannot be suppressed … The main feature of this aid remains, however, its macroporosity which, by allowing air to circulate … • **NPIAP S3I classification**: non-powered, reactive undefined surfaces. • **Number of participants randomised**: n = 35 • **Number of participants analysed**: n = 35 • **Co-interventions**: not reported Akton gel overlay • **Description of interventions**: the overlay in gel (Akton® Overlay, Action products) (15.9 mm thick), used as a control, is made of Akton® 100% dry viscoelastic polyurethane polymer, weighs 35kg. • **NPIAP S3I classification**: non-powered, reactive gel surfaces. • **Number of participants randomised**: n = 37 • **Number of participants analysed**: n = 37 • **Co-interventions**: not reported
Outcomes	*Proportion of participants with pressure ulcers healed* • **Outcome type**: binary • **Time points**: week 4, 8, 12 • **Reporting**: fully reported • **Definition and measurement method (e.g. scale, self-reporting)**: resolution of the lesions • **Dropouts and reasons**: total 33 suspended (19 in three dimensional overlay; 14 in gel) majority suspended due to worsening of lesions; 1 withdrew reasons not provided. Ten of the 72 patients died, 3 in Aiaterx and 7 in Akton gel overlay. • **Data and results**: week 12 data: 3 of 35 in Aiartex overlay and 5 of 37 in Akton gel group. • **Notes (e.g. other results reported)**: week 4 and 8 ulcer healing data presented in the paper but not extracted. Reduction of the area outcome presented also but not extracted for this review. 13.8% mortality over 12-week period. *Time to pressure ulcer healing* • **Not reporting** *Support-surface-associated patient comfort* • **Outcome type**: binary • **Time points**: not described • **Reporting**: partially reported • **Definition and measurement method (e.g. scale, self-reporting)**: patient comfort graded as poor, fair, good, excellent. • **Dropouts and reasons**: all included • **Data and results**: 8 poor, 13 fair, 10 good, 4 excellent in Aiartex, and 18 poor, 12 fair, 6 good, 1 excellent in Akton. *All reported adverse events*

Cassino 2013a *(Continued)*

- **Notes (e.g. other results reported)**: total 33 suspended (19 in three dimensional overlay; 14 in gel) majority suspended due to worsening of lesions; 10 of the 72 patients died, 3 in Aiaterx and 7 in Akton gel overlay. Safety assessment was stated to be a secondary objective but was not reported on in this paper and suspension might be the safety outcome in this study.

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

- **Reporting**: not reported

Outcomes that are not considered in this review but reported in trials:

- Ease of care and bed-making, nursing evaluation
- Ulcer incidence

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Assignment to one aid or the other was randomised using closed envelopes which were opened at the moment of assignment. In the randomization lists the two aids were balanced at a ratio of 1:1" Comment: unclear risk of bias because the method of generating random numbers is not described.
Allocation concealment (selection bias)	Unclear risk	Quote: "Assignment to one aid or the other was randomised using closed envelopes which were opened at the moment of assignment." Comment: unclear risk of bias because it is not state if the envelopes are opaque and sequentially numbered.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	***Outcome group: all outcomes*** Quote: "Clinical evaluation was performed by previously trained medical staff of the facilities involved" Comment: no information provided.
Incomplete outcome data (attrition bias) All outcomes	High risk	***Outcome group: all outcomes*** Comment: high risk of bias because suspensions due to worsening lesions make this 50% withdrawal rate.
Selective reporting (reporting bias)	Unclear risk	Comment: the study protocol is not available but it is unclear whether safety assessments have been reported as pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Day 1993

Study characteristics	
Methods	**Study objective**: not given **Study design including the number of centres**: randomised controlled trial, single centre. **Study grouping**: parallel group **Duration of follow-up**: at least 7 days **Number of arms**: 2 **Study start date and end date**: not given **Care setting**: acute care setting
Participants	**Baseline characteristics** **Inclusion criteria**: hospitalised patients older than 18 years of age with Stage II, III, or IV pressure ulcers; life expectancy of at least 1 week; activity limited to chair or bed during hospitalisation; informed consent signed by the patient, or patient's family or guardian, and permission of the attending physician. **Exclusion criteria**: patients previously enrolled in the study; patient hospitalised for less than 7 days; patient having undergone skin grafting or flap within 7 days of enrolment in the study. **Sex (M/F)**: 17/27 in air-suspension bed; 18/21 in foam overlay. **Age (years)**: mean 75.09 (SD 15.37; range 32 to 102) years in air-suspension bed; mean 77.13 (SD 10.76; range 54 to 93) in foam overlay; estimated overall 76.0 (13.4). **The stage of pressure ulcers at baseline**: using 1989 NPUAP stage criteria; 25 Stage II, 6 Stage III, 11 Stage IV, 2 unable to stage in air-suspension bed (modified Norton mean 8.84, SD 2.84); 23 Stage II, 8 Stage III, 4 Stage IV, 4 unable to stage in foam overlay (Norton mean 9.03, SD 3.19). **Group difference**: no difference in other variables but the initial ulcer size (t[81] = 2.13, P = 0.036) with more severe wounds in the air-suspension group. **Total number of participants**: 118 enrolled, 83 patients randomised/analysed. **Unit of analysis:** individuals **Unit of randomisation (per patient):** individuals (1 ulcer per patient selected)
Interventions	**Intervention characteristics** Air-suspension bed • **Description of interventions**: air-suspension bed (TheraPulse, Kinetic Concepts). The pulsating, computer-controlled air-suspension bed contained 23 Gore-Tex fabric cushions, which alternated inflating and deflating at an adjustable rate to produce continuous pulsating action. • **NPIAP S3I classification**: powered, alternating pressure (active) air surface. • **Number of participants randomised**: 44 • **Number of participants analysed**: 44 • **Co-interventions**: not given Foam overlay • **Description of interventions**: GeoMatt, SpanAmerica. The foam overlay incorporated a geometric design that reduced tissue pressures. It was contour cut to provide individual foam units which responded to patient pressure points as required. • **NPIAP S3I classification**: non-powered, reactive foam surfaces. • **Number of participants randomised**: 39

Day 1993 *(Continued)*

- **Number of participants analysed**: 39
- **Co-interventions**: not given

Outcomes	*Proportion of participants with pressure ulcers healed* • **Outcome type**: binary • **Time points**: not given • **Reporting**: partially reported • **Definition and measurement method (e.g. scale, self-reporting)**: ulcer size measured by tracing the borders on clear plastic transparencies; measured each ulcer with a centimetre ruler initially and weekly thereafter. • **Dropouts and reasons**: no • **Data and results**: not reported • **Notes (e.g. other results reported)**: analysis of covariance revealed no statistically significant difference in the healing of pressure ulcers with respect to type of support surface used (F[1,78] = 0.35, P > 0.05). Ulcer sizes at baseline and the end of the trial reported by group in Table II that were not extracted. The examination of the differences between the initial and ending ulcer sizes suggested that the air-suspension bed was more effective than the foam overlay in ulcer healing for patients with Stage III and IV ulcers, the proportion of patients improving more than 10 cm^2 was higher in the air-suspension group. There was relatively little difference in Stage II patients. *Time to pressure ulcer healing* • **Not reported** *Support-surface-associated patient comfort* • **Outcome type**: continuous • **Time points**: 7 days • **Reporting**: partially reported • **Definition and measurement method (e.g. scale, self-reporting)**: perception of comfort self-rated by patients using the visual analogue scale (weekly comfort assessment form) ranging from very comfortable at one end of the line to very uncomfortable at the other end of the line. • **Dropouts and reasons**: 39 patients able to mark their perception of comfort. • **Data and results**: mean 4.1 (SD 1.3) over 20 patients on air-suspension bed; mean 3.7 (SD 1.3) over 19 patients on foam overlay (t[37] = 0.91, P > 0.05). *All reported adverse events* • **Not reported** *Health-related quality of life (HRQOL)* • **Not reported** *Cost-effectiveness* • **Not reported** **Outcomes that are not considered in this review but reported in trials**: • The association between nutrition status and ulcer healing
Notes	118 patients were enrolled in this study. Of these, 35 patients (19 from the air-suspension group and 16 from foam overlay group) did not complete the study due to either death or discharge earlier (i.e. not meeting inclusion criteria).

Risk of bias

Bias	Authors' judgement	Support for judgement

Day 1993 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Quote: “Patients were randomised to either the air-suspension bed or the foam mattress overlay” Quote: "In spite of randomisation there was a statistically significant difference in the initial ulcer size between the two groups (t[81] = 2.13, p=.036) with more severe wounds in the air-suspension group" Comment: unclear risk of bias because the method of generating random numbers is unspecified.
Allocation concealment (selection bias)	Unclear risk	Quote: “An equal distribution of labels marked foam mattress overlay or air-suspension bed were sealed in envelops” Comment: unclear risk of bias because no sufficient information on the allocation process.
Blinding of participants and personnel (performance bias) All outcomes	High risk	***Outcome group: ulcer healing*** Comment: high risk of bias because the report seemed to indicate that the allocation was unblinded.
Blinding of outcome assessment (detection bias) All outcomes	High risk	***Outcome group: ulcer healing*** Comment: high risk of bias because the report seemed to indicate that randomisation groups were unblinded to outcome assessors.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	***Outcome group: ulcer healing*** Comment: it appeared to include all 83 patients in analysis. However, the authors enrolled 118 patients in the study but excluded 35 based on inclusion criterion. It was unclear if the exclusion was prior to randomisation.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Devine 1995

Study characteristics	
Methods	**Study objective**: to assess the role of this type of mattress [large celled alternating pressure mattress] in the treatment of existing pressure sores and to compare the more established Pegasus Airwave version with the newer Nimbus I Dynamic Flotation System. **Study design including the number of centres**: randomised controlled trial, single centre **Study grouping**: parallel group **Duration of follow-up**: 4 weeks **Number of arms**: 2 **Study start date and end date**: not described **Care setting**: hospital
Participants	**Baseline characteristics**

Devine 1995 *(Continued)*

Inclusion criteria: patients in the Geriatric Unit who were admitted with or who developed sores of grade 2 or above and who agreed to being included in the study.

Exclusion criteria: not described

Sex (M/F): 17:24 overall; 12:10 in NIMBUS I and 5:14 in Airwave.

Age (years): mean 82.5 (range 69 to 98) overall; mean 81 (SD 5) in NIMBUS I and 84 (8) in Airwave.

The stage of pressure ulcers at baseline: sores of grade 2 or above (2 having grade 2 sores, 26 having grade 3, 8 having grade 4 sores and 5 having the most severe grade 5); initial sore size (cm^2) 13.5 in NIMBUS I and 12 in Airwave (estimated overall 12.8); mean Norton score 10 (range 7 to 14) in NIMBUS I and 10 (6 to 14) in Airwave.

Group difference: no difference

Total number of participants: 41

Unit of analysis: individuals

Unit of randomisation (per patient): individuals

Interventions

Intervention characteristics

Nimbus I

- **Description of interventions**: the Nimbus I DFS (HNE Healthcare, Luton, UK) is modular in construction, composed of rows of figure of 8 shaped cells. Two alternative sets of cells are inflated and deflated over a 10 minute cycle. A sensor pad (auto-mat) enables the system to automatically adjust inflation pressure to compensate for changes in the position of the patient.
- **NPIAP S3I classification**: powered, alternating pressure (active) air surfaces.
- **Number of participants randomised**: n = 22
- **Number of participants analysed**: n = 16
- **Co-interventions**: dressing

Airwave mattress

- **Description of interventions**: the airwave mattress (Pegasus, Ltd. Waterlooville) is a double layer mattress with a 3 cell alternating cycle lasting 7 ½ minutes.
- **NPIAP S3I classification**: powered, alternating pressure (active) air surfaces.
- **Number of participants randomised**: n = 19
- **Number of participants analysed**: n = 14
- **Co-interventions**: dressings

Outcomes

Proportion of participants with pressure ulcers healed

- **Outcome type**: binary
- **Time points**: 4 weeks
- **Reporting**: partially reported
- **Definition and measurement method (e.g. scale, self-reporting)**: healing of the pressure sore.
- **Dropouts and reasons**: 6 dropouts in NIMBUS (5 died and 1 moved to other hospital) and 5 in Airwave (4 died and 1 moved to other hospital).
- **Data and results**: completed cases: 10 of 16 patients with healed sores in NIMBUS and 5 of 14 healed in Airwave; ITT: 10 of 22 in NIMBUS and 5 of 19 in Airwave. Sore size (cm^2) 2.5 (0 to 110) in NIMBUS and 4 (0 to 272) in Airwave. The rate of reduction in size of pressure sores was similar in the 2 groups studied, with a median rate of 0.089 and 0.107 cm^2 per day for Nimbus and Airwave respectively. The estimated difference between medians was 0.0 cm^2, 95% confidence interval 0.179 to 0.143, P = 0.92.
- **Notes (e.g. other results reported)**: ITT analysis was mentioned in Discussion, saying "it was thought reasonable to include these individuals on an intention to treat basis. When looking at both groups combined the figure of 61 % for patients who had their pressure sores healed or improved …"

Devine 1995 *(Continued)*

Time to pressure ulcer healing

- **Reporting**: not reported

Support-surface-associated patient comfort

- **Outcome type**: continuous
- **Time points**: not described
- **Reporting**: partially reported
- **Definition and measurement method (e.g. scale, self-reporting)**: self-reported patient comfort (how comfortable the test mattress felt to lie on) measured using a simple 10 point linear scale; probably higher = better.
- **Dropouts and reasons**: 13 of 22 in NIMBUS and 8 of 19 in Airwave (dropouts due to general illness and dementia).
- **Data and results**: 8 (5 to 10) in NIMBUS and 8 (3 to 10) in Airwave.
- **Notes (e.g. other results reported)**: only a limited number of patients responded to the scale.

All reported adverse events

- **Reporting**: not reported
- **Notes (e.g. other results reported)**: 5 died in NIMBUS and 4 in Airwave.

