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Dressings and topical agents for preventing pressure ulcers (Review)

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[Intervention Review]

Dressings and topical agents for preventing pressure ulcers

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ABSTRACT

Background

Pressure ulcers occur when people cannot reposition themselves to relieve pressure over bony prominences. They are difficult to heal, costly, and reduce quality of life. Dressings and topical agents (lotions, creams, and oils) for pressure ulcer prevention are widely used. However, their effectiveness is unclear. This is the third update of this review.

Objectives

To evaluate the effects of dressings and topical agents on pressure ulcer prevention, in people of any age without existing pressure ulcers, but at risk of developing one, in any healthcare setting.

Search methods

We used the Cochrane Wounds Specialised Register, CENTRAL, MEDLINE, two other databases, and two trial registers, together with reference checking, citation searching, and contact with study authors to identify the studies that are included in the review. The latest search date was November 2022. We imposed no restrictions on language, publication date, or setting.

Selection criteria

We included randomised controlled trials that enroled people at risk of developing a pressure ulcer.

Data collection and analysis

We used standard Cochrane methodological procedures.

Main results

In this update, we added 33 new studies, resulting in a total of 51 trials (13,303 participants). Of these, 31 studies involved dressings, 16 topical agents, and four included both dressings and topical agents. All trials reported the primary outcome of pressure ulcer incidence.

Dressings

Pressure ulcer incidence

We made a total of 13 comparisons with 9027 participants. We present seven prioritised comparisons in the summary of findings (SoF) tables, as follows: silicone foam dressing versus no dressing (18 trials, 5903 participants; risk ratio (RR) 0.50, 95% confidence interval (CI) 0.33 to 0.77); foam dressing versus film dressing (3 trials, 569 participants; RR 0.72, 95% CI 0.20 to 2.67); hydrocellular foam dressing versus hydrocolloid dressing (1 trial, 80 participants; RR not estimable); silicone foam dressing type 1 versus silicone foam dressing type 2 (2 trials, 376 participants; RR 0.80, 95% CI 0.56 to 1.15); foam dressing versus fatty acid (2 trials, 300 participants; RR 1.67, 95% CI 0.49 to 5.72); polyurethane film versus hydrocolloid dressing (1 trial, 160 participants; RR 0.58, 95% CI 0.24 to 1.41); and hydrocolloid dressing versus no dressing (2 trials, 230 participants; RR 0.60, 95% CI 0.46 to 0.78). All low or very low-certainty evidence. The evidence is very uncertain about the effect of dressings on pressure ulcer development.

Pressure ulcer stage

Three comparisons reported pressure ulcer (PU) stage. Silicone foam dressing versus no dressing: PU stage 1 (8 trials, 1823 participants; RR 0.32, 95% CI 0.13 to 0.79); PU stage 2 (10 trials, 2873 participants; RR 0.47, 95% CI 0.30 to 0.73); PU stage 3 (3 trials, 718 participants; RR 0.45, 95% CI 0.06 to 3.21); PU stage 4 (2 trials, 610 participants; RR 0.21, 95% CI 0.02 to 1.77); unstageable PU (1 trial, 366 participants; RR 0.20, 95% CI 0.01 to 4.09); deep tissue injury (3 trials, 840 participants; RR 0.32, 95% CI 0.09 to 1.08). Foam dressing versus film dressing: PU stage 1 (1 trial, 270 participants; RR 0.56, 95% CI 0.39 to 0.80); PU stage 2 (1 trial, 270 participants; RR 1.00, 95% CI 0.06 to 15.82); deep tissue injury (1 trial, 270 participants; RR 0.67, 95% CI 0.11 to 3.93). Hydrocolloid dressing versus no dressing: PU stage 1 (1 trial, 108 participants; RR 0.54, 95% CI 0.31 to 0.94); PU stage 2 (1 trial, 108 participants; RR 0.86, 95% CI 0.28 to 2.66). All low or very low-certainty evidence. The evidence is very uncertain about the effect of dressings on different stages of pressure ulcer development.

Adverse events

One comparison reported adverse events: silicone foam dressing versus no dressing (3 trials, 2317 participants; RR not estimable; very low-certainty evidence). Silicone foam dressings may have little to no effect on the incidence of adverse events, but the evidence is very uncertain.

Topical agents

Pressure ulcer incidence

We evaluated seven comparisons with 4276 participants. We present five prioritised comparisons in the SoF tables as follows: fatty acid versus placebo (6 trials, 2201 participants; RR 0.86, 95% CI 0.54 to 1.36); fatty acid versus usual care (7 trials, 1058 participants; RR 0.64, 95% CI 0.46 to 0.84); cream versus fatty acid (1 trial, 120 participants; RR 3.00, 95% CI 0.32 to 28.03); cream versus placebo (3 trials, 513 participants; RR 1.18, 95% CI 0.59 to 2.36); and cream versus usual care (1 trial, 47 participants; RR 1.60, 95% CI 0.84 to 3.04). All very low-certainty evidence. It is very uncertain whether they make any difference to PU development.

Pressure ulcer stage

Two comparisons reported PU stage. Fatty acid versus usual care: PU stage 1 (2 trials, 180 participants; RR 1.00, 95% CI 0.49 to 2.03); PU stage 2 (2 trials, 180 participants; RR 0.19, 95% CI 0.07 to 0.53). Cream versus placebo: PU stage 3 (1 trial, 258 participants; RR 1.25, 95% CI 0.34 to 4.55); PU stage 4 (1 trial, 258 participants; RR 0.33, 95% CI 0.01 to 8.11). Both low or very low-certainty evidence. It is uncertain whether they make any difference to the stage of PU development.

Adverse events

One comparison reported adverse events: fatty acid versus placebo (3 trials, 967 participants; RR 4.38, 95% CI 0.50 to 38.30; very low-certainty evidence). Fatty acid may have little to no effect on the incidence of adverse events compared to placebo, but the evidence is very uncertain.

Risk of bias and imprecision were the main reasons for downgrading the certainty of the evidence.

Authors' conclusions

The included studies tested a wide variety of dressings and topical agents. The evidence for all interventions is uncertain or very uncertain; thus, it is unclear whether any of the dressings or topical agents studied make any difference to pressure ulcer development. Future studies should engage with stakeholders to determine priority interventions.