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

- **Reporting**: not reported

Outcomes that are not considered in this review but reported in trials:

- Ease of use for staff

Notes

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" Comment: low risk of bias because of the use of a proper randomisation method.
Allocation concealment (selection bias)	Unclear risk	Quote: "Allocation to each group was achieved using a computer generated list of random numbers kept separately from the trial co-ordinator" Comment: unclear risk of bias because the method of concealing allocation is not specified.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no information provided.

Devine 1995 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: ulcer healing*** Quote: "it was thought reasonable to include these individuals on an intention to treat basis" Comment: low risk of bias because despite it being unclear if ITT analysis was performed as was mentioned in the Discussion, reasons of exclusions from analysis are mainly related to deaths and these data can be re-included in the analysis by review authors.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Evans 2000a

Study characteristics	
Methods	**Study objective**: assessed the clinical effectiveness of the Nimbus 3 alternating pressure mattress replacement system (APMRS) on pressure ulcer healing and comfort in subjects > 65 years, with at least a Grade 2 ulcer and some mobility problems. **Study design including the number of centres**: randomised controlled trial, single centre. **Study grouping**: parallel group **Duration of follow-up**: not described; median days in trial 20.5 (range 10 to 41) overall; 20 (13 to 41) in Nimbus 3 and 28 (10 to 37) in control. **Number of arms**: 2 **Study start date and end date**: not described **Care setting**: hospital
Participants	**Baseline characteristics** **Inclusion criteria**: aged ≥ 65 years with a Grade 3 pressure ulcer, or ≥ 65 years with a Grade 2 pressure ulcer and 1 or more of the following: difficulty repositioning in bed and unable to tolerate a 30° tilt; unable to move in bed; in bed for more than 20h in 24h; weight ≥ 108kg (17 stone) and bed bound; undergone spinal anaesthetic. **Exclusion criteria**: spinal metastases; exudating wounds that may lead to hygiene or infection control problems; weight > 250kg (39 stone). **Sex (M/F)**: hospital setting – 4:3 in Nimbus 3; 2:3 in control. **Age (years)**: hospital setting – median 68 (range 66 to 91) in Nimbus 3; 78 (65 to 91) in control; estimated overall 72.2. **The stage of pressure ulcers at baseline**: hospital setting – 3 reference ulcers of Grade 2 and 4 reference ulcers of Grade 3; with median reference ulcer size at baseline (cm^2) 3.1 (range 1.6 to 12.4) in Nimbus 3; 2 reference ulcer of Grade 2 and 3 ulcers of Grade 3; with median baseline size 5.7 (range 2.4 to 11.5); estimated overall size 4.2. **Group difference**: no difference **Total number of participants**: 12 patients with 12 reference ulcers

Evans 2000a *(Continued)*

Unit of analysis: individuals

Unit of randomisation (per patient): individuals

Interventions

Intervention characteristics

NIMBUS 3

- **Description of interventions**: Nimbus 3 alternating pressure mattress replacement system.
- **NPIAP S3I classification**: powered, alternating pressure (active) air surfaces.
- **Number of participants randomised**: n = 7
- **Number of participants analysed**: n = 7
- **Co-interventions**: wound dressings as per 1 specified protocol, organisations established practice for regular pressure area care (not specified how often).

Alternating pressure mattress overlay

- **Description of interventions**: Pegasus Airwave, Pegasus Biwave and AlphaXcell, and the Pegasus Cairwave.
- **NPIAP S3I classification**: powered, alternating pressure (active) air surfaces.
- **Number of participants randomised**: n = 5 (1 each to the Pegasus Airwave, Pegasus Biwave and AlphaXcell, and 2 to the Pegasus Cairwave).
- **Number of participants analysed**: n = 5
- **Co-interventions**: wound dressings as per 1 specified protocol, organisations established practice for regular pressure area care (not specified how often).

Outcomes

Proportion of participants with pressure ulcers healed

- **Outcome type**: binary
- **Time points**: not described
- **Reporting**: fully reported
- **Definition and measurement method (e.g. scale, self-reporting)**: ulcers assessed by the same TVN twice weekly through tracing ulcers' outlines onto sterile cellophane; using planimetry, the outline of each ulcer was plotted into a computer, and the wound surface area (WSA) calculated.
- **Dropouts and reasons**: no dropouts
- **Data and results**: 3 of 7 patients with ulcers completely healed in Nimbus 3; and 0 of 5 with complete healing in control (data summarised and extracted by reviewers based on raw data of Table 3).
- **Notes (e.g. other results reported)**: median absolute reduction in WSA per day (and range) of reference ulcers of subjects on Nimbus 3 compared to controls 0.12 cm^2 (0 cm^2 to 0.21 cm^2) versus 0.08 cm^2 (0.04 cm^2 to 0.33 cm^2); median relative reduction in WSA %/day (and range) 2.44% (0–7.14%) versus 1.34% (1.11–2.88%).

Time to pressure ulcer healing

- **Reporting**: not reported

Support-surface-associated patient comfort

- **Outcome type**: continuous
- **Time points**: not described
- **Reporting**: partially reported
- **Definition and measurement method (e.g. scale, self-reporting)**: patients indicated the comfort of their mattress weekly using a 5-point scale.
- **Dropouts and reasons**: no dropouts
- **Data and results**: median 5 (range 5 to 5) in Nimbus 3; and 4 (4 to 5) in control; Mann-Whitney U test P = 0.006.

All reported adverse events

Evans 2000a *(Continued)*

- **Reporting**: partially reported
- **Notes (e.g. other results reported)**: 1 of 7 developed MRSA in Nimbus 3 and 2 of 5 died in control.

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

- **Reporting**: not reported

Notes	The authors conducted trials at 2 different settings separately but used the same methods and reported both trials in the same paper. Data for each trial were extracted for this review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Treatments were randomly allocated to sequentially-labelled sealed envelopes" Comment: unclear risk of bias because the method of generating random numbers is not described.
Allocation concealment (selection bias)	Unclear risk	Quote: "Treatments were randomly allocated to sequentially-labelled sealed envelopes. After baseline assessment, the TVN opened the top envelope that indicated which surface a subject would be nursed on." Comment: unclear risk of bias because it is unclear if envelopes are opaque and numbered.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group:*** Quote: "Both groups were cared for in a similar manner, except for the PR device used" Comment: unclear risk of bias because it is challenging to blind participants and personnel but the attempts are made to keep deviations from interventions fewer.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	***Outcome group:*** Quote: "Two research team members, blind to the surface used, carried out the WSA measurements" Comment: low risk of bias as the quotation states.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group:*** Quote: "Even when in the study for a short time subjects were included on an intention-to-treat basis" Comment: low risk of bias because ITT analysis was performed.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Evans 2000b

Study characteristics	
Methods	**Study objective**: assessed the clinical effectiveness of the Nimbus 3 alternating pressure mattress replacement system (APMRS) on pressure ulcer healing and comfort in subjects > 65 years, with at least a Grade 2 ulcer and some mobility problems. **Study design including the number of centres**: randomised controlled trial, single centre **Study grouping**: parallel group **Duration of follow-up**: not described; median days in trial 53.5 (range 4 to 467) overall; 33 (7 to 217) in Nimbus 3 and 87 (4 to 467) in control. **Number of arms**: 2 **Study start date and end date**: not described **Care setting**: nursing home
Participants	**Baseline characteristics** **Inclusion criteria**: aged ≥ 65 years with a Grade 3 pressure ulcer, or ≥ 65 years with a Grade 2 pressure ulcer and 1 or more of the following: difficulty repositioning in bed and unable to tolerate a 30° tilt; unable to move in bed; in bed for more than 20h in 24h; weight ≥ 108kg (17 stone) and bed bound; undergone spinal anaesthetic. **Exclusion criteria**: spinal metastases; exudating wounds that may lead to hygiene or infection control problems; weight > 250kg (39 stone). **Sex (M/F)**: 0:10 in Nimbus 3; and 1:9 in control. **Age (years)**: median 84.5 (range 71 to 99) in Nimbus 3; and 88.5 (72 to 94) in control; estimated overall 86.5. **The stage of pressure ulcers at baseline**: 1 reference ulcer of Grade 2, 7 Grade 3 and 2 reference ulcers of Grade 4; with median reference ulcer size at baseline (cm^2) 6.9 (range 2.2 to 21.0) in Nimbus 3; 2 reference ulcers of Grade 2, 4 ulcers of Grade 3 and 4 Grade 4; with median baseline size 6.3 (range 0.1 to 37.4); overall estimated ulcer size 6.6. **Group difference**: no difference **Total number of participants**: 20 patients with 20 reference ulcers. **Unit of analysis:** individuals **Unit of randomisation (per patient):** individuals
Interventions	**Intervention characteristics** NIMBUS 3 • **Description of interventions**: Nimbus 3 alternating pressure mattress replacement system. • **NPIAP S3I classification**: powered, alternating pressure (active), air surfaces. • **Number of participants randomised**: n = 10 • **Number of participants analysed**: n = 10 • **Co-interventions**: wound dressings as per 1 specified protocol, organisations established practice for regular pressure area care (not specified how often). Alternating pressure mattress overlay • **Description of interventions**: Pegasus AlphaXcell, and the Quattro. • **NPIAP S3I classification**: powered, alternating pressure (active), air surfaces.

Evans 2000b *(Continued)*

- **Number of participants randomised**: n = 10 (9 allocated to the Pegasus AlphaXcell, and 1 to the Quattro).
- **Number of participants analysed**: n = 10
- **Co-interventions**: wound dressings as per 1 specified protocol, organisations established practice for regular pressure area care (not specified how often).

Outcomes

Proportion of participants with pressure ulcers healed

- **Outcome type**: binary
- **Time points**: not described
- **Reporting**: partially reported
- **Definition and measurement method (e.g. scale, self-reporting)**: ulcers assessed by the same TVN twice weekly through tracing ulcers' outlines onto sterile cellophane; using planimetry, the outline of each ulcer was plotted into a computer, and the wound surface area (WSA) calculated.
- **Dropouts and reasons**: no dropouts
- **Data and results**: 1 of 10 patients with ulcers completely healed in Nimbus 3; and 5 of 10 with complete healing in control (data summarised and extracted by reviewers based on raw data of Table 6).
- **Notes (e.g. other results reported)**: median absolute reduction in WSA per day (and range) of reference ulcers of subjects on Nimbus 3 compared to controls 0.11 cm^2 (0.04 cm^2 to 0.41 cm^2) versus 0.05 cm^2 (0 cm^2 to 0.48 cm^2); median relative reduction in WSA %/day (and range) 1.57% (0.45% to 5.00%) versus 0.99% (0 % to 2.54%).

Time to pressure ulcer healing

- **Reporting**: not reported

Support-surface-associated patient comfort

- **Outcome type**: continuous
- **Time points**: not described
- **Reporting**: partially reported
- **Definition and measurement method (e.g. scale, self-reporting)**: patients indicated the comfort of their mattress weekly using a 5-point scale; higher = better.
- **Dropouts and reasons**: no dropouts
- **Data and results**: median 5 (range 3 to 5) in Nimbus 3; and 4 (2 to 5) in control; Mann-Whitney U test P = 0.002. Raw data presented: 1 rated at 3 and 9 rated at 5 in Nimbus; 1 rated 2, 2 rated at 3, 5 rated at 4, and 2 rated at 5 in control.

All reported adverse events

- **Reporting**: partially reported
- **Notes (e.g. other results reported)**: 7 of 10 died in Nimbus 3 and 1 of 10 died in control.

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

- **Reporting**: not reported

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Treatments were randomly allocated to sequentially-labelled sealed envelopes"

Evans 2000b *(Continued)*

		Comment: unclear risk of bias because the method of generating random numbers is not described.
Allocation concealment (selection bias)	Unclear risk	Quote: "Treatments were randomly allocated to sequentially-labelled sealed envelopes. After baseline assessment, the TVN opened the top envelope that indicated which surface a subject would be nursed on." Comment: unclear risk of bias because it is unclear if envelopes are opaque and numbered.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group:*** Quote: "Both groups were cared for in a similar manner, except for the PR device used" Comment: unclear risk of bias because it is challenging to blind participants and personnel but the attempts are made to keep deviations from interventions fewer.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	***Outcome group:*** Quote: "Two research team members, blind to the surface used, carried out the WSA measurements" Comment: low risk of bias as the quotation states.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group:*** Quote: "Even when in the study for a short time subjects were included on an intention-to-treat basis" Comment: low risk of bias because ITT analysis was performed.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Ferrell 1993

Study characteristics	
Methods	**Study objective**: to assess the effectiveness of low-air-loss beds for the treatment of pressure ulcers in nursing homes. **Study design including the number of centres**: randomised controlled trial, multiple centres. **Study grouping**: parallel group **Duration of follow-up**: median 37.5 days **Number of arms**: 2 **Study start date and end date**: recruited between November 1987 and March 1991. **Care setting**: nursing homes
Participants	**Baseline characteristics**

Ferrell 1993 *(Continued)*

	Inclusion criteria: presence of pressure ulcers on the trunk, buttocks, or trochanters; informed consent from the patient or patient's proxy for health care decisions; and approval of the primary care physician. Ulcers were defined by the presence of abrasion, bulla, skin necrosis, or ulcer formation as a result of pressure over a bony prominence (stage 2 or greater by the Shea scale). The largest ulcer was chosen as the index ulcer among those with multiple ulcers. **Exclusion criteria**: expected survival less than 1 month; previous participation in the study; or previous or planned surgical excision of the pressure ulcer. **Sex (M/F)**: 22/21 in low-air-loss bed; 20/21 in foam mattress. **Age (years)**: median 85 (IQR 71 and 92) in low-air-loss; 84 (88 and 91) in foam mattress; estimated overall 84.5. **The stage of pressure ulcers at baseline**: using Shea criteria: 25 superficial ulcers and 18 deep ulcers in low-air-loss; 27 superficial and 14 deep ulcers in foam mattress. Initial surface area (cm^2) median 4.3 (IQR 2.6 to 14.0) in low-air-loss bed; 4.1 (0.97 and 8.95) in foam mattress; estimated overall ulcer size 4.2. **Group difference**: no difference **Total number of participants**: 84 patients analysed **Unit of analysis:** individuals **Unit of randomisation (per patient):** individuals
Interventions	**Intervention characteristics** Low-air-loss bed • **Description of interventions**: low-air-loss bed (Kinair bed, Kinetic Concepts International, San Antonio, Tex) … consists of multiple inflatable fabric pillows … An electrical blower (fan) maintains comfortable buoyancy of the pillows as the heated air escapes from the fabric air sacks. • **NPIAP S3I classification**: powered, reactive air surface: low air loss. • **Number of participants randomised**: 43 • **Number of participants analysed**: 43 • **Co-interventions**: any usual treatments. 10-cm corrugated foam mattress • **Description of interventions**: consists of a 10-cm convoluted foam mattress overlying a regular hospital mattress. • **NPIAP S3I classification**: powered, reactive foam surface. • **Number of participants randomised**: 41 • **Number of participants analysed**: 41 • **Co-interventions**: any usual treatments.
Outcomes	*Proportion of participants with pressure ulcers healed* • **Outcome type**: binary • **Time points**: median follow up 37.5 days • **Reporting**: fully reported • **Definition and measurement method (e.g. scale, self-reporting)**: index ulcer healing (completely epithelialized). • **Dropouts and reasons**: ITT analysis (9 subjects using foam mattress deviated; 11/43 died in the low-air-loss bed; 7/41 died from foam mattress group; 4/43 transferred to another facility from low-air-loss bed and 4/41 from foam mattress group; 2/43 discontinued at patient's request in low-air-loss bed and 2/41 from foam mattress). • **Data and results**: 26 of 43 patients with complete ulcer healing in low-air-loss bed; 19 of 41 patients in foam mattress.

Ferrell 1993 *(Continued)*

- **Notes (e.g. other results reported)**: ulcer surface area for low-air-loss bed decreased more than 3 times faster than did the ulcer surface area on subjects in the foam mattress (median 9.0 with IQR 4.0 and 19.8 vs. 2.5 with IQR 0.5 and 6.5 mm^2/d, P = 0.0002).

Time to pressure ulcer healing

- **Outcome type**: time-to-event data
- **Time points**: not given
- **Reporting**: partially reported
- **Definition and measurement method (e.g. scale, self-reporting)**: see above
- **Dropouts and reasons**: not relevant
- **Data and results**: hazard ratio from Cox regression (adjusted for fecal continence) 2.66 (95% CI 1.34 to 5.17), P = 0.004. Figure 1 having data for subgroups of superficial ulcers and of deep ulcers.
- **Notes (e.g. other results reported)**: using life-table methods to account for early treatment termination also revealed no group differences.

Support-surface-associated patient comfort

- **Not reported**

All reported adverse events

- **Notes (e.g. other results reported)**: 11 of 43 died in low-air-loss, 7 of 41 died in foam mattress. 9 patients from foam mattress group deviated from the protocol as their pressure ulcers became substantially worse or failed to heal.

Health-related quality of life (HRQOL)

- **Not reported**

Cost-effectiveness

- **Not reported**

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "At each facility, groups of 10 subjects were separately randomised, five to each treatment" Comment: unclear risk of bias because the method of generating random sequence is unspecified.
Allocation concealment (selection bias)	Unclear risk	Quote: "Assignment were sealed in individual envelopes and opened sequentially on establishment of subject criteria" Comment: unclear risk of bias because the available information on using envelopes is not sufficient for judging the allocation is concealed.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: ulcer healing*** Quote: "The treatment protocol was similar between groups and consistent with each facility's routine policy and procedure for pressure ulcer management" Comment: no information provided.
Blinding of outcome assessment (detection bias)	Unclear risk	Comment: no information provided.

Ferrell 1993 *(Continued)*
All outcomes

Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: ulcer healing*** Comment: all patients included in analysis.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Ferrell 1995

Study characteristics	
Methods	**Study objective**: to estimate cost-effectiveness based on patient and ulcer characteristics. **Study design including the number of centres**: cost-effectiveness analysis. See Ferrell 1993 for the details of the trial associated with this cost-effectiveness analysis.
Participants	See Ferrell 1993 for the details of the trial associated with this cost-effectiveness analysis. From 3 nursing homes, 84 subjects with trunk or trochanter pressure ulcers (Shea stage II or greater) were randomly allocated.
Interventions	See Ferrell 1993 for the details of the trial associated with this cost-effectiveness analysis. Briefly, a low-air-loss bed (Kinair Bed; Kinetic Concepts International, San Antonio, TX) (n = 43) compared with a 4-inch corrugated foam mattress overlying a conventional hospital mattress (n = 41).
Outcomes	*Cost-effectiveness* • **Perspectives**: nursing home administrators (not substantially different from that of third party payers or society). • **Time horizon**: 1 year • **Health benefit**: additional days without an ulcer with the low-air-loss bed = the number of days until cure with the standard care minus the number of days until cure with the low air-loss-bed. • **Costs**: additional costs of treatment with a low-air-loss bed compared to standard treatment = [the costs per day of low-air-loss beds] x [the number of days until the ulcer is healed] - [the costs of averted pressure ulcer care]. • **Cost-effectiveness**: the additional cost of the low-air-loss bed divided by the additional days without an ulcer. • **Base case**: a subject with a pressure ulcer followed for 1 year with a mortality of 40%, standard care healing rate of 0.09 mm/day, a differential healing rate of 0.42 mm/day on the low-air-loss bed, and a standard care cost of $9.00 per day. (1) ***Average healing rate*** estimated using a regression model; on average the diameter of their ulcer would decrease by 0.09 mm/day on the standard bed and by 0.51 mm/day on the low-air-loss bed, representing an average of 172 days to cure using standard care as opposed to 75 days to cure on the low-air-loss bed; (2) $9.00 per patient per day used for ***standard care costs*** (average nursing labor ~ $6.00 + average other treatment costs = $3.00 per patient per day), in which. (3) The ***estimate of low-air-loss beds cost*** = $45 per day. (4) Additional nursing time for pressure ulcer care (including preparation, cleanup, travel, overhead, and down time) = 29 minutes per patient per day, which was assumed to be equal for both groups. • **Base case analysis results**: by assuming a negotiated lease of $45 per day, the cost-effectiveness for a standard patient of using the low-air-loss bed was $26 per additional day without an ulcer in the first year.

Ferrell 1995 *(Continued)*

	• **Sensitivity analysis**: assuming cost of leasing a low-air-loss bed $70/day, cost effectiveness = $45 per additional day without an ulcer; assuming a cost of leasing a low-air-loss bed $20/day, cost-effectiveness = $6 per additional day. Results of assuming low-air-loss bed more effective (with 0.62 mm/day) or less effective (with 0.22 mm/day), of assuming 60% death rate or 20% death rate, of assuming time horizon of 2 years, of assuming care cost $5/day, and of assuming care cost $20/day were presented in Table 3 of Ferrell 1995. Not extracted for this review.
Notes	This cost-effectiveness analysis is related to Ferrell 1993 trial. Risk of bias judgements of Ferrell 1993 are applied for this cost-effectiveness analysis.

Groen 1999

Study characteristics	
Methods	**Study objective**: to determine the effectiveness of high-quality foam replacement mattresses (TheraRest) in the treatment of pressure ulcers compared with a water mattress (Secutex). **Study design including the number of centres**: randomised controlled trial, 3 sites. **Study grouping**: parallel group **Duration of follow-up**: 4 weeks **Number of arms**: 2 **Study start date and end date**: not given **Care setting**: nursing home
Participants	**Baseline characteristics** **Inclusion criteria**: aged 60 years or over and had pressure ulcers on the trunk that had been classified Grade III (superficial cutaneous or subcutaneous necrosis) or IV (deep subcutaneous necrosis). **Exclusion criteria**: patients with severe or terminal illness. **Sex (M/F)**: not described **Age (years)**: average age 81.9 years in foam mattress and 83.5 in water mattress; estimated overall 82.7. **The stage of pressure ulcers at baseline**: pressure ulcer severity 4.8 in foam mattress and 5.5 in water mattress. **Group difference**: higher number of patients with occasional incontinence of urine in water mattress. **Total number of participants**: 120 randomised (101 analysed) **Unit of analysis:** individuals **Unit of randomisation (per patient):** individuals
Interventions	**Intervention characteristics** Foam replacement mattress • **Description of interventions**: foam replacement mattress (TheraRest) … 14 cm thick, weighs 9 kg and consists of three layers of polyurethane foam of differing thicknesses designed to be a 'comfort' layer, a load-distributing layer and a support layer … has a non-stretch polyurethane cover and can be easily adjusted to an angle that enables the patient to sit up. • **NPIAP S3I classification**: non-powered, reactive foam surfaces.

Groen 1999 *(Continued)*

- **Number of participants randomised**: n = 60
- **Number of participants analysed**: n = 49
- **Co-interventions**: treated in accordance with hospital guidelines, including turning every 2 to 3 hours.

Water mattress

- **Description of interventions**: water mattress (Secutex) placed on top of the standard hospital mattress … consists of 3 PVC sections, each of which hold approximately 26 litres of water, held in place by a foam frame. The filled mattress weighs approximately 80 kg and contains a heating element.
- **NPIAP S3I classification**: non-powered, reactive water surfaces.
- **Number of participants randomised**: n = 60
- **Number of participants analysed**: n = 52
- **Co-interventions**: treated in accordance with hospital guidelines, including turning every 2 to 3 hours.

Outcomes

Proportion of participants with pressure ulcers healed

- **Outcome type**: binary
- **Time points**: 4 weeks
- **Reporting**: partially reported
- **Definition and measurement method (e.g. scale, self-reporting)**: pressure ulcer severity assessed once a week using a validated quantitative scoring system (severity determined according to 3 aspects: largest diameter; wound depth; and wound bed); score ranging from 0 to 13 (higher = more severe).
- **Dropouts and reasons**: 19 dropouts in total (11 in foam and 8 in water) due to severe illness or discharge from nursing home.
- **Data and results**: 45% (22/49) of the patients with complete healing in foam mattress compared to 48% (25/52) in water.
- **Notes (e.g. other results reported)**: healing progressed more or less equally in the 2 groups until the final score in week 4 (Fig 1). No significant difference in the numbers of patients who were completely healed in the 2 groups (Fig 2).

Time to pressure ulcer healing

- **Not reported**

Support-surface-associated patient comfort

- **Not reported**

All reported adverse events

- **Outcome type**: binary
- **Time points**: 5 time points (baseline, and 1 to 4 weeks).
- **Reporting**: partially reported
- **Definition and measurement method (e.g. scale, self-reporting)**: percentage of patients with complicating factors (including eczema, maceration and pain) by weeks.
- **Dropouts and reasons**: 19 dropouts in total (11 in foam and 8 in water) due to severe illness or discharge from nursing home.
- **Data and results**: eczema data at week 4 (no data); maceration data at week 4 (4.1% in foam and 3.8% in water); pain data at week 4 (4.1% in foam and 3.8% in water).
- **Notes (e.g. other results reported)**: outcome data reported for baseline, week 1, week 2, week 3 also, but not extracted by reviewers for this review.

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

Groen 1999 *(Continued)*

- **Reporting**: not reported

Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Subjects were randomly divided into two groups of 60 by selection of sealed envelopes." Comment: unclear risk of bias because the method of generating random numbers is not described.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	High risk	***Outcome group: all outcomes*** Quote: "The outcome assessment was not blinded because the disturbance caused by moving patients from the mattresses was thought to be undesirable" Comment: high risk of bias because unblinded assessment is stated.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: all outcomes*** Quote: "All patients who took part in the trial for 14 days or longer were included" Quote: "Of the 120 patients in the trial, 19 withdrew – 11 from Group A and eight from Group B" Comment: low risk of bias because of the low rate of missing data.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Mulder 1994

Study characteristics

Methods	**Study objective**: to determine the effectiveness of the use of the low air loss therapy versus a standard support surface in the treatment of patients with Stage III or Stage IV pressure ulcers. **Study design including the number of centres**: randomised controlled trial, single site. **Study grouping**: parallel group **Duration of follow-up**: 12 weeks

Mulder 1994 *(Continued)*

	Number of arms: 2 **Study start date and end date**: not given **Care setting**: nursing home
Participants	**Baseline characteristics** **Inclusion criteria**: patients with full thickness pressure ulcers (Stages III, IV) within a range of 1.5 cm x 1.5 cm to 10.0 cm x 20.0 cm. **Exclusion criteria**: patients with carcinomatosis, osteomyelitis affecting the target ulcer, uncontrolled target ulcer infection, immune deficiency disorders, and inadequate nutritional status. **Sex (M/F)**: not given **Age (years)**: not given **The stage of pressure ulcers at baseline**: all Stage III or IV **Group difference**: no difference **Total number of participants**: 49 patients analysed **Unit of analysis:** individuals (1 ulcer per individual) **Unit of randomisation (per patient):** ulcers
Interventions	**Intervention characteristics** Therapulse beds • **Description of interventions**: Therapulse low air loss bed (Kinetic Concepts, Inc., San Antonio, TX) providing pulsating air suspension therapy by the cushions alternately partially deflating and reinflating. • **NPIAP S3I classification**: powered, alternating pressure (active) air surfaces; low air loss. • **Number of participants randomised**: unclear • **Number of participants analysed**: n = 31 • **Co-interventions**: turning every 2 hours Conventional treatment • **Description of interventions**: Geomatt mattress overlay (Span-America Inc., Greenville, SC). • **NPIAP S3I classification**: non-powered, reactive foam surfaces. • **Number of participants randomised**: unclear • **Number of participants analysed**: n = 18 • **Co-interventions**: turning every 2 hours
Outcomes	*Proportion of participants with pressure ulcers healed* • **Outcome type**: binary • **Time points**: 12 weeks • **Reporting**: fully reported • **Definition and measurement method (e.g. scale, self-reporting)**: complete wound closure (defined as 100% granulation and re-epithelialisation). • **Dropouts and reasons**: 49 patients analysed and 10 lost; however it is unclear if the 10 is from the 49. • **Data and results**: 5 ulcers receiving low air loss therapy healed completely and 3 healed on conventional therapy. • **Notes (e.g. other results reported)**: the use of low air loss beds can significantly increase the healing rate of pressure ulcers.