PLAIN LANGUAGE SUMMARY

Can dressings, creams, or oils help prevent pressure ulcers (bed sores)?

Key messages

The uncertainty of the evidence we identified means that we do not know whether dressings or topical agents (including various creams, lotions, and oils) make any difference to the number of pressure ulcers that develop in at-risk people.

What is a pressure ulcer?

Pressure ulcers, also known as pressure injuries, bed sores, or pressure sores, happen when the skin or tissue beneath it gets injured due to prolonged pressure on bony areas of the body. They are common amongst elderly and less mobile individuals. They can be challenging and costly to treat.

How can pressure ulcers be prevented?

Prevention options for pressure ulcers include: moving and repositioning while lying or seated; using the right type of surface to lie and sit on; and having a good intake of nutritious food and fluids. More recently, various dressings and creams are also used to prevent the development of pressure ulcers.

What did we want to find out?

We wanted to know if specific dressings or creams could effectively prevent pressure ulcers in at-risk individuals. Additionally, we aimed to assess factors such as pain, quality of life, and treatment costs when these dressings and creams were used.

What did we do?

We updated the review from 2018, and it now includes 51 studies. The studies included 13,303 at-risk people. The studies tested products such as fatty acids and creams, and dressings made from different materials.

What did we find?

We cannot be sure if dressings or creams made a difference in preventing pressure ulcers, or in preventing unwanted effects, due to inadequate research methods employed in the studies we examined. As a result, our confidence in these results remains limited.

Main results

We conducted a total of 20 different comparisons related to dressings and creams. This means we looked at how different types of dressings and creams performed in various situations to prevent pressure ulcers. There is an important amount of uncertainty in the evidence within the studies we included. Therefore, we do not know whether the dressings or creams included in this review have an impact on preventing new pressure ulcers or in preventing unwanted effects from developing. There was limited evidence both about the cost of treatment and whether people in the studies experienced any pain. Only one study reported on participants' quality of life.

What are the limitations of the evidence?

We are not confident in the evidence for three main reasons. First, it is possible that people in the studies were aware of which treatment they were getting. Second, results were very inconsistent across the different studies. Finally, some studies were very small.

How current is this evidence?

We conducted our search for studies up to November 2022, ensuring that this review includes the most recent research available.

SUMMARY OF FINDINGS

Summary of findings 1. Silicone foam dressing versus no dressing

Silicone foam dressing versus no dressing

Patient or population: individuals at risk of pressure ulcer development
Setting: intensive care units (ICUs); medical/surgical/emergency department/ICU units; general hospitals; hip fracture units; orthopaedic surgery; long-term care

Intervention: silicone foam dressing
Comparison: no dressing

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk with no dressing	**Corresponding risk with** silicone foam dressing				
Pressure ulcer incidence Assessed with observation Follow-up: mean 12.44 days (SD: 6.7; median 13)	**Study population** 104 per 1000	**52 per 1000** (34 to 80)	**RR 0.50** (0.33 to 0.77)	5903 (18 RCTs)	⊕⊝⊝⊝ **Very low**[a]	Silicone foam dressings may reduce pressure ulcer incidence (any stage) compared to no dressing, but the evidence is very uncertain (silicone foam dressing group: 5.6%, 180/3192; no-dressing group: 10.4%, 281/2711).
Pressure ulcer stage 1 Follow-up: mean 12.8 days (SD: 8.06; median 11)	**Study population** 61 per 1000	**19 per 1000** (8 to 48)	**RR 0.32** (0.13 to 0.79)	1823 (8 RCTs)	⊕⊝⊝⊝ **Very low**[b]	Silicone foam dressings may reduce stage 1 pressure ulcer incidence compared to no dressing, but the evidence is very uncertain (silicone foam dressing group: 2%, 15/904; no-dressing group: 6%, 56/919).
Pressure ulcer stage 2 Follow-up: mean 12.8 days (SD: 7.5; median 13)	**Study population** 51 per 1000	**24 per 1000** (15 to 37)	**RR 0.47** (0.30 to 0.73)	2873 (10 RCTs)	⊕⊝⊝⊝ **Very low**[c]	Silicone foam dressings may reduce the incidence of stage 2 pressure ulcers compared to no dressing (silicone foam dressing group: 2%, 33/1426, no-dressing group: 5%, 74/1447).
Pressure ulcer stage 3	**Study population**		**RR 0.45**	718 (3 RCTs)	⊕⊝⊝⊝ **Very low**[d]	Silicone foam dressings may have little to no effect on the incidence of stage 3 pressure ulcers compared to

Follow-up: mean 10 days (SD: 4.2; median 10)	14 per 1000	**6 per 1000** (1 to 44)	(0.06 to 3.21)			no dressing, but the evidence is very uncertain (silicone foam dressing group: 0.3%, 1/355; no-dressing group: 1%, 5/363).
Pressure ulcer stage 4 Follow-up: mean 17 days (SD: 15.5; median 17)	**Study population**		**RR 0.21** (0.02 to 1.77)	610 (2 RCTs)	⊕⊖⊖⊖ **Very low**[d]	Silicone foam dressings may have little to no effect on the incidence of stage 4 pressure ulcers compared to no dressing, but the evidence is very uncertain (silicone foam dressing group: 0%, 0/299; no-dressing group: 1%, 4/311).
	13 per 1000	**3 per 1000** (0 to 23)				
Unstageable pressure ulcer Follow-up: 14 days	**Study population**		**RR 0.20** (0.01 to 4.09)	366 (1 RCT)	⊕⊖⊖⊖ **Very low**[d]	Silicone foam dressings may have little to no effect on the incidence of unstageable pressure ulcers compared to no dressing, but the evidence is very uncertain (silicone foam dressing group: 0%, 0/184; no dressing group: 1%, 2/182).
	11 per 1000	**2 per 1000** (0 to 45)				
Deep tissue injury Follow-up: mean 14 days (SD: 0.6; median 14)	**Study population**		**RR 0.32** (0.09 to 1.08)	840 (3 RCTs)	⊕⊖⊖⊖ **Very low**[d]	Silicone foam dressings may have little to no effect on the incidence of deep tissue injury compared to no dressing, but the evidence is very uncertain (silicone foam dressing group: 0.7%, 3/422; no dressing group: 3%, 11/418).
	26 per 1000	**8 per 1000** (2 to 28)				
Adverse events: Santamaria 2015	**Study population**		**RR** not estimable	440 (1 RCT)	⊕⊖⊖⊖ **Very low**[e]	Silicone foam dressings may have little to no effect on the incidence of adverse events compared to no dressing, but the evidence is very uncertain (silicone foam dressing group: 0%, 0/220; no-dressing group: 0%, 0/220).
	0 per 1000	**0 per 1000** (0 to 0)				
Adverse events: Beeckman 2021	**Study population**		**RR** not estimable	1633 (1 RCT)	⊕⊖⊖⊖ **Very low**[f]	Silicone foam dressings may have little to no effect on the incidence of adverse events, but the evidence is very uncertain (silicone foam dressing group: 3%, 33/1087; no-dressing group: unknown).
	Unknown	33 adverse events				
Adverse events: De Wert 2019	**Study population**		**RR** not estimable	244 (1 RCT)	⊕⊖⊖⊖ **Very low**[e]	Silicone foam dressings may have little to no effect on the incidence of adverse events, but the evidence is very uncertain (silicone foam dressing group: 50%, 58/117; no-dressing group: unknown).
	Unknown	58 participants had an adverse event				