Mulder 1994 *(Continued)*

Time to pressure ulcer healing

- **Not reporting**

Support-surface-associated patient comfort

- **Not reporting**

All reported adverse events

- **Notes (e.g. other results reported)**: 'no major adverse affects which could be attributed to the study devices'

Health-related quality of life (HRQOL)

- **Not reporting**

Cost-effectiveness

- **Not reporting**

Outcomes that are not considered in this review but reported in trials:

- Percentage changes in initial area/final area

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: no information provided.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Patients were seen on a weekly basis. During each visit, wounds were photographed and volume and area measured. Wound tracings were taken using an acetate film, which was then analyzed by computerized photoplanimetry" Comment: unclear risk of bias.
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "A total of 49 evaluable patients were entered into the study. Ten individuals were dropped from the study and not included in the data analysis. Eight patients died, one was lost to follow-up and one patient was dropped due to a break in the protocol" Comment: high risk of bias.
Selective reporting (reporting bias)	Unclear risk	Comment: unclear risk of bias because pain and care cost were both seemingly mentioned but it is unclear if they were measured.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Munro 1989

Study characteristics	
Methods	**Study objective**: to examine if air fluidised bed is better than standard beds with usual pressure-relieving devices. **Study design including the number of centres**: randomised controlled trial, single centre. **Study grouping**: parallel group **Duration of follow-up**: 15 days **Number of arms**: 2 **Study start date and end date**: not described **Care setting**: Veterans' Administration Medical Center.
Participants	**Baseline characteristics** **Inclusion criteria**: eligible, consenting patients with Stage II or III ulcers, who were expected to remain in the hospital for at least 15 days. **Exclusion criteria**: patients with Stage IV ulcers; those who weigh more than 250 pounds; extremely malnourished patients – those at less than 70 percent of ideal body weight or with serum albumin less than 2.1 g/100 mL. **Sex (M/F)**: 40:0 overall; 20:0 in each group. **Age (years)**: mean 67.2 (range 48 to 88). **The stage of pressure ulcers at baseline**: 21 (52.5%) with Stage II ulcers and 19 (47.5%) with Stage III ulcers; average ulcer size at day 1 (1464 mm^2 in standard bed and 2660 mm^2 in Clinitron; estimated overall 18.62 cm^2). **Group difference**: no difference **Total number of participants**: 40 patients analysed **Unit of analysis:** individuals **Unit of randomisation (per patient):** individuals
Interventions	**Intervention characteristics** Clinitron bed • **Description of interventions**: air-fluidised support system • **NPUAP S3I classification**: non-powered, reactive air surfaces; air-fluidised bed • **Number of participants randomised**: not described • **Number of participants analysed**: n = 20 • **Co-interventions**: not described Standard bed • **Description of interventions**: not described • **NPUAP S3I classification**: standard hospital surfaces • **Number of participants randomised**: not described • **Number of participants analysed**: n = 20 • **Co-interventions**: sheepskin, gel pads, positioning and massage

Munro 1989 *(Continued)*

Outcomes

Proportion of participants with pressure ulcers healed

- **Outcome type**: continuous
- **Time points**: day 1, 3, 8, 15
- **Reporting**: not reported
- **Definition and measurement method (e.g. scale, self-reporting)**: ulcers graded using the protocol developed at Beth Israel Hospital in Boston – coloured pictures and written descriptions; ulcers measured by tracing their perimeters on a Saran-wrap sheet placed over the lesions; then a digitiser tablet and the Zeiss MOP Videoplan used to determine area.
- **Notes (e.g. other results reported)**: repeated-measures analysis of variance (F = 2.6, P = 0.05): the mean size of the ulcers shrank over time in the Clinitron group and expanded over time in the standard-bed group.

Time to pressure ulcer healing

- **Reporting**: not reported

Support-surface-associated patient comfort

- **Outcome type**: continuous
- **Time points**: not described
- **Reporting**: fully reported
- **Definition and measurement method (e.g. scale, self-reporting)**: self-rated patient satisfaction measured by an 8-item scale with a totality of 11 points (from total dissatisfaction to complete satisfaction).
- **Dropouts and reasons**: no data on 22 of 40 patients because they cannot respond to the scale as too ill.
- **Data and results**: the experimental group rated their satisfaction higher (X = 57.5, n = 8, SD = 6.I) than did the control group (X = 48.6, n =10, SD = 12.3), but the difference was not statistically significant (t = 1.99, P = 0.067).

All reported adverse events

- **Outcome type**: continuous
- **Time points**: day 1, 3, 8 and 15
- **Reporting**: partially reported
- **Definition and measurement method (e.g. scale, self-reporting)**: patient's perception of pain rated using an adaptation of the Levitt and Derogatis scale (with 3 items – pain the patient was feeling that day, amount of pain the pressure ulcer was causing that day, and how comfortable the patient felt that day) with an 11-point scale from "no pain" to "worst pain imaginable"
- **Dropouts and reasons**: 13 of 40 patients responded.
- **Data and results**: pain scores fell over time in both groups, with the Clinitron group demonstrating the greatest change. No statistical difference (F = 0.87, P = 0.359).
- **Notes (e.g. other results reported)**: no differences found between groups on complications during this study (F = 0.69, P = 0.56).

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

- **Reporting**: not reported
- **Definition and measurement method (e.g. scale, self-reporting)**: costs associated with supplies and medications used for ulcer treatment on the 8th day.
- **Data and results**: average cost of supplies $17.85 for standard beds, and $6.70 for Clinitron bed (significant difference t = 3.12, P = 0.004).
- **Notes (e.g. other results reported)**: only costs associated with supplies used to treat the ulcers compared; cost-effectiveness analysis not conducted; concluded that “pressure ulcer healing is enhanced

Munro 1989 *(Continued)*

	on the Clinitron bed and that fewer supplies and medications are used to treat the ulcers of the patients than are used for those in the standard hospital bed." **Outcomes that are not considered in this review but reported in trials**: • Amount of time nurses and aides spent with subjects.
Notes	The study authors stated "No attempt was made to standardise the treatment because we wanted to measure the results with common nursing practice versus those with the Clinitron bed".

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: those who "were expected to remain in the hospital for at least 15 days were randomly assigned …" Comment: unclear risk of bias because the method of generating random numbers is not described.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	***Outcome group: all outcomes*** Quote: "No attempt was made to standardize the treatment …" Comment: high risk of bias because it is understandably challenging to blind participants and personnel for a trial of non-drug interventions and there is a clear statement above.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no information provided.
Incomplete outcome data (attrition bias) All outcomes	High risk	***Outcome group: adverse events and comfort*** Comment: high risk of bias because more than half of included participants did not respond to outcome assessment.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available and it is unclear if the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Russell 2000a

Study characteristics

Methods	**Study objective**: to compare the efficacy of the Pegasus Cairwave mattress and Proactive seating cushion and the Huntleigh Nimbus 3 mattress and Aura cushion. **Study design including the number of centres**: randomised controlled trial, single centre **Study grouping**: parallel group **Duration of follow-up**: 18 months

Russell 2000a *(Continued)*

	Number of arms: 2 **Study start date and end date**: recruitment between August 1997 and December 1998 **Care setting**: care of the elderly unit at a hospital
Participants	**Baseline characteristics** **Inclusion criteria**: all patients admitted to the Health Care of the Elderly Unit with a pressure sore of grade 2 and above on the Torrance grading system. **Exclusion criteria**: unwilling to participate; randomised equipment not available; had previously been included in the trial and were re-admitted with a pressure ulcer; or weighed more than 25 stone. **Sex (M/F)**: not described **Age (years)**: mean 83.9 (SD 5.91) in Nimbus 3 and 84.6 (6.21) in Cairwave (n = 112 completed cases); estimated overall 84.2 (SD 6.0). **The stage of pressure ulcers at baseline**: using Torrance stage criteria; average severity of ulcers 2.46 (SD 0.49) in Nimbus 3; 2.57 (0.48) in Cairwave (n = 183 all cases). **Group difference**: a statistical significant difference between patient groups for incontinence, with a greater proportion of patients on the Nimbus Bed incontinent. **Total number of participants**: n = 183 patients; 112 analysed **Unit of analysis:** individuals **Unit of randomisation (per patient):** individuals
Interventions	**Intervention characteristics** Cairwave • **Description of interventions**: Pegasus Cairwave therapy system with the Proactive cushion (Group B) • **NPIAP S3I classification**: powered, alternating pressure (active) air surfaces • **Number of participants randomised**: not described • **Number of participants analysed**: n = 55 • **Co-interventions**: using a standard protocol; turning once per 8 hour shift Nimbus 3 • **Description of interventions**: Huntleigh Nimbus 3 with the Aura cushion (Group A) • **NPIAP S3I classification**: powered, alternating pressure (active) air surfaces • **Number of participants randomised**: not described • **Number of participants analysed**: n = 57 • **Co-interventions**: using a standard protocol; turning once 4 hourly
Outcomes	*Proportion of participants with pressure ulcers healed* • **Outcome type**: binary • **Time points**: 12 months and 18 months • **Reporting**: partially reported • **Definition and measurement method (e.g. scale, self-reporting)**: improvement of ulcers that were not defined • **Dropouts and reasons**: 41 were discharged too early for any valid assessment, 4 patients withdrew (2 didn't like being photographed; 2 could not sleep on alternating-cell beds) • **Data and results**: not extracted because no data on complete healing reported • **Notes (e.g. other results reported)**: no statistical difference between groups for improvement or healing of sacral pressure sores; Nimbus 3 has statistically significant difference for the healing of heel

Russell 2000a *(Continued)*

sores. Raw data by groups were not reported; but the Cochrane review McGinnis 2014 received data from Russell 2000a: 24/55 participants healed in the Nimbus group and 17/58 participants healed in the Cairwave group (RR 1.49; 95% CI 0.90 to 2.45).

Time to pressure ulcer healing

- **Reporting**: not reported

Support-surface-associated patient comfort

- **Outcome type**: continuous
- **Time points**: not described
- **Reporting**: partially reported
- **Definition and measurement method (e.g. scale, self-reporting)**: patients' opinions on the comfort of the bed measured by an observer from the clinical audit team using a questionnaire (Russell 1999 (see Russell 2000a)); comfort assessed using digital analogue scales on a 10-point scale derived from the British furniture industry standard scale and then converted into a 5-point scale ranging from 'very uncomfortable' to 'very comfortable'.
- **Dropouts and reasons**: those who did not complete the trial and patients with dementia not included in analysis.
- **Data and results**: presented by specific question items of the scale and thus not extracted for this review.
- **Notes (e.g. other results reported)**: both groups equally comfortable, with no statistical difference.

All reported adverse events

- **Reporting**: partially reported
- **Notes (e.g. other results reported)**: 26 (16 in Nimbus 3 and 10 in Cairwave) died during the course of the trial.

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

- **Reporting**: not reported although it is stated economic evaluation undertaken alongside this study (Russell 1999).

Outcomes that are not considered in this review but reported in trials:

- Patients-rated sleep
- Length of stay in hospital
- Equipment performance
- Pressure ulcer incidence during study (with a totality of 0.13%; denominator unspecified; not presented by groups)

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "All patients … were randomly allocated a Pegasus Cairwave or Huntleigh Nimbus 3 mattress and matching seat cushion" (Russell 1999) Quote: "On admission to the study, subjects were randomly allocated to trial equipment." Comment: unclear risk of bias because the method of generating random numbers is not described.