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the mean risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).
CI: confidence interval; **RCT**: randomised controlled trial; **RR**: risk ratio; **SD:** standard deviation

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 bias, primarily performance, detection, and other bias or unclear risk of bias, primarily selection bias; downgraded once for inconsistency because the I^2 is 73%.
[b]Downgraded twice for high risk of bias or unclear risk of bias, primarily performance and detection bias; downgraded once for inconsistency because the I^2 is 44%; and downgraded once for imprecision due to a very wide 95% confidence interval. The risk ratio is large, but we did not upgrade as there is uncertainty around the effect size.
[c]Downgraded twice for high risk of performance and detection bias and unclear risk of selection bias; downgraded once for inconsistency due to a very wide 95% confidence interval. The risk ratio is large, but we did not upgrade as there is uncertainty around the effect size.
[d]Downgraded twice for high risk of performance and detection bias and downgraded twice for very serious imprecision due to few events and a very wide confidence interval which includes 1. The risk ratio is large, but we did not upgrade as there is uncertainty around the effect size.
[e]Downgraded twice for high risk of performance and detection bias and unclear risk of selection bias; downgraded once for imprecision due to no events.
[f]Downgraded twice for high risk of performance and detection bias; downgraded once for imprecision due to no adverse events measured in the control group.

Summary of findings 2. Foam dressing versus film dressing

Foam dressing versus film dressing

Patient or population: individuals at risk of pressure ulcer development

Settings: intensive care unit; operating room; hospital setting

Intervention: foam dressing

Comparison: film dressing

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk with film	Corresponding risk with foam				
Pressure ulcer incidence	**Study population**		**RR 0.72** (0.20 to 2.67)	569 (3 RCTs)	⊕⊖⊖⊖ **Very low**[a]	Foam dressings may have little to no effect on the incidence of pressure ulcers compared to film dressings, but the evidence is very uncertain (foam
	264 per 1000	**190 per 1000**				

Assessed with observation Follow-up: 3 days		(53 to 705)				dressing group: 16%, 46/285; film dressing group: 26.4%, 75/284).
Pressure ulcer stage 1 Assessed with observation Follow-up: 3 days	**Study population**		**RR 0.56** (0.39 to 0.80)	270 (1 RCT)	⊕⊖⊖⊖ **Very low**[b]	Foam dressings may reduce stage 1 pressure ulcer incidence compared to film dressings, but the evidence is very uncertain (foam dressing group: 24.4%, 33/135; film dressing group: 43.7%, 59/135).
	437 per 1000	**245 per 1000** (170 to 330)				
Pressure ulcer stage 2 Assessed with observation Follow-up: 3 days	**Study population**		**RR 1.00** (0.06 to 15.82)	270 (1 RCT)	⊕⊖⊖⊖ **Very low**[c]	Foam dressings may have little to no effect on the incidence of stage 2 pressure ulcers compared to film dressings, but the evidence is very uncertain (foam dressing group: 0.7%, 1/135; film dressing group: 0.7%, 1/135)
	7 per 1000	**7 per 1000** (0 to 117)				
Deep tissue injury Assessed with observation Follow-up: 3 days	**Study population**		**RR 0.67** (0.11 to 3.93)	270 (1 RCT)	⊕⊖⊖⊖ **Very low**[c]	Foam dressings may have little to no effect on the incidence of deep tissue injury compared to film dressings, but the evidence is very uncertain (foam dressing group: 1.5%, 2/135; film dressing group: 2.2%, 3/135)
	22 per 1000	**15 per 1000** (2 to 87)				
Adverse events	Not reported					

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT**: randomised controlled trial; **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/unclear risk of performance and detection bias and unclear risk of selection and reporting bias; downgraded once for inconsistency because I^2 is 76%; downgraded once for imprecision due to a wide confidence interval which includes 1.
[b]Downgraded twice for high risk of performance and detection bias; downgraded once for imprecision due to a small sample size.
[c]Downgraded twice for high risk of performance and detection bias; downgraded twice for imprecision due to a small sample size, a small number of events, and a very wide confidence interval which includes 1.

Summary of findings 3. Hydrocellular foam dressing versus hydrocolloid dressing

Hydrocellular foam dressing versus hydrocolloid dressing for preventing pressure ulcers

Patient or population: individuals at risk of pressure ulcer development

Settings: hospital setting

Intervention: hydrocellular foam dressing

Comparison: hydrocolloid dressing

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk with hydrocolloid dressing	Corresponding risk with hydrocellular foam dressing				
Pressure ulcer incidence Assessed with observation Follow-up: 56 days	**Study population**		**RR not estimable**	80 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	Hydrocellular foam dressings may have little to no effect on the incidence of pressure ulcers compared to hydrocolloid dressings, but the evidence is very uncertain (hydrocellular foam dressing group: 0%, 0/40; hydrocolloid dressing group: 0%, 0/40).
	0 per 1000	**0 per 1000** (0 to 0)				
Pressure ulcer stage	Not reported					
Adverse events	Not reported					

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT**: randomised controlled trial; **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 once for high risk of performance and detection bias; downgraded twice for serious imprecision due to no events and a small sample size.

Summary of findings 4. Silicone foam dressing type 1 versus silicone foam dressing type 2

Silicone foam dressing type 1 versus silicone foam dressing type 2

Patient or population: individuals at risk of pressure ulcer development

Settings: intensive care unit

Intervention: silicone foam dressing type 1

Comparison: silicone foam dressing type 2

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk with silicone foam dressing type 1	Corresponding risk with silicone foam dressing type 2				
Pressure ulcer incidence Assessed with observation Follow-up: 6 days	**Study population** 146 per 1000	117 per 1000 (82 to 168)	RR 0.80 (0.56 to 1.15)	376 (2 RCTs)	⊕⊖⊖⊖ **Very low**[a]	Silicone foam dressing type 1 may have little to no effect on the incidence of pressure ulcers compared to silicone foam dressing type 2, but the evidence is very uncertain (silicone foam dressing type 1 group: 13.4%, 22/164; silicone foam dressing type 2 group: 14.6%, 31/212).
Stage of pressure ulcer	Not reported					
Adverse events	Not reported					

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT**: randomised controlled trial; **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 selection, performance, detection, and attrition bias, and unclear risk of performance, reporting bias, and other bias; downgraded twice for serious imprecision due to a small number of events and a very wide confidence interval.

Summary of findings 5. Foam dressing versus fatty acid

Foam dressing versus fatty acid

Patient or population: individuals at risk of pressure ulcer development
Settings: hospital setting, high dependency unit, medicine and surgery
Intervention: foam dressing

Comparison: fatty acid

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk with fatty acid	Corresponding risk with foam dressing				
Pressure ulcer incidence Assessed with observation, Follow-up: 14.5 hours to 14 days	Study population 107 per 1000	**231 per 1000** (138 to 390)	**RR 1.67** (0.49 to 5.72)	300 (2 RCTs)	⊕⊖⊖⊖ **Very low**[a]	Foam dressings may have little to no effect on the incidence of pressure ulcers compared to fatty acid, but the evidence is very uncertain (foam dressing group: 32.5%, 52/160; fatty acid group: 8%, 15/140).
Stage of pressure ulcer	Not reported					
Adverse events	Not reported					

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT**: randomised controlled trial; **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 performance, detection and attrition bias, and unclear risk of reporting bias; downgraded once for inconsistency (I^2 = 70%); downgraded twice for imprecision due to the wide confidence interval and the small sample size. The risk ratio is very large, but we did not upgrade as there is a lot of uncertainty around the effect size.

Summary of findings 6. Polyurethane film versus hydrocolloid dressing

Polyurethane film dressing versus hydrocolloid dressing

Patient or population: individuals at risk of pressure ulcer development
Settings: intensive care unit, coronary care unit, medical clinic
Intervention: polyurethane film dressing

Comparison: hydrocolloid dressing

Outcomes	**Illustrative comparative risks* (95% CI)**		**Relative effect (95% CI)**	**№** of participants (trials)	**Certainty of the evidence (GRADE)**	**Comments**
	Assumed risk with hydrocolloid dressing	Corresponding risk with polyurethane film **dressing**				
Pressure ulcer incidence Assessed with observation Follow-up: 30 days	**Study population**		**RR 0.58** (0.24 to 1.41)	160 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	Polyurethane film dressing may have little to no effect on the incidence of pressure ulcers compared to hydrocolloid dressing, but the evidence is very uncertain (polyurethane film group: 9%; 7/80; hydrocolloid dressing group: 15%; 12/80).
	150 per 1000	**87 per 1000** (36 to 211)				
Pressure ulcer stage	Not reported					
Adverse events	Not reported					

*The basis for the **assumed risk** (e.g. the median control group risk across trials) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT**: randomised controlled trial; **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 once for high risk of performance bias and unclear risk of selection, detection, and reporting bias; downgraded twice for very serious imprecision due to a small number of events and a wide confidence interval which includes 1.

Summary of findings 7. Hydrocolloid dressing versus no dressing

Hydrocolloid dressing versus no dressing

Patient or population: individuals at risk of pressure ulcer development
Settings: neonatal intensive care
Intervention: hydrocolloid dressing

Comparison: no dressing

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	№ of participants (trials)	Certainty of the evidence (GRADE)	Comments
	Assumed risk with no dressing	Corresponding risk with hydrocolloid dressing				
Pressure ulcer incidence Assessed with observation Follow-up: 36 weeks	**Study population**		**RR 0.60** (0.46 to 0.78)	230 (2 RCTs)	⊕⊖⊖⊖ **Very low**[a]	Hydrocolloid dressings may reduce pressure ulcer incidence compared to no dressing, but the evidence is very uncertain (hydrocolloid dressing group: 56%, 63/113; no-dressing group: 65%, 76/117).
	650 per 1000	**390 per 1000** (434 to 721)				
Pressure ulcer stage 1 Assessed with observation Follow-up: 36 weeks	**Study population**		**RR 0.54** (0.31 to 0.94)	108 (1 RCT)	⊕⊖⊖⊖ **Very low**[b]	Hydrocolloid dressing may reduce stage 1 pressure ulcer incidence compared to no dressing, but the evidence is very uncertain (hydrocolloid dressing group: 25%, 13/53, no-dressing group: 45%, 25/55).
	455 per 1000	**234 per 1000** (141 to 427)				
Pressure ulcer stage 2 Assessed with observation Follow-up: 36 weeks	**Study population**		**RR 0.86** (0.28 to 2.66)	108 (1 RCT)	⊕⊖⊖⊖ **Very low**[c]	Hydrocolloid dressings may have little to no effect on the incidence of stage 2 pressure ulcers compared to no dressing, but the evidence is very uncertain (hydrocolloid dressing group: 9%, 5/53, no-dressing group: 10%, 6/55).
	109 per 1000	**94 per 1000** (31 to 290)				

Adverse events	Not reported

*The basis for the **assumed risk** (e.g. the median control group risk across trials) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT**: randomised controlled trial; **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 performance and detection bias and unclear risk of reporting bias; downgraded once for imprecision due to a small sample size.
[b]Downgraded once for high risk of performance and detection bias; downgraded twice for serious imprecision due to a small number of events and a small sample size.
[c]Downgraded once for high risk of performance and detection bias; downgraded twice for serious imprecision due to a small number of events, small sample size, and a wide confidence interval which includes 1.