Russell 2000a *(Continued)*

Allocation concealment (selection bias)	Low risk	Quote: "To prevent bias, randomisation of bed allocation and interim statistical monitoring to ensure ethical compliance coordination was undertaken by a member of the team who had no responsibility for direct patient care or knowledge of pressure-relieving systems" (Russell 2000a) Comment: low risk of bias.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: "No additional pressure-relieving equipment was used during the trial." Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	***Outcome group: ulcer healing*** Quote: "ulcers were graded during the trial by one of three designated nurses who regularly work together" (Russell 2000a) Quote: "All pressure sores were photographed digitally on a weekly basis and the images stored on CD-ROM." (Russell 1999) Quote: "Images were stored on compact discs, using codes that ensured image analysis could be carried out 'blind' to treatment group" (Russell 2000a) Comment: low risk of bias given this is likely to blind ulcer outcome assessment. ***Outcome group: comfort*** Quote: "patients with dementia were not included in the comfort survey" (Russell 2000a) Comment: low risk of bias because patients' opinions on the comfort of the bed are measured by an impartial observer from the clinical audit team using a questionnaire.
Incomplete outcome data (attrition bias) All outcomes	High risk	***Outcome group: ulcer healing*** Quote: "Data from patients who did not complete the trial are not included in the statistical analysis" Quote: "183 subjects were recruited … Of the 112 who completed the trial …" Comment: high risk of bias given the rate of dropouts is more than 20%. ***Outcome group: comfort*** Quote: "patients with dementia were not included in the comfort survey" and Table 3 Comment: high risk of bias because Table 3 shows only 29 in Nimbus 3 and 24 in Cairwave completed comfort outcome assessment.
Selective reporting (reporting bias)	High risk	Comment: the study protocol is not available but it is clear that the published reports do not include all expected outcomes, e.g. economic evaluation was specified in Russell 1999 but not in Russell 2000a.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Strauss 1991

Study characteristics	
Methods	**Study objective**: to compare air-fluidised bed therapy with conventional home therapy in terms of costs and cost savings. **Study design including the number of centres**: randomised controlled trial, multi-centres alongside a trial-based economic evaluation **Study grouping**: parallel group **Duration of follow-up**: 36 weeks **Number of arms**: 2 **Study start date and end date**: not given **Care setting**: community
Participants	**Baseline characteristics** **Inclusion criteria**: (1) had at least one 3rd stage or 4th stage pressure sore; (2) had an attending physician who believed that the patient would probably require future hospitalisation for pressure-sore-related care; (3) had severely limited mobility; (4) had adequate social support to use home air-fluidised bed therapy (usually the assistance of a relative, friend, or paid caregiver); (5) was likely to comply with the home care regimen; (6) was likely to live at least 1 year; (7) was at least 16 years of age; (8) had been out of the hospital for at least 3 weeks; and (9) had a personal physician who was willing to closely manage care in the patient's home. **Exclusion criteria**: were febrile or septic or otherwise required immediate hospitalisation; had pressure sores on radiated skin. **Sex (M/F)**: 29/29 in air-fluidised bed and 28/26 in control. **Age (years)**: mean 65 in air-fluidised bed and 63 in control; estimated overall 64. **The stage of pressure ulcers at baseline**: using Shea stage criteria; patients with Stage III or IV; ulcer size and stages not reported. **Group difference**: no difference **Total number of participants**: n = 112 **Unit of analysis:** individuals **Unit of randomisation (per patient):** individuals
Interventions	**Intervention characteristics** Air-fluidised bed therapy • **Description of interventions**: CLINITRON Therapy Unit (Support Systems International, Charleston, SC) … a bed of beadlike ceramic spherules through which filtered air is circulated, thereby simulating the mechanics of "fluid" movement. Once ulcers healed to a 2nd stage or better, the air-fluidised bed removed. • **NPIAP S3I classification**: non-powered, reactive air surfaces; air-fluidised bed. • **Number of participants randomised**: 58 • **Number of participants analysed**: 47 • **Co-interventions**: home visit weekly for the first 4 weeks and then biweekly. Moist or wet-to-dry dressings Conventional therapy

Strauss 1991 *(Continued)*

- **Description of interventions**: including alternating pressure pads, air support mattresses, water mattresses, and high-density foam pads
- **NPIAP S3I classification**: standard hospital surfaces
- **Number of participants randomised**: 54
- **Number of participants analysed**: 50
- **Co-interventions**: moist or wet-to-dry dressings

Outcomes

Proportion of participants with pressure ulcers healed

- **Outcome type**: binary
- **Time points**: 36 weeks
- **Reporting**: partially reported
- **Definition and measurement method (e.g. scale, self-reporting)**: healing to 2nd stage or better. Ulcer categorised using Shea stages: 1st stage is the epidermis, with acute inflammatory response in all soft tissue; a 2nd stage is acute and chronic inflammation that involves the dermis; a 3rd stage is an inflammatory reaction with fibrosis extending into subcutaneous tissues: and a 4th stage extends beyond the deep fascia and involves muscle or bone.
- **Dropouts and reasons**: 11 completely dropped off in air-fluidised bed; 4 completely dropped off in control.
- **Data and results**: 29 of 47 patients healed to 2nd stage or better; data not reported for control group.
- **Notes (e.g. other results reported)**: compared with control patients, a higher proportion of air-fluidised bed therapy patients was classified as improved, although the difference was not significant.

Time to pressure ulcer healing

- **Not reported**

Support-surface-associated patient comfort

- **Not reported**

All reported adverse events

- **Notes (e.g. other results reported)**: 14 died in air-fluidised bed; 19 died in control. Several patients noted dry skin, and 1 experienced mild dehydration (among those using air-fluidised bed).

Health-related quality of life (HRQOL)

- **Not reported**

Cost-effectiveness

- **Reporting**: not reported
- **Notes (e.g. other results reported)**: total medical charges per patients mean $29,016 (SD $19,484) in air-fluidised bed; $34,747 ($37,499) in control group. The total charges for control patients were 20% higher over the 36 weeks, although the difference was not statistically significant (P = 0.34).

Outcomes that are not considered in this review but reported in trials:

- Medicare payment costs per patient
- Safety and Efficacy
- Length of stay hospitalisation

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement

Strauss 1991 *(Continued)*

Random sequence generation (selection bias)	Low risk	Quote: “Using forms created by a computerized random number-generating system, the study physician or nurse would assign the patient to either the air-fluidized bed therapy group or the control group” Comment: low risk of bias.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: ulcer healing*** Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	***Outcome group: ulcer healing*** Quote: “assessed clinical outcome through reviews by two independent nurses … who were blinded to treatment category” Comment: low risk of bias.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	***Outcome group: ulcer healing*** Quote: "Excluding patients in the 'completely dropped' category, there were 47 patients in the group that received air-fluidized bed therapy and 50 patients in the control group who were receiving conventional therapy" Comment: unclear risk of bias due to the moderate level of dropout and the unspecified dropout reasons.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Andersen 1982	Prevention study
Andrews 1988	Ineligible study design - not an RCT
Anonymous 2006	Ineligible study design - review article
Aronovitch 1999	Prevention study
Ballard 1997	Prevention study
Beeckman 2019	Prevention study
Bell 1993	Ineligible study design - not an RCT
Bennett 1998	Prevention study

Study	Reason for exclusion
Berthe 2007	Prevention study
Bliss 1966	Ineligible study design - not an RCT
Bliss 1967	Prevention study
Bliss 1993	Ineligible study design - review article
Bliss 1995a	Prevention study
Bliss 1995b	Ineligible study design - review article
Bliss 2003	Reproduction of previous work
Bliss 2004	Commentary on a trial
Branom 1999	Incorrect randomisation (treatment study; alternate randomisation)
Branom 2001	Incorrect randomisation (treatment study; alternate randomisation)
Brown 2001	Summary of the Cochrane Review McInnes 2015
Bueno de Camargo 2018	Prevention study
Cadue 2008	This RCT was to compare heel suspending device with the package of interventions
Caley 1994	Ineligible outcomes (did not report any relevant outcome)
Cassino 2013b	Prevention study
Cavicchioli 2007	Prevention study
Chaloner 2000a	Incorrect randomisation method (quasi-randomisation)
ChiCTR1800017466	Ineligible interventions
Chou 2013	Review articles
Cobb 1997	Prevention study
Collier 1996	Prevention study
Conine 1990	Prevention study
Cooper 1998	Prevention study
Cummins 2019	Ineligible study design - quality improvement project without RCT design
Daechsel 1985	Prevention study
Defloor 2005	Ineligible interventions - different combinations of turning and support surfaces under evaluations
Demarre 2012	Prevention study

Study	Reason for exclusion
De Oliveira 2017	Review article
Economides 1995	This RCT was to observe the breakdown of flaps after operations rather than the incidence of new ulcers
Ewing 1964	Prevention study
Exton-Smith 1982	This trial used alternation to allocate patients into groups. Proper randomisation not completed.
Feuchtinger 2006	Prevention study
Finnegan 2008	Prevention study
Fleischer 1997	Ineligible study design
García Fernández 2004	Commentary on an RCT
Gardner 2008	Prevention study
Gazzerro 2008	Ineligible outcome (wound healing of flap surgery)
Gebhardt 1994a	Incorrect randomisation method (randomisation based on participants' hospital numbers)
Gebhardt 1994b	Incorrect randomisation method (randomisation based on participants' hospital numbers)
Gebhardt 1996	Incorrect randomisation method
Geelkerken 1994	Commentary
Goldstone 1982	Incorrect randomisation method
Gray 1994	Prevention study
Gray 2000	Prevention study
Gray 2008	Prevention study
Greer 1988	Ineligible study design (treatment study; case control design)
Grindley 1996	Prevention study
Gunningberg 2000	Prevention study
Gunningberg 2001	Ineligible study design (cross sectional design)
Haalboom 1994	Commentary
Hale 1990	Ineligible study design (cost analysis without RCT data)
Hampton 1997	Prevention study
Hampton 1998	Ineligible study design (not an RCT)

Study	Reason for exclusion
Hampton 1999	Ineligible study design (not an RCT)
Hawkins 1997	Ineligible study design (not an RCT)
Hofman 1994	Prevention study
Holzgreve 1993	Ineligible study design (not an RCT)
Hommel 2008	Ineligible study design (not an RCT)
Hoshowsky 1994	Prevention study
Hoskins 2007a	Summary of findings of Nixon 2006
Hoskins 2007b	Summary of findings of Nixon 2006
Huang 2013	Review article
Huang 2018	Ineligible interventions (head pad rather than beds or mattresses)
Hungerford 1998	Commentary on a RCT
Iglesias 2006	Prevention study
Inman 1993	Prevention study
IRCT2015110619919N3	Prevention study
IRCT2016091129781N1	Prevention study
Ismail 2001	Prevention study
Jiang 2014	Prevention study
Jolley 2004	Prevention study
Kemp 1993	Prevention study
Keogh 2001	Prevention study
Klein 1989	Review article
Laurent 1998	Prevention study
Lazzara 1991	Prevention study
Lee 1974	Ineligible study design (not an RCT)
Maklebust 1988	Prevention study
Malbrain 2010	Prevention study
Marutani 2019	Incorrect randomisation method
Mastrangelo 2010a	Incorrect randomisation (treatment study; alternate randomisation)

Study	Reason for exclusion
Mastrangelo 2010b	Prevention study
McGinnis 2011	Review article
McGowan 2000	Prevention study
McInnes 2015	Review article
McInnes 2018	Review article
Mendoza 2019	Ineligible participants and outcome (flap closure)
Mistiaen 2010a	Prevention study
Mistiaen 2010b	Prevention study
Nakahara 2012	Ineligible study design (not an RCT)
NCT01402765	Ineligible outcome (interface pressure)
NCT02565797	Ineligible study design (case control design)
NCT02634892	Prevention study
NCT02735135	Prevention study
NCT03048357	Prevention study
NCT03211910	Prevention study
NCT03351049	Prevention study
Nixon 1998	Prevention study
Nixon 2006	Prevention study
Nixon 2019	Prevention study
Ooka 1995	Ineligible study design (not an RCT)
Osterbrink 2005	Ineligible outcome (not reported any relevant outcome)
Ozyurek 2015	Prevention study
Park 2017	Prevention study
Phillips 1999	Prevention study
Price 1999	Prevention study
Pring 1998	Prevention study
Rae 2018	Review article
Rafter 2011	Prevention study

Study	Reason for exclusion
Reddy 2006	Review article
Reddy 2008	Review article
Ricci 2013a	Prevention study
Ricci 2013b	Duplicate record
Rithalia 1995	Ineligible participants (healthy people)
Rosenthal 2003	Prevention study
Russell 2000b	Prevention study
Russell 2003a	Ineligible outcome (did not report any relevant outcome)
Russell 2003b	Prevention study
Sanada 2003	Prevention study
Santy 1994	Prevention study
Santy 1995	Review article
Sauvage 2017	Prevention study
Scheffel 2011	Summary of a review
Schultz 1999	Prevention study
Scott 2000	Prevention study
Scott-Williams 2006	Ineligible study design (not an RCT)
Serraes 2018	Review article
Shakibamehr 2019	Ineligible interventions (cushions rather than beds or mattresses)
Sharp 2007	Ineligible study design
Shi 2018a	Review article
Sideranko 1992	Prevention study
Smith 2013	Review article
Stannard 1993	Commentary on an RCT
Stapleton 1986	Prevention study
Sterzi 2003	Ineligible study design (not an RCT)
Takala 1994	Ineligible study design (not an RCT)
Takala 1996	Prevention study

Study	Reason for exclusion
Taylor 1999	Prevention study
Tewes 1993	Review article
Theaker 2005	Prevention study
Vanderwee 2005	Prevention study
Van Leen 2011	Prevention study
Van Leen 2013	Prevention study
Van Leen 2018	Prevention study
Van Rijswijk 1994	Commentary
Vermette 2012	Prevention study
Vyhlidal 1997	Prevention study
Wallace 2009	Review article
Whitney 1984	Prevention study
Whittingham 1999	Prevention study
Yao 2018	Review article

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

Chaloner 2000b

Methods	Not available
Participants	Not available
Interventions	Two types of alternating pressure air surfaces.
Outcomes	Not available
Notes	Unable to obtain its full text.

Henn 2004

Methods	Not available
Participants	Not available
Interventions	Alternating pressure air surfaces and a type of surface that cannot be defined.
Outcomes	Not available

Henn 2004 *(Continued)*

Notes	Unable to obtain its full text.

Knight 1999

Methods	Not available
Participants	Not available
Interventions	Pressure relieving surfaces that cannot be defined.
Outcomes	Not available
Notes	Unable to obtain its full text.

Melland 1998

Methods	Not available
Participants	Not available
Interventions	'Freedom bed' that cannot be defined.
Outcomes	Not available
Notes	Unable to obtain its full text.