Summary of findings 8. Polyurethane foam dressing versus padded bandage

Polyurethane foam dressing versus padded bandage

Patient or population: individuals at risk of pressure ulcer development

Settings: hospital setting

Intervention: polyurethane foam dressing

Comparison: padded bandage

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk with padded bandage	Corresponding risk with polyurethane foam				
Pressure ulcer incidence Assessed with observation Follow-up: 15 days	**Study population**		RR 0.41 (0.11 to 1.58)	409 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	Polyurethane foam dressings may have little to no effect on the incidence of pressure ulcers compared to padded bandages, but the evidence is very uncertain (polyurethane foam dressing
	35 per 1000	**24 per 1000** (8 to 75)				

		group: 2.4%, 3/208; padded bandage group: 3.5%, 7/201).
Stage of pressure ulcer	Not reported	
Adverse events	Not reported	

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT**: randomised controlled trial; **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 once for unclear risk of selection, performance, detection, and reporting bias; downgraded twice for very serious imprecision due to a small number of events and a very wide confidence interval which includes 1.

Summary of findings 9. Fatty acid versus placebo

Fatty acid versus placebo

Patient or population: individuals at risk of pressure ulcer development
Settings: intensive care unit, nursing home, geriatrics, home care, medicine and surgery
Intervention: fatty acid

Comparison: placebo

Outcomes	**Illustrative comparative risks* (95% CI)**		**Relative effect (95% CI)**	**№** of participants (trials)	**Certainty of the evidence (GRADE)**	**Comments**
	Assumed risk with p**lacebo**	**Corresponding risk with fatty acid**				
Pressure ulcer incidence Assessed with observation	**Study population**		**RR 0.86** (0.54 to 1.36)	2201 (6 RCTs)	⊕⊖⊖⊖ **Very low**[a]	Fatty acid may have little to no effect on pressure ulcer incidence compared to placebo, but the evidence is very uncertain (fatty acid group: 7%, 80/1075; placebo group: 9%; 100/1126).
	89 per 1000	**76 per 1000** (49 to 121)				

Follow-up: Mean: 40 days (SD: 41 days)						
Pressure ulcer stage	Not reported					
Adverse events Assessed with observation Follow-up: 21 to 30 days	**Study population**		**RR 4.38** (0.50 to 38.30)	967 (3 RCTs)	⊕⊖⊖⊖ **Very low**[b]	Fatty acid may have little to no effect on the incidence of adverse events compared to placebo, but the evidence is very uncertain (fatty acid: 0.6%, 3/481; placebo group: 0%, 0/486).
	0 per 1000	**0 per 1000** (0 to 0)				

*The basis for the **assumed risk** (e.g. the median control group risk across trials) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT:** randomised controlled trial; **RR:** risk ratio; **SD:** standard deviation

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 once for high risk of performance and attrition bias and unclear risk of selection, reporting, and other bias; downgraded once for inconsistency (I^2 = 61%); downgraded once for serious risk of imprecision due to a wide confidence interval which crosses 1.
[b]Downgraded once for high risk of attrition bias and unclear risk of reporting bias; downgraded twice for serious imprecision due to few events and an extremely wide confidence interval which includes 1. The risk ratio is very large, but we did not upgrade as there is a lot of uncertainty around the effect size.

Summary of findings 10. Fatty acid versus usual care

Fatty acid versus usual care for preventing pressure ulcers

Patient or population: individuals at risk of pressure ulcer development
Settings: intensive care unit, orthopaedic
Intervention: fatty acid

Comparison: usual care

Outcomes	**Illustrative comparative risks* (95% CI)**		**Relative effect (95% CI)**	**№** of participants (trials)	**Certainty of the evidence (GRADE)**	**Comments**
	Assumed risk with usual care	**Corresponding risk with fatty acid**				

Pressure ulcer incidence Assessed with observation Follow-up: unclear or 30 days	**Study population** 156 per 1000	**97 per 1000** (72 to 131)	**RR 0.62** (0.46 to 0.84)	1058 (7 RCTs)	⊕⊖⊖⊖ **Very low**[a]	Fatty acid may reduce pressure ulcer incidence compared to usual care, but the evidence is very uncertain (fatty acid: 10.9%, 52/476; usual care: 15.6%, 91/582).
Pressure ulcer stage 1 Assessed with observation Follow-up: unclear or 30 days	**Study population** 144 per 1000	**144 per 1000** (71 to 293)	**RR 1.00** (0.49 to 2.03)	180 (2 RCTs)	⊕⊖⊖⊖ **Very low**[b]	Fatty acid may have little to no effect on stage 1 pressure ulcer incidence compared to usual care, but the evidence is very uncertain (fatty acid: 14.4%, 13/90; usual care: 14.4%, 13/90).
Pressure ulcer stage 2 Assessed with observation Follow-up: unclear or 30 days	**Study population** 233 per 1000	**44 per 1000** (16 to 124)	**RR 0.19** (0.07 to 0.53)	180 (2 RCTs)	⊕⊕⊖⊖ **Low**[c]	The evidence suggests fatty acid results in a large reduction in stage 2 pressure ulcer development compared to usual care (fatty acid: 4.4%, 4/90; usual care: 23.3%, 21/90).
Adverse events	Madadi 2015 reported no adverse events in the fatty acid group.					

*The basis for the **assumed risk** (e.g. the median control group risk across trials) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT**: randomised controlled trial; **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 selection, performance, detection, and attrition bias; downgraded once for imprecision due to a small sample size.
[b]Downgraded twice for high risk of selection, performance, and detection bias; downgraded twice for imprecision due to a small sample size, a small event size and a wide confidence interval which crosses 1.