Characteristics of ongoing studies *[ordered by study ID]*

ACTRN12618000319279

Study name	Comparison of active and reactive pressure mattresses in the treatment of Stage 2, unstageable pressure injuries and Suspected Deep Tissue Injuries for people over 50 years residing in the community
Methods	Randomised controlled trial Randomisation methods: central randomisation by computer; eligible participants will be allocated to groups by an online random number generator between 1 and 2. Blinding: the people assessing the outcomes, the people analysing the results/data blinded.
Participants	Eligibility criteria: 1. aged 50 years or older 2. residing in a community setting i.e. in a private home 3. existing Stage 2 pressure injury, unstageable pressure injury or Suspected Deep Tissue Injury - any location or aetiology 4. have a bed that is appropriate for the support surfaces 5. inability to re-position off the pressure injury

ACTRN12618000319279 *(Continued)*

	Sample size: a priori sample was determined for a total sample of n = 80 to aim for a minimum final total sample of n = 60 (n = 30 for each group, utilising the central limit theorem) after allowing for withdrawals.
Interventions	Interventions: Provision of a reactive pressure mattress chosen from a range of mattresses (following list is not exhaustive): - ROHO overlay (3x ROHO sections and 1x foam section) - Curocell AreaZone mattress replacement - Curocell SAM mattress overlay - Softform Premier mattress replacement - Pressureguard CFT mattress replacement - BetterLiving Triple layer mattress replacement Provision of an active pressure mattress chosen from a range of mattresses (following list is not exhaustive): - Curocell Uno mattress replacement - Viruoso mattress replacement - Salsbury mattress overlay - Premium Digital 9 mattress replacement - Premium Digital 5 mattress overlay
Outcomes	1. Time to complete healing of the primary pressure injury as determined by the Revised Photographic Wound Assessment Tool (RevPWAT). 2. Rate of healing will be used as determined by changes in RevPWAT points over time (RevPWAT baseline score - RevPWAT 8 week score)/8 (no. of weeks in study). 3. User acceptability of the provided mattress as determined by a survey designed specifically for this study. 4. Changes in sleeping habits as determined by a survey designed specifically for this study. 5. Changes in pain levels as determined by a 10-point pain scale and subjective comments from a survey designed specifically for this study.
Starting date	26 March 2018
Contact information	Mrs Katherine E Rae Address Occupational Therapist, ACT Health Directorate: Canberra, Australian PhD Candidate, University of Canberra; Canberra, Australia Village Creek Health Centre, 37 Kingsmill St, Kambah, ACT, 2905, AustraliaCountry AustraliaPhone +61 2 5124 1057Fax Email katherine.rae@act.gov.au
Notes	

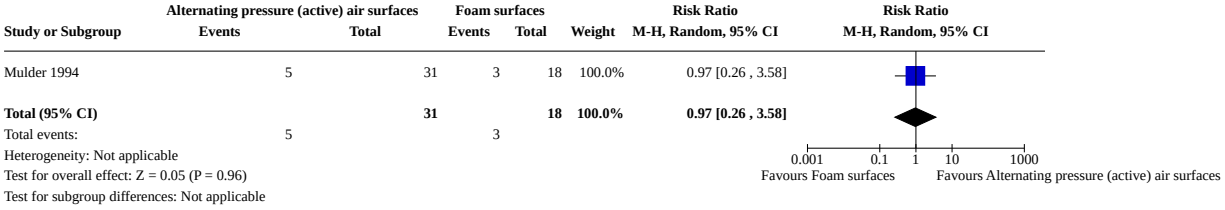
JPRN-UMIN000029680	
Study name	Effects of robotic mattress on pressure ulcer healing, comfort level among pressure ulcer patients, and nursing work load: a randomised controlled trial
Methods	randomised controlled trial
Participants	Eligibility criteria: 1. More than 20 years old 2. Male and female 3. Patients with pressure ulcers in their sacral, coccyx, ischial tuberosity, greater trochanter, or heel
Interventions	Not specified
Outcomes	1. Wound healing rate within 3 weeks 2. Patient comfort level 3. Nursing work load
Starting date	1 November 2017
Contact information	Aya Kitamura Address Faculty of Medicine Bldg. 5-301, 7-3-1, Hongo, Bunkyo-ku, Tokyo,Japan Japan Telephone 03-5841-3451 E-mail ktmr-tky@umin.ac.jp Affiliation The University of Tokyo Graduate School of Medicine
Notes	

DATA AND ANALYSES

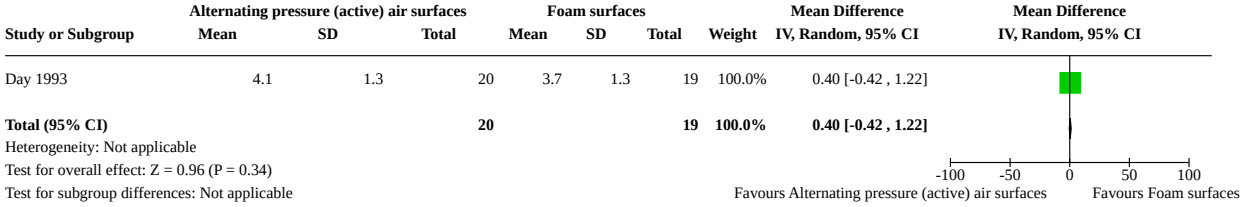
Comparison 1. Alternating pressure (active) air surfaces compared with foam surfaces

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Proportion of participants with pressure ulcers completely healed	1	49	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.26, 3.58]
1.2 Support surface associated patient comfort	1	39	Mean Difference (IV, Random, 95% CI)	0.40 [-0.42, 1.22]

Analysis 1.1. Comparison 1: Alternating pressure (active) air surfaces compared with foam surfaces, Outcome 1: Proportion of participants with pressure ulcers completely healed



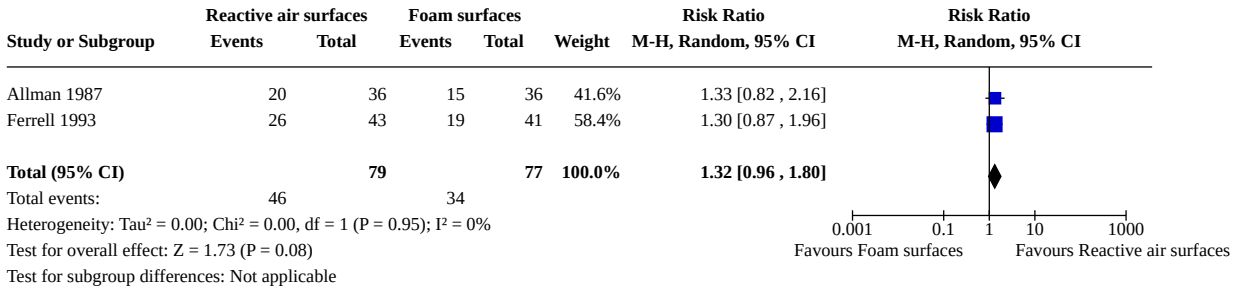
Analysis 1.2. Comparison 1: Alternating pressure (active) air surfaces compared with foam surfaces, Outcome 2: Support surface associated patient comfort



Comparison 2. Reactive air surfaces compared with foam surfaces

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Proportion of participants with pressure ulcers completely healed	2	156	Risk Ratio (M-H, Random, 95% CI)	1.32 [0.96, 1.80]

Analysis 2.1. Comparison 2: Reactive air surfaces compared with foam surfaces, Outcome 1: Proportion of participants with pressure ulcers completely healed



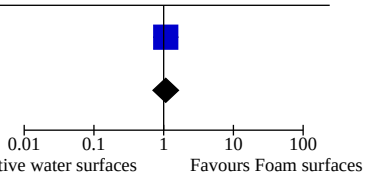
Comparison 3. Reactive water surfaces compared with foam surfaces

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Proportion of participants with pressure ulcers completely healed	1	101	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.70, 1.63]

Analysis 3.1. Comparison 3: Reactive water surfaces compared with foam surfaces, Outcome 1: Proportion of participants with pressure ulcers completely healed

Study or Subgroup	Reactive water surfaces Events	Total	Foam surfaces Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Groen 1999	25	52	22	49	100.0%	1.07 [0.70 , 1.63]
Total (95% CI)		**52**		**49**	**100.0%**	**1.07 [0.70 , 1.63]**
Total events:	25		22			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.32 (P = 0.75)
Test for subgroup differences: Not applicable



ADDITIONAL TABLES

Table 1. All reported adverse events

Study ID	Results		Comment
Comparison: reactive air surfaces versus foam surfaces			
Allman 1987	8 died, 2 pneumonia, 10 urinary tract infections, 6 hypotension, 5 hypernatraemia, 5 oliguria, 7 sepsis, 16 fever, and 3 heart failure	7 died, 4 pneumonia, 7 urinary tract infections, 7 hypotension, 5 hypernatraemia, 8 oliguria, 6 sepsis, 22 fever, and 6 heart failure on conventional therapy	Some participants may have had multiple adverse events.
Ferrell 1993	11 of 43 participants died	7 of 41 died	The deaths were unlikely related to the use of specific support surfaces.
Comparison: foam surfaces versus reactive water surfaces			
Groen 1999	Percentage of participants with complications at week 4 • Eczema: no data; • Maceration: 4.1%; • Pain: 4.1%	Percentage of participants with complications at week 4 • Eczema: no data; • Maceration: 3.8%; • Pain: 3.8%	
Comparison: alternating pressure (active) air surfaces (Nimbus system) versus alternating pressure (active) air surfaces (Pegasus system)			
Devine 1995	5 of 22 participants died	4 of 19 participants died	The deaths were unlikely related to the use of specific support surfaces.
Evans 2000a	1 of 7 participants developed methicillin-resistant *Staphylococcus aureus* (MRSA)	2 of 5 participants died	The deaths were unlikely related to the use of specific support surfaces.
Evans 2000b	7 of 10 participants died	1 of 10 participants died	The deaths were unlikely related to the use of specific support surfaces.
Russell 2000a	16 of 57 participants died	10 of 55 participants died	The deaths were unlikely related to the use of specific support surfaces.

Table 2. Pressure ulcer healing outcome results reported in studies that compared different types of alternating pressure (active) air surfaces

Study ID	Results		Comment
Comparison: alternating pressure (active) air surfaces compared with other types of alternating pressure (active) air surfaces			
Devine 1995	Alternating pressure (active) air surfaces (Nimbus I DFS) • Proportion of participants with pressure ulcers completely healed: 10/16 (62.5%)	Alternating pressure (active) air surfaces (Pegasus Airwave) • Proportion of participants with pressure ulcers completely healed: 5/14 (35.7%)	• Proportion of participants with pressure ulcers completely healed: RR 1.75 (95% CI 0.79 to 3.89).
Evans 2000a	Alternating pressure (active) air surfaces (Nimbus 3) • Proportion of participants with pressure ulcers completely healed: 3/7 (42.9%)	Alternating pressure (active) air surfaces (Pegasus Airwave, Pegasus Biwave and AlphaXcell, or Pegasus Cairwave) • Proportion of participants with pressure ulcers completely healed: 0/5 (0.0%)	• Proportion of participants with pressure ulcers completely healed: RR 5.25 (95% CI 0.33 to 83.59).
Evans 2000b	Alternating pressure (active) air surfaces (Nimbus 3) • Proportion of participants with pressure ulcers completely healed: 1/10 (10.0%)	Alternating pressure (active) air surfaces (Pegasus AlphaXcell, and Quattro) • Proportion of participants with pressure ulcers completely healed: 5/10 (50.0%)	• Proportion of participants with pressure ulcers completely healed: RR 0.20 (95% CI 0.03 to 1.42).
Russell 2000a	Alternating pressure (active) air surfaces (Nimbus 3) • Proportion of participants with pressure ulcers completely healed: 24/55 (43.6%)	Alternating pressure (active) air surfaces (Pegasus Cairwave therapy system) • Proportion of participants with pressure ulcers completely healed: 17/58 (29.3%)	• Proportion of participants with pressure ulcers completely healed: RR 1.49 (95% CI 0.90 to 2.45). • The study authors claimed no statistical difference between groups for improvement or healing of sacral pressure sores; Nimbus 3 has statistically significant difference for the healing of heel sores.

Table 3. Support-surface-associated patient comfort

Study ID	Results		Comment
Comparison: alternating pressure (active) air surface type (Nimbus system) versus alternating pressure (active) air surface type (Pegasus system)			
Devine 1995	Median 8 (range 5 to 10)	Median 8 (range 3 to 10)	• This outcome was self-reported patient comfort (how comfortable the test mattress felt to lie on) measured using a simple 10 point linear scale (probably higher = better). Only a limited number of participants responded to the scale and 13 of 22 participants in the Nimbus system and 8 of 19 in the Air-

Table 3. Support-surface-associated patient comfort *(Continued)*

			wave system dropped out due to general illness and dementia.
Evans 2000a	Median 5 (range 5 to 5)	Median 4 (range 4 to 5)	• Participants indicated the comfort of their mattress using a 5-point scale. • Mann-Whitney U test P = 0.006
Evans 2000b	Median 5 (range 3 to 5)	Median 4 (2 to 5)	• Participants indicated the comfort of their mattress using a 5-point scale. • Mann-Whitney U test P = 0.002
Russell 2000a	Participants in both study arms were equally comfortable (no statistical difference).	Participants in both study arms were equally comfortable (no statistical difference).	• Participants' opinions on the comfort of the bed measured by an observer from the clinical audit team using digital analogue scales on a 10-point scale derived from the British furniture industry standard scale and then converted into a 5-point scale ranging from 'very uncomfortable' to 'very comfortable'. Results were presented by specific question items of the scale.

APPENDICES

Appendix 1. Full details of support surfaces classifications

Overarching class of support surface (as used in this review)	Corresponding subclasses of support surfaces used in Shi 2018b	Descriptions of support surfaces	Selected examples (with example brands where possible)
Reactive air surfaces	Powered/non-powered reactive air surfaces	A group of support surfaces constructed of air cells, which redistribute body weight over a maximum surface area (i.e. has reactive pressure redistribution mode), with or without the requirement for electrical power.	Static air mattress overlay, dry flotation mattress (e.g. Roho, Sofflex), static air mattress (e.g. EHOB), and static mode of Duo 2 mattress.
	Powered/non-powered reactive low-air-loss air surfaces	A group of support surfaces made of air cells, which have reactive pressure redistribution modes and a low-air-loss function, with or without the requirement for electrical power.	Low-air-loss hydrotherapy.
	Powered reactive air-fluidised surfaces	A group of support surfaces made of air cells, which have reactive pressure redistribution modes and an air-fluidised function, with the requirement for electrical power.	Air-fluidised bed (e.g. Clinitron).
Foam surfaces	Non-powered reactive foam surfaces	A group of support surfaces made of foam materials, which have a reactive pressure redistribution function, without the requirement for electrical power.	Convoluted foam overlay (or pad), elastic foam overlay (e.g. microfluid static overlay), polyether foam pad, foam mattress replacement (e.g. MAXIFLOAT), solid foam overlay, viscoelastic foam mattress/overlay (e.g.

(Continued)

			Tempur, CONFOR-Med, Akton, Thermo).
Alternative reactive support surfaces (non-foam or air-filled): reactive fibre surfaces	Non-powered reactive fibre surfaces	A group of support surfaces made of fibre materials, which have a reactive pressure redistribution function, without the requirement for electrical power.	Silicore (e.g. Spenco) overlay/pad.
Alternative reactive support surfaces (non-foam or air-filled): reactive gel surfaces	Non-powered reactive gel surfaces	A group of support surfaces made of gel materials, which have a reactive pressure redistribution function, without the requirement for electrical power.	Gel mattress, gel pad used in operating theatre.
Alternative reactive support surfaces (non-foam or air-filled): reactive sheepskin surfaces	Non-powered reactive sheepskin surfaces	A group of support surfaces made of sheepskin, which have a reactive pressure redistribution function, without the requirement for electrical power.	Australian Medical Sheepskins overlay.
Alternative reactive support surfaces (non-foam or air-filled): reactive water surfaces	Non-powered reactive water surfaces	A group of support surfaces based on water, which has the capability of a reactive pressure redistribution function, without the requirement for electrical power.	Water mattress.
Alternating pressure (active) air surfaces	Powered active air surfaces	A group of support surfaces made of air cells, which mechanically alternate the pressure beneath the body to reduce the duration of the applied pressure (mainly via inflating and deflating to alternately change the contact area between support surfaces and the body; i.e. alternating pressure, or active, mode), with the requirement for electrical power.	Alternating pressure-relieving air mattress (e.g. Nimbus II, Cairwave, Airwave, MicroPulse), large-celled ripple.
	Powered active low-air-loss air surfaces	A group of support surfaces made of air cells, which have the capability of alternating pressure redistribution as well as low air loss for drying local skin, with the requirement for electrical power.	Alternating pressure low-air-loss air mattress.
	Powered hybrid system air surfaces	A group of support surfaces made of air cells, which offer both reactive and active pressure redistribution modes, with the requirement for electrical power.	Foam mattress with dynamic and static modes (e.g. Softform Premier Active).
	Powered hybrid system low-air-loss air surfaces	A group of support surfaces made of air cells, which offer both reactive and active pressure redistribution modes as well as a low-air-loss function, with the requirement for electrical power.	Stand-alone bed unit with alternating pressure, static modes and low air-loss (e.g. TheraPulse).
Standard hospital surfaces	Standard hospital surfaces	A group of support surfaces made of any materials, used as-usual in a hospital and without reactive nor active pressure redistribution capabilities, nor any other functions (e.g. low-air-loss, or air-fluidised).	Standard hospital (foam) mattress, NHS Contract hospital mattress, standard operating theatre surface configuration, standard bed unit and usual care.

Appendix 2. Search strategies

Cochrane Wounds Specialised Register

1 MESH DESCRIPTOR beds EXPLODE ALL AND INREGISTER

2 mattress* AND INREGISTER

3 (foam or transfoam) AND INREGISTER

4 overlay* AND INREGISTER

5 (pad or pads) AND INREGISTER

6 gel AND INREGISTER

7 (pressure NEXT relie*) AND INREGISTER

8 (pressure NEXT reduc*) AND INREGISTER

9 (pressure NEXT alleviat*) AND INREGISTER

10 ("low pressure" near2 device*) AND INREGISTER

11 ("low pressure" near2 support) AND INREGISTER

12 (constant near2 pressure) AND INREGISTER

13 "static air" AND INREGISTER

14 (alternat* next pressure) AND INREGISTER

15 (air next suspension*) AND INREGISTER

16 (air next bag*) AND INREGISTER

17 (water next suspension*) AND INREGISTER

18 sheepskin AND INREGISTER

19 (turn* or tilt*) next (bed* or frame*) AND INREGISTER

20 kinetic next (therapy or table*) AND INREGISTER

21 (net next bed*) AND INREGISTER

22 #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 AND INREGISTER

23 MESH DESCRIPTOR Pressure Ulcer EXPLODE ALL AND INREGISTER

24 (pressure next (ulcer* or sore* or injur*)) AND INREGISTER

25 (decubitus next (ulcer* or sore*)) AND INREGISTER

26 ((bed next sore*) or bedsore*) AND INREGISTER

27 #23 OR #24 OR #25 OR #26 AND INREGISTER

28 #22 AND #27 AND INREGISTER

The Cochrane Central Register of Controlled Clinical Trials (CENTRAL)

#1 MeSH descriptor: [Beds] explode all trees

#2 mattress*:ti,ab,kw

#3 (foam or transfoam):ti,ab,kw

#4 overlay*:ti,ab,kw

#5 "pad" or "pads":ti,ab,kw

#6 "gel":ti,ab,kw

#7 (pressure next relie*):ti,ab,kw

#8 (pressure next reduc*):ti,ab,kw

#9 (pressure next alleviat*):ti,ab,kw

#10 ("low pressure" near/2 device*):ti,ab,kw

#11 ("low pressure" near/2 support):ti,ab,kw

#12 (constant near/2 pressure):ti,ab,kw

#13 "static air":ti,ab,kw

#14 (alternat* next pressure):ti,ab,kw

#15 (air next suspension*):ti,ab,kw

#16 (air next bag*):ti,ab,kw

#17 (water next suspension*):ti,ab,kw

#18 sheepskin:ti,ab,kw

#19 (turn* or tilt*) next (bed* or frame*):ti,ab,kw

#20 kinetic next (therapy or table*):ti,ab,kw

#21 (net next bed*):ti,ab,kw

#22 {or #1-#21}

#23 MeSH descriptor: [Pressure Ulcer] explode all trees

#24 (pressure next (ulcer* or sore* or injur*)):ti,ab,kw

#25 (decubitus next (ulcer* or sore*)):ti,ab,kw

#26 ((bed next sore*) or bedsore*):ti,ab,kw

#27 {or #23-#26}

#28 (#22 and #27) in Trials

Ovid MEDLINE

1 exp Beds/

2 mattress*.mp.

3 (foam or transfoam).mp.

4 overlay*.mp.

5 (pad or pads).ti,ab.

6 gel.ti,ab.

7 pressure relie*.mp.

8 pressure reduc*.mp.

9 pressure alleviat*.mp.

10 (low pressure adj2 device*).mp.

11 (low pressure adj2 support).mp.

12 (constant adj2 pressure).mp.

13 static air.mp.

14 (alternat* adj pressure).mp.

15 air suspension*.mp.

16 air bag*.mp.

17 water suspension*.mp.

18 sheepskin.mp.

19 ((turn* or tilt*) adj (bed* or frame*)).mp.

20 (kinetic adj (therapy or table*)).mp.

21 net bed*.mp.

22 or/1-21

23 exp Pressure Ulcer/

24 (pressure adj (ulcer* or sore*)).mp.

25 (decubitus adj (ulcer* or sore*)).mp.

26 (bed adj (ulcer* or sore*)).mp.

27 or/23-26

28 and/22,27

29 randomized controlled trial.pt.

30 controlled clinical trial.pt.

31 randomi?ed.ab.

32 placebo.ab.

33 clinical trials as topic.sh.

34 randomly.ab.

35 trial.ti.

36 or/29-35

37 exp animals/ not humans.sh.

38 36 not 37

39 28 and 38

Ovid Embase

1 exp Bed/

2 mattress*.mp.

3 (foam or transfoam).mp.

4 overlay*.mp.

5 (pad or pads).ti,ab.

6 gel.ti,ab.

7 pressure relie*.mp.

8 pressure reduc*.mp.

9 pressure alleviat*.mp.

10 (low pressure adj2 device*).mp.

11 (low pressure adj2 support).mp.

12 (constant adj2 pressure).mp.

13 static air.mp.

14 (alternat* adj pressure).mp.

15 air suspension*.mp.

16 air bag*.mp.

17 water suspension*.mp.

18 sheepskin.mp.

19 ((turn* or tilt*) adj (bed* or frame*)).mp.

20 (kinetic adj (therapy or table*)).mp.

21 net bed*.mp.

22 or/1-21

23 exp Decubitus/

24 (pressure adj (ulcer* or sore*)).mp.

25 (decubitus adj (ulcer* or sore*)).mp.

26 (bed adj (ulcer* or sore*)).mp.

27 or/23-26

28 and/22,27

29 Randomized controlled trials/

30 Controlled clinical study/

31 Single-Blind Method/

32 Double-Blind Method/

33 Crossover Procedure/

34 (random* or factorial* or crossover* or cross over* or cross-over* or placebo* or assign* or allocat* or volunteer*).ti,ab.

35 (doubl* adj blind*).ti,ab.

36 (singl* adj blind*).ti,ab.

37 or/29-36

38 exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/

39 human/ or human cell/

40 and/38-39

41 38 not 40

42 37 not 41

43 28 and 42

EBSCO CINAHL Plus

S50 S26 AND S49

S49 S48 NOT S47

S48 S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41

S47 S45 NOT S46

S46 MH (human)

S45 S42 OR S43 OR S44

S44 TI (animal model*)

S43 MH (animal studies)

S42 MH animals+

S41 AB (cluster W3 RCT)

S40 MH (crossover design) OR MH (comparative studies)

S39 AB (control W5 group)

S38 PT (randomized controlled trial)

S37 MH (placebos)

S36 MH (sample size) AND AB (assigned OR allocated OR control)

S35 TI (trial)

S34 AB (random*)

S33 TI (randomised OR randomized)

S32 MH cluster sample

S31 MH pretest-posttest design

S30 MH random assignment

S29 MH single-blind studies

S28 MH double-blind studies

S27 MH randomized controlled trials

S26 S20 AND S25

S25 S21 OR S22 OR S23 OR S24

S24 TI decubitus or AB decubitus

S23 TI (bed sore* or bedsore*) or AB (bed sore* or bedsore*)

S22 TI (pressure ulcer* or pressure sore*) or AB (pressure ulcer* or pressure sore*)

S21 (MH "Pressure Ulcer")

S20 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

S19 TI net bed* or AB net bed*

S18 TI (kinetic therapy or kinetic table*) or AB (kinetic therapy or kinetic table*)

S17 TI (turn* bed* or tilt* bed*) or AB (turn* frame* or tilt* frame*)

S16 TI sheepskin OR AB sheepskin

S15 TI water suspension or AB water suspension

S14 TI air bag* or AB air bag*

S13 TI air suspension or AB air suspension

S12 TI alternat* pressure or AB alternat* pressure

S11 TI static air or AB static air

S10 TI constant N2 pressure or AB constant N2 pressure

S9 TI low pressure N2 support or AB low pressure N2 support

S8 TI low pressure N2 device* or AB low pressure N2 device*

S7 TI pressure alleviat* or AB pressure alleviat*

S6 TI pressure reduc* or AB pressure reduc*

S5 TI pressure relie* or AB pressure relie*

S4 TI (overlay* or pad or pads or gel) or AB (overlay* or pad or pads or gel)

S3 TI (foam or transfoam) or AB (foam or transfoam)

S2 TI mattress* or AB mattress*

S1 (MH "Beds and Mattresses+")

US National Institutes of Health Ongoing Trials Register (ClinicalTrials.gov)

bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air | Pressure Ulcer

bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air | Pressure Injury

bed OR mattress OR sheepskin OR gel OR pad OR foam OR pressure OR support OR air | Pressure Ulcers buttock

bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air | Ulcer, Pressure

bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air | Pressure Ulcer Stage 1

bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air | Pressure Ulcers Stage II

bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air | Pressure Ulcers Stage III

World Health Organization International Clinical Trials Registry Platform

pressure ulcer [title] and bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air [intervention]

pressure ulcer [condition] and bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air [intervention]

pressure injury [title] and bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air [intervention]

pressure injury [condition] and bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air [intervention]

Appendix 3. Risk of bias

1 'Risk of bias' assessment in individually randomised controlled trials

1. Was the allocation sequence randomly generated?

Low risk of bias

The study authors 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 study authors 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 study authors 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 study authors enrolling participants could possibly foresee assignments and thus introduce selection bias, e.g. allocation was based on using an open random allocation schedule (e.g. a list of random numbers), assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or 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 by participants and personnel adequately prevented during the study?

Low risk of bias

Any one of the following.

- No blinding, but the review authors judge that the outcome is 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.

High risk of bias

Any one of the following.

- No blinding or incomplete blinding, and the outcome 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 is likely to introduce bias.

Unclear

Any one of the following.

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

4. Blinding: was knowledge of the allocated interventions by outcome assessors adequately prevented during the study?

Low risk of bias

Any one of the following.

- No blinding, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding.
- Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.

High risk of bias

Any one of the following.

- No blinding or incomplete blinding, and the outcome measurement is likely to be influenced by lack of blinding.
- Blinding of outcome assessment attempted, but likely that the blinding could have been broken.

Unclear

Any one of the following.

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

5. 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 is not sufficient to have a clinically relevant impact on the intervention effect estimate.
- For continuous outcome data, the plausible effect size (difference in means or standardised difference in means) among missing outcomes is not sufficient 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 is likely to be related to the 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 is sufficient to induce clinically relevant bias in intervention effect estimate.
- For continuous outcome data, the plausible effect size (difference in means or standardised difference in means) among missing outcomes is sufficient to induce clinically relevant bias in the 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

Any one 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.

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

Low risk of bias

Any of the following.

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

High risk of bias

Any one of the following.

- Not all of the study's prespecified primary outcomes have been reported.
- One or more primary outcomes are reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not prespecified.
- One or more reported primary outcomes were not prespecified (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.