[c]Downgraded twice for high risk of selection, performance, detection, and attrition bias; downgraded once for imprecision due to a small sample size. The risk ratio is large, and while the confidence interval is slightly wide, the limits fall almost entirely within a range considered to indicate a large effect. Thus, we upgraded the evidence by 1 level.

Summary of findings 11. Cream versus fatty acid

Cream versus fatty acid for preventing pressure ulcers

Patient or population: individuals at risk of pressure ulcer development
Settings: geriatrics
Intervention: cream

Comparison: fatty acid

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	№ of participants (trials)	Certainty of the evidence (GRADE)	Comments
	Assumed risk with fatty acid	Corresponding risk with cream				
Pressure ulcer incidence Assessed with observation Follow-up: 3 weeks	**Study population** 17 per 1000	**50 per 1000** (5 to 467)	**RR 3.00** (0.32 to 28.03)	120 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	Cream may have little to no effect on pressure ulcer incidence compared to fatty acid, but the evidence is very uncertain (cream group: 5%, 3/60; fatty acid group: 2%, 1/60).
Stage of pressure ulcer	Not reported					
Adverse events	Not reported					

*The basis for the **assumed risk** (e.g. the median control group risk across trials) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT**: randomised controlled trial; **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 attrition and other bias and unclear risk of selection, detection, and reporting bias; downgraded twice for serious imprecision due to a small number of events and a very wide confidence interval which includes 1.

Summary of findings 12. Cream versus placebo

Cream versus placebo for preventing pressure ulcers

Patient or population: individuals at risk of pressure ulcer development
Settings: nursing homes; hospital
Intervention: cream

Comparison: placebo

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	№ of participants (trials)	Certainty of the evidence (GRADE)	Comments
	Assumed risk with placebo	Corresponding risk with cream				
Pressure ulcer incidence Assessed with observation Follow-up: 2 to 24 weeks	**Study population**		**RR 1.18** (0.59 to 2.36)	513 (3 RCTs)	⊕⊖⊖⊖ **Very low**[a]	Cream may have little to no effect on pressure ulcer incidence compared to placebo, but the evidence is very uncertain (cream group: 24.1%, 62/257; placebo group: 25%, 64/256).
	250 per 1000	**295 per 1000** (148 to 590)				
Pressure ulcer stage 3 Assessed with observation, Follow-up: 4 weeks	**Study population**		**RR 1.25** (0.34 to 4.55)	258 (1 RCT)	⊕⊖⊖⊖ **Very low**[b]	Cream may have little to no effect on the incidence of stage 3 pressure ulcer compared to placebo, but the evidence is very uncertain (cream group: 3.9%, 5/129; placebo group: 3.1%, 4/129).
	31 per 1000	**39 per 1000** (11 to 141)				
Pressure ulcer stage 4 Assessed with observation, Follow-up: 4 weeks	**Study population**		**RR 0.33** (0.01 to 8.11)	258 (1 RCT)	⊕⊖⊖⊖ **Very low**[b]	Cream may have little to no effect on the incidence of stage 4 pressure ulcer compared to placebo, but the evidence is very uncertain (cream group: 0%, 0/129; placebo group: 0.7%, 1/129).
	8 per 1000	**3 per 1000** (0 to 63)				
Adverse events	Not reported					

*The basis for the **assumed risk** (e.g. the median control group risk across trials) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT**: randomised controlled trial; **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 once for high risk of other bias and unclear risk of selection and reporting bias; downgraded once for inconsistency (I^2 = 76%); downgraded twice for very serious imprecision due to a small sample size and a confidence interval which crosses 1.
[b]Downgraded once for unclear risk of selection, reporting, and other bias; downgraded twice for very serious imprecision due to a small sample and event size and a very wide confidence interval which crosses 1.

Summary of findings 13. Cream versus usual care

Cream versus usual care

Patient or population: individuals at risk of pressure ulcer development
Setting: nursing homes

Intervention: cream
Comparison: usual care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	№ of participants (trials)	Certainty of the evidence (GRADE)	Comments
	Assumed risk with usual care	Corresponding risk with cream				
Pressure ulcer incidence Assessed with observation Follow-up: 4 weeks	**Study population** 389 per 1000	**622 per 1000** (327 to 1000)	**RR 1.60** (0.84 to 3.04)	47 (1 RCT)	⊕⊝⊝⊝ **Very low**[a]	Cream may have little to no effect on the incidence of pressure ulcer compared to usual care, but the evidence is very uncertain (cream group: 62%, 18/29; usual care group: 39%, 7/18).
Stage of pressure ulcer	Not reported					
Adverse events	Not reported					

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the mean risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT**: randomised controlled trial; **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.

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[a]Downgraded once for unclear risk of selection bias and other bias, where the effect of the clustering was not accounted for in the analysis; downgraded twice for imprecision due to a small number of events and a small sample size.

BACKGROUND

Description of the condition

A pressure ulcer is defined as localised damage to the skin, underlying tissue, or both, as a result of pressure or pressure in combination with shear (EPUAP/NPIAP/PPPIA 2019). A meta-analysis identified that the pooled prevalence of pressure ulcers in over 1.36 million hospitalised adults was 12.8%, and the pooled incidence in over 680,000 hospitalised adults was 5.4 per 10,000 patients (Li 2020). Pressure ulcers are classified by increasing visible tissue loss into four stages (1 to 4), with two additional presentations: unstageable and suspected deep tissue injury (EPUAP/NPIAP/PPPIA 2019; Appendix 1). The most common anatomical sites for pressure ulcers to occur are the sacrum and the heels, and the majority are stage 1 or stage 2 in severity (Li 2020; Moore 2019a; Rogers 2021).

Understanding of the aetiology of pressure ulcers has advanced in the past decade (Gefen 2021). Pressure, both intense and prolonged, and shear, underpin skin and tissue damage. Pressure is equal to force divided by area: the same amount of force applied to a small area, when compared with a larger area, will result in greater pressure (O'Callaghan 2007). Shear is the mechanical stress acting parallel to a plane of interest, which occurs when a person sitting in bed begins to slide down the bed, with their skin remaining in the same place because it 'sticks' to the bed linen (Collier 2006). Intense or prolonged pressure and shear forces increase the mechanical load on tissues and appear to lead to pressure ulcer development. Cell deformation (Bader 1990; Gefen 2021), inflammation (Gefen 2021), and local ischaemia (lack of oxygen) (Kosiak 1959; Gefen 2021) result in tissue damage. Other factors, such as impaired interstitial fluid flow and lymphatic drainage (Reddy 2006) and reperfusion injury (injury to cells caused by the restoration of blood supply to tissues) (Tsuji 2005), are also purported to result in tissue damage. These mechanisms, alone, or in combination, lead to cell damage and inevitable tissue destruction. Another factor that influences the development of a pressure ulcer is the microclimate, described as the temperature, humidity, and airflow around the area of the skin (Gefen 2021). When there is increased warmth and humidity, the skin becomes more vulnerable to injury. Minimising both pressure and shear on the body, along with ensuring the skin is not too warm or excessively moist, has the potential to decrease the risk of pressure ulcer development (Gefen 2021; Oomens 2015).

Numerous factors that influence mechanical load, pressure ulcer susceptibility, and tissue tolerance increase the risk of pressure ulcer development (Oomens 2015). For example, immobility, poor perfusion, malnourishment, and conditions such as infection and oedema may have either an indirect or direct relationship with the development of a pressure ulcer (Coleman 2014). Critically ill or injured people, those with spinal cord injuries or other neurologic conditions, older individuals, and those with diabetes mellitus are at an increased risk of pressure ulcer (EPUAP/NPIAP/PPPIA 2019). The heel is particularly vulnerable to pressure ulcer development, given its anatomical shape, which is curved and sharp (Gefen 2017). As a result, tissues in the heel become highly distorted, stretched, compressed and sheared, making pressure ulcer development highly likely unless prevention strategies are quickly employed (Gefen 2017). Certain people with Stage 1 pressure ulcers are also at increased risk of the pressure ulcer progressing to stage 4 (Vanderwee 2009). For example, individuals with hypotension, contractures, or a history of a cerebral vascular accident, tend to develop more serious pressure ulcers despite standard preventive measures (Vanderwee 2009). Thus, a clear focus on the adoption of targeted prevention strategies is important at the outset, so that the individual is not exposed to pressure ulcers in the first instance (Sullivan 2013).

Pressure ulcers have a negative impact on an individual's quality of life. Indeed, the emotional, physical, mental, and social domains of life are all profoundly affected (Gorecki 2012). Pain is described as one of the most significant problems for individuals with pressure ulcers, and many of the treatment regimens adopted exacerbate this adverse effect (Gorecki 2012; Kim 2019; Zhao 2021). Thus, it is important to consider the impact of prevention and treatment strategies on the individual, and to choose those that will reduce discomfort and enhance rehabilitation wherever possible (Gorecki 2009). Pressure ulcers are also associated with increased mortality (Hauck 2017). Whether this relates to the fact that pressure ulcers occur in a population that is for the most part debilitated, with a high incidence of comorbidities, or whether it relates to the presence of a pressure ulcer alone, remains unclear (Tarnowski Goodell 2013).

Pressure ulcers impose a significant financial burden on healthcare systems, and more so for treatment than prevention (Demarre 2015; Padula 2019). Guest 2018 predicted that, in 2017/2018, pressure ulcers cost the UK National Health Service an estimated 1.74 billion pounds sterling (GBP) (or GBP 1740 million) in the first 12 months from onset. Another UK analysis of 273 hospitals showed pressure ulcers resulted in over 15 excess bed days per ulcer, and the loss of 26 healthy life years (Hauck 2017). In Australian public hospitals, the annual cost of pressure ulcers, including opportunity cost of excess length of stay, treatment costs, and productivity loss, is 9.1 billion Australian dollars (AUD) (or AUD 9100 million) (Ngheim 2022). In the USA, hospital-acquired pressure ulcers cost an average USD 10,708 per patient and about USD 26.8 billion (USD 26,800 million) per annum (Padula 2019). A systematic review of 17 studies found that, annually, nations spend from 121.4 to 2.6 billion euros (EUR) (or EUR 121,400 million to 2,600 million) or EUR 275,761 million to EUR 126.15 million per 100,000 people (Demarre 2015). In fact, an Organisation for Economic Cooperation and Development (OECD) report on the economics of patient safety conservatively estimates that 15% of hospital expenditure is spent on treating safety failures, with pressure ulcers being the most burdensome (Slawomirski 2017).

Description of the intervention

Pressure ulcer prevention involves a range of interventions, including risk assessment (Moore 2019b), nutritional support (Langer 2014), use of pressure redistribution surfaces (Shi 2021a; Shi 2021b; Shi 2021c; Shi 2021d; Shi 2021e), repositioning (Avsar 2020; Gillespie 2020), and early mobilisation (Azuh 2016). Implementation of skin care regimens – to help ensure skin is clean, hydrated, and moisturised – is also important in preventing pressure ulcers (Bateman 2013; Park 2014). Skin care regimens may include a selection of topical therapies where creams or ointments are applied directly to the skin (Reddy 2006), or impregnated in dressings applied to the skin. Topical interventions are widely used within clinical settings in isolation, or in combination with other preventive strategies such as dressings (EPUAP/NPIAP/PPPIA 2019). For the purposes of this review, we define a topical agent as 'any product or substance applied to the skin'.

Dressings to protect the skin from damage are increasingly used in clinical settings as another pressure ulcer prevention strategy. While the certainty of evidence for using prophylactic dressings remains low (Marshall 2019; Moore 2018), their clinical effectiveness has been demonstrated in large multisite trials in acute and critical care patient populations (Beeckman 2021; Hahnel 2020; Forni 2018).

There is a wide range of dressings for the prevention of pressure ulcers, although those that are most reviewed in the literature are (Reid 2016):

- film dressings;
- hydrocolloid dressings;
- foam dressings.

Of these, multilayered silicone foam dressings are the most widely evaluated (Beeckman 2021; Forni 2018; Forni 2022; Hahnel 2020; Kalowes 2016; Santamaria 2015; Santamaria 2018), and their use is recommended by international guidelines (EPUAP/NPIAP/PPPIA 2019).