7. 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
- 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.

2 'Risk of bias' assessment in cluster-randomised controlled trials (cluster-RCTs)

1. Recruitment bias

Recruitment bias (or identification bias) is the bias that occurs in cluster-RCTs if the personnel recruiting participants know individuals' allocation, even when the allocation of clusters has been concealed appropriately. The knowledge of the allocation of clusters may lead to bias because the individuals' recruitment in cluster trials is often behind the clusters' allocation to different interventions; and the knowledge of allocation can determine whether individuals are recruited selectively.

This bias can be judged through considering the following questions.

- Were all the individual participants identified/recruited before randomisation of clusters?
- Is it likely that selection of participants was affected by knowledge of the intervention?
- Were there baseline imbalances that suggest differential identification or recruitment of individual participants between arms?

2. Baseline imbalance

Baseline imbalance between intervention groups can occur due to chance, problems with randomisation, or identification/recruitment bias. The issue of recruitment bias has been considered above.

In terms of study design, the risk of chance baseline imbalance can be reduced by the use of stratified or pair-matched randomisation. Minimisation — an equivalent technique to randomisation — can be used to achieve better balance in cluster characteristics between intervention groups if there is a small number of clusters.

Concern about the influence of baseline imbalance can be reduced if studies report the baseline comparability of clusters, or statistical adjustment for baseline characteristics.

3. Loss of clusters

Similar to missing outcome data in individually randomised trials, bias can occur if clusters are completely lost from a cluster-RCT, and are omitted from the analysis.

The amount of missing data, the reasons for missingness and the way of analysing data given the missingness should be considered in assessing the possibility of bias.

4. Incorrect analysis

Data analyses, which do not take the clustering into account, in cluster-RCTs will be incorrect. Such analyses lead to a 'unit of analysis error' and over-precise results (overly small standard error) and overly small P values. Though these analyses will not result in biased estimates of effect, they (if not correctly adjusted) will lead to too much weight allocated to cluster trials in a meta-analysis.

Note that the issue of analysis may not lead to concern any more and will not be considered substantial if approximate methods are used by review authors to address clustering in data analysis.

5. Comparability with individually randomised trials

In the case that a meta-analysis includes, for example, both cluster-randomised and individually randomised trials, potential differences in the intervention effects between different trial designs should be considered. This is because the 'contamination' of intervention effects may occur in cluster-RCTs, which would lead to underestimates of effect. The contamination could be known as a 'herd effect': that is, within clusters, individuals' compliance with using an intervention may be enhanced, which in return affects the estimation of effect.

Appendix 4. Interventions used in the included studies

Study ID	Specific support surfaces	Specific comparators
Comparison: alternating pressure (active) air surfaces versus alternating pressure (active) air surfaces		
Devine 1995	Nimbus I DFS (HNE Healthcare, Luton, UK), 2 alternative sets of cells are inflated and deflated over a 10 minute cycle. • **NPIAP S3I classification**: powered, alternating pressure (active) air surfaces.	Airwave mattress (Pegasus, Ltd. Waterlooville), a double layer mattress with a 3 cell alternating cycle lasting 7 ½ minutes. • **NPIAP S3I classification**: powered, alternating pressure (active) air surfaces.
Evans 2000a	Nimbus 3 alternating pressure mattress replacement system. • **NPIAP S3I classification**: powered, alternating pressure (active) air surfaces.	Alternating pressure mattress overlay (Pegasus Airwave, Pegasus Biwave and AlphaXcell, and the Pegasus Cairwave). • **NPIAP S3I classification**: powered, alternating pressure (active) air surfaces.
Evans 2000b	Nimbus 3 alternating pressure mattress replacement system. • **NPIAP S3I classification**: powered, alternating pressure (active) air surfaces.	Alternating pressure mattress overlay (Pegasus Airwave, Pegasus Biwave and AlphaXcell, and the Pegasus Cairwave). • **NPIAP S3I classification**: powered, alternating pressure (active) air surfaces.
Russell 2000a	Huntleigh Nimbus 3 with the Aura cushion (Group A). • **NPIAP S3I classification**: powered, alternating pressure (active) air surfaces.	Pegasus Cairwave therapy system with the Proactive cushion (Group B). • **NPIAP S3I classification**: powered, alternating pressure (active) air surfaces.
Comparison: alternating pressure (active) air surfaces versus foam surfaces		
Day 1993	Air-suspension bed (TheraPulse, Kinetic Concepts). • **NPIAP S3I classification**: powered, alternating pressure (active) air surface.	Foam overlay (GeoMatt, SpanAmerica). • **NPIAP S3I classification**: non-powered, reactive foam surfaces.
Mulder 1994	Therapulse low air loss bed (Kinetic Concepts, Inc., San Antonio, TX). • **NPIAP S3I classification**: powered, alternating pressure (active) air surfaces; low air loss.	Geomatt mattress overlay (Span-America Inc., Greenville, SC). • **NPIAP S3I classification**: non-powered, reactive foam surfaces.

(Continued)

Comparison: reactive air surfaces versus foam surfaces		
Allman 1987	Air-fluidised bed (Clinitron Therapy, Support Systems International, Inc.) … contain ceramic beads … warm, pressurized air is forced up through the beads, on the characteristics of a fluid. • **NPIAP S3I classification**: non-powered, reactive air surfaces; air-fluidised bed.	Conventional therapy used a vinyl alternating air-mattress covered by a 19-mm thick foam pad (Lapidus Air Float System, American Pharmaceal Company) on a regular bed. • **NPIAP S3I classification**: non-powered, reactive foam surfaces.
Ferrell 1993; Ferrell 1995	Low-air-loss bed (Kinair bed, Kinetic Concepts International, San Antonio, Tex). • **NPIAP S3I classification**: powered, reactive air surface: low air loss.	10-cm convoluted foam mattress overlying a regular hospital mattress. • **NPIAP S3I classification**: powered, reactive foam surface.
Comparison: reactive air surfaces versus undefined 'standard hospital surfaces'		
Munro 1989	Clinitron bed air-fluidised support system. • **NPUAP S3I classification:** non-powered, reactive air surfaces; air-fluidised bed.	Standard bed, unspecified. • **NPUAP S3I classification**: standard hospital surfaces.
Strauss 1991	Air-fluidised bed therapy (CLINITRON Therapy Unit, Support Systems International, Charleston, SC). • **NPIAP S3I classification**: non-powered, reactive air surfaces; air-fluidised bed.	Conventional therapy (including alternating pressure pads, air support mattresses, water mattresses, and high-density foam pads). • **NPIAP S3I classification**: standard hospital surfaces.
Comparison: foam surfaces versus reactive water surfaces		
Groen 1999	Foam replacement mattress (TheraRest). • **NPIAP S3I classification**: non-powered, reactive foam surfaces.	Water mattress (Secutex) placed on top of the standard hospital mattress. • **NPIAP S3I classification**: non-powered, reactive water surfaces.
Comparison: reactive gel surfaces versus undefined reactive surfaces		
Cassino 2013a	Akton gel overlay (Akton® Overlay, Action products) (15.9 mm thick). • **NPIAP S3I classification**: non-powered, reactive gel surfaces.	Aiartex®: the three-dimensional overlay (Aiartex®, Herniamesh srl). • **NPIAP S3I classification**: non-powered, reactive undefined surfaces.

Appendix 5. Results of studies with surfaces that were not classified

Outcomes	Results
Comparison: reactive air surfaces compared with undefined 'standard hospital surfaces'	
Support surface associated patient comfort (median follow-up duration 15 days)	Only Munro 1989 (40 participants) reported this outcome defined as self-rated participant satisfaction measured using an 8-item scale with a totality of 11 points ranging from 'total dissatisfaction'

(Continued)

	to 'complete satisfaction'. In total, 18 of 40 participants responded on the scale and we analysed these data. The MD is 8.90 (95% CI 0.18 to 17.62; I^2 = 0%).
All reported adverse events (follow-up duration 15 days and 36 weeks)	Two studies (152 participants) reported this outcome (Munro 1989; Strauss 1991). We did not pool these data as the definitions of adverse events varied between studies (Appendix 6). It is uncertain if there is any difference in adverse events between reactive air surfaces and standard hospital surfaces.
Comparison: reactive gel surfaces versus undefined reactive surfaces	
Proportion of participants with pressure ulcers completely healed (follow-up duration 12 weeks)	Cassino 2013a (72 participants) reported this outcome and the proportions of participants with pressure ulcers completely healed were 13.5% (5/37) in people using reactive gel surfaces and 8.6% (3/35) in those using undefined reactive surfaces. The RR is 1.58 (95% CI 0.41 to 6.11).
Support surface associated patient comfort (follow-up duration 12 weeks)	Cassino 2013a (72 participants) reported this outcome which was defined as patient comfort with 4 responses: 'Poor', 'Fair', 'Good' and 'Excellent'. Eighteen participants using reactive gel surfaces responded with 'Poor', 12 with 'Fair', 6 with 'Good', and 1 with 'Excellent' whilst 8 participants using the undefined reactive surfaces responded with 'Poor', 13 with 'Fair', 10 with 'Good', and 4 with 'Excellent'.
All reported adverse events (follow-up duration 12 weeks)	Cassino 2013a (72 participants) reported this outcome. We did not pool these data (Appendix 6). It is uncertain if there is any difference in adverse events between reactive gel surfaces and undefined reactive surfaces.

Appendix 6. All reported adverse events in the studies involving undefined surfaces

Study ID	Results		Comment
Comparison: reactive air surfaces versus undefined 'standard hospital surfaces'			
Munro 1989	Patients' perception of pain scores reduced over time.	Patients' perception of pain scores reduced over time.	Patients' perception of pain rated using an adaptation of the Levitt and Derogatis scale and 13 of 40 participants responded. No statistical difference in pain scores between groups (F = 0.87, P = 0.359).
Strauss 1991	14 died; several patients noted dry skin, and 1 experienced mild dehydration.	19 died.	The deaths were unlikely related to the use of specific support surfaces.
Comparison: reactive gel surfaces versus undefined reactive surfaces			
Cassino 2013a	14 participants suspended in reactive gel surfaces group; majority suspended due to worsening of lesions; 7 died. Safety assessment was mentioned but not reported.	19 suspended in undefined reactive surfaces group; majority suspended due to worsening of lesions; 3 died. Safety assessment was mentioned but not reported.	

HISTORY

Protocol first published: Issue 5, 2020
Review first published: Issue 5, 2021

CONTRIBUTIONS OF AUTHORS

Chunhu Shi: conceived the review; designed the review; coordinated the review; extracted data; checked quality of data extraction; analysed or interpreted data; undertook quality assessment; performed statistical analysis; produced the first draft of the review; contributed to writing or editing the review; wrote to study authors/experts/companies; approved the final review prior to publication; is guarantor of the review.

Jo Dumville: conceived the review; designed the review; coordinated the review; checked quality of data extraction; analysed or interpreted data; checked quality of statistical analysis; produced the first draft of the review; contributed to writing or editing the review; advised on the review; secured funding; approved the final review prior to publication.

Nicky Cullum: conceived the review; designed the review; coordinated the review; checked quality of data extraction; analysed or interpreted data; contributed to writing or editing the review; advised on the review; secured funding; approved the final review prior to publication.

Sarah Rhodes: conceived the review; designed the review; checked quality of data extraction; analysed or interpreted data; checked quality assessment; checked quality of statistical analysis; contributed to writing or editing the review; advised on the review; approved the final review prior to publication.

Asmara Jammali-Blasi: checked quality of data extraction; checked quality assessment; advised on the review; performed previous work that was the foundation of the current review; approved final review prior to publication.

Victoria Ramsden: checked quality of data extraction; checked quality assessment; advised on the review; performed previous work that was the foundation of the current review; approved the final review prior to publication.

Elizabeth McInnes: conceived the review; designed the review; coordinated the review; checked quality of data extraction; analysed or interpreted data; checked quality assessment; contributed to writing or editing the review; advised on the review; performed previous work that was the foundation of the current review; approved the final review prior to publication.

Contributions of the editorial base

Gill Norman (Editor): edited the protocol; advised on methodology, interpretation and content; approved the final protocol prior to publication.
Gill Rizzello (Managing Editor): coordinated the editorial process; advised on content; edited the protocol and the review.
Sophie Bishop (Information Specialist): designed the search strategy and edited the search methods section.
Tom Patterson (Editorial Assistant): edited the reference sections of the protocol and the review.

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Chunhu Shi: I received research funding from the National Institute for Health Research (NIHR; Research for Patient Benefit, Evidence synthesis for pressure ulcer prevention and treatment, PB-PG-1217-20006). I received support from the Tissue Viability Society to attend conferences unrelated to this work. The Doctoral Scholar Awards Scholarship and Doctoral Academy Conference Support Fund (University of Manchester) also supported a PhD and conference attendance respectively; both were unrelated to this work.

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Nicky Cullum: I am Co-investigator on a National Institute for Health Research grant that funded the conduct of this review (Research for Patient Benefit, Evidence synthesis for pressure ulcer prevention and treatment, PB-PG-1217-20006). This research was co-funded by the NIHR Manchester Biomedical Research Centre, and partly funded by the National Institute for Health Research Applied Research Collaboration Greater Manchester.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

- We changed the title of this review to 'Beds, overlays and mattresses for treating pressure ulcers' whilst the title of the published protocol was 'Beds and mattresses for treating pressure ulcers' (Shi 2020).
- Two review authors independently assessed the titles and abstracts of the new search results for relevance using Rayyan rather than using Covidence.
- For new included studies, one review author independently extracted data and another review author checked all data, rather two review authors carrying out independent data extraction.
- We presented separate 'Summary of findings' tables for three of the four comparisons evaluated in this review. We did not present the table for the comparison between different types of alternating pressure (active) air surfaces.
- Where we did not pool data, we conducted a GRADE assessment and presented these assessments in a narrative format in 'Summary of findings' tables. This was not previously planned.