How the intervention might work

Our understanding of how prophylactic dressings and topical agents prevent pressure ulcers has improved (Gefen 2020; Marshall 2019). Previous hypotheses suggested these dressings and topical agents prevented pressure ulcers by reducing friction forces (Butcher 2009). Recent evidence confirms prophylactic dressings prevent pressure ulcers by either minimising friction forces exerted on the skin, preventing the skin from stretching or tearing, or absorbing skin surface moisture (Marshall 2019). It must be noted that commercially available prophylactic dressings have substantial differences in their design and composition, which determines the dressing's biomechanical performance in terms of tissue protection and durability (Gefen 2020; Grigatti 2021). Hence, dressing selection must align with both the patient and clinical needs (EPUAP/NPIAP/PPPIA 2019; Gefen 2019). Furthermore, international guidelines recommend the use of prophylactic dressings as an adjunct to offloading pressure and other prevention strategies, such as repositioning (EPUAP/NPIAP/PPPIA 2019; NICE 2014). In relation to topical agents, there is a lack of empirical evidence to confirm how they prevent pressure ulcers (EPUAP/NPIAP/PPPIA 2019). It is hypothesised that topical agents applied directly to the skin will moisturise and protect the skin by reducing dryness, a known risk factor for pressure ulcer development. Optimal skin conditioning is of paramount importance, especially for individuals with low sebum production, such as the elderly. This preparation is essential to fortify the skin against mechanical stress and promote improved circulation. Additionally, these interventions play a pivotal role in maintaining skin pH balance, reinforcing the skin's barrier integrity, and establishing a protective occlusive layer (Diaz-Valenzuela 2019; EPUAP/NPIAP/PPPIA 2019; Verdú 2012).

Why it is important to do this review

The use of dressings and topical agents for preventing pressure ulcers is discussed in the literature and in international pressure ulcer prevention guidelines. Prior to the publication of the original version of this review (Moore 2013), the level of evidence to support these recommendations had not been systematically assessed (Butcher 2009). The use of adjunct therapies (for example, dressings, creams, or lotions) as part of prevention strategies adds to the overall costs. Therefore, it is important to explore whether the use of these therapies provides potential benefit to patients (Moore 2018). This is the third update of this review.

OBJECTIVES

To evaluate the effects of dressings and topical agents on pressure ulcer prevention, in people of any age without existing pressure ulcers, but at risk of developing one, in any healthcare setting.

METHODS

Criteria for considering studies for this review

Types of studies

Trials that randomised individuals (randomised controlled trials (RCTs)) or groups (cluster-RCTs) were eligible for inclusion.

Types of participants

People of any age without a pressure ulcer, but considered to be at risk of developing a pressure ulcer, in any care setting.

Types of interventions

The intervention was any wound dressing or topical agent applied to the skin at any frequency with the aim of preventing the development of a pressure ulcer. We included studies comparing the use of dressings, topical agents, or topical agents with dressings, compared with a different dressing, topical agent, combined topical agent and dressing, no intervention or standard care, or any other intervention.

Types of outcome measures

Primary outcomes

Pressure ulcer incidence (the proportion of people developing any new pressure ulcer(s) of any stage). For the purpose of this review, we defined a pressure ulcer as a localised injury to the skin, underlying tissue, or both, usually over a bony prominence, as a result of pressure, or pressure in combination with shear. This review included all stages of pressure ulcer damage, following the definition of the EPUAP/NPIAP/PPPIA 2019. We accepted trial authors' definitions of, and methods for measuring, pressure ulcer incidence. We extracted data from the longest follow-up period reported in the individual studies.

Secondary outcomes

- Stage of any new pressure ulcer(s)
- Time to ulcer development
- Anatomical location of pressure ulcer development
- Costs of interventions
- Quality of life, measured on a validated scale
- Pain at dressing change, measured using a validated scale
- Acceptability of the intervention (or satisfaction) with respect to patient comfort
- Adverse events
- Length of hospital stay

Search methods for identification of studies

Electronic searches

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

- Cochrane Wounds Specialised Register (searched 3 November 2022);
- Cochrane Central Register of Controlled Trials (CENTRAL; 2022, Issue 10) in the Cochrane Library (searched 3 November 2022);
- MEDLINE Ovid including In-Process & Other Non-Indexed Citations (1946 to 3 November 2022);
- Embase Ovid (1974 to 3 November 2022);
- CINAHL Plus EBSCO (Cumulative Index to Nursing and Allied Health Literature; 1937 to 3 November 2022).

The search strategies for electronic databases can be found in Appendix 2. We combined the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version (2008 revision) (Lefebvre 2022). We combined the Embase search with the Ovid Embase filter developed by the UK Cochrane Centre (Lefebvre 2022). 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 searched the following clinical trial registries:

- US National Institutes of Health Ongoing Trials Register, ClinicalTrials.gov (www.clinicaltrials.gov; searched 9 November 2022);
- World Health Organization International Clinical Trials Registry Platform (www.who.int/clinical-trials-registry-platform; searched 9 November 2022).
- Cochrane Central Register of Controlled Trials (CENTRAL; 2022, Issue 10) in the Cochrane Library (searched 3 November 2022).

Search strategies for clinical trial registries can be found in Appendix 2. Details of the search strategies used for the previous version of the review are given in Moore 2018.

Searching other resources

Searching reference lists of included trials and relevant reviews

We aimed to identify other potentially eligible trials or ancillary publications by searching the reference lists of retrieved included trials, as well as relevant systematic reviews, meta-analyses, and health technology assessment reports. However, we identified no further eligible trials.

Searching by contacting individuals or organisations

We contacted 19 authors of key papers and abstracts to request further information regarding registered trials. We received one reply, and the author reported the trial was not conducted.

Adverse effects

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

Data collection and analysis

We carried out data collection and analysis according to methods stated in the published protocol (Moore 2011), which were based on the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a).

Selection of studies

Two review authors independently assessed titles and, where available, abstracts of the trials identified by the search strategy against the eligibility criteria for inclusion in the review. We obtained full versions of potentially relevant trials and the two review authors independently screened these against the inclusion criteria. Any differences in opinion were resolved by discussion and, where necessary, reference to Cochrane Wounds editorial base. We completed a PRISMA flowchart to summarise this process (Liberati 2009; Figure 1).

Figure 1. Study flow diagram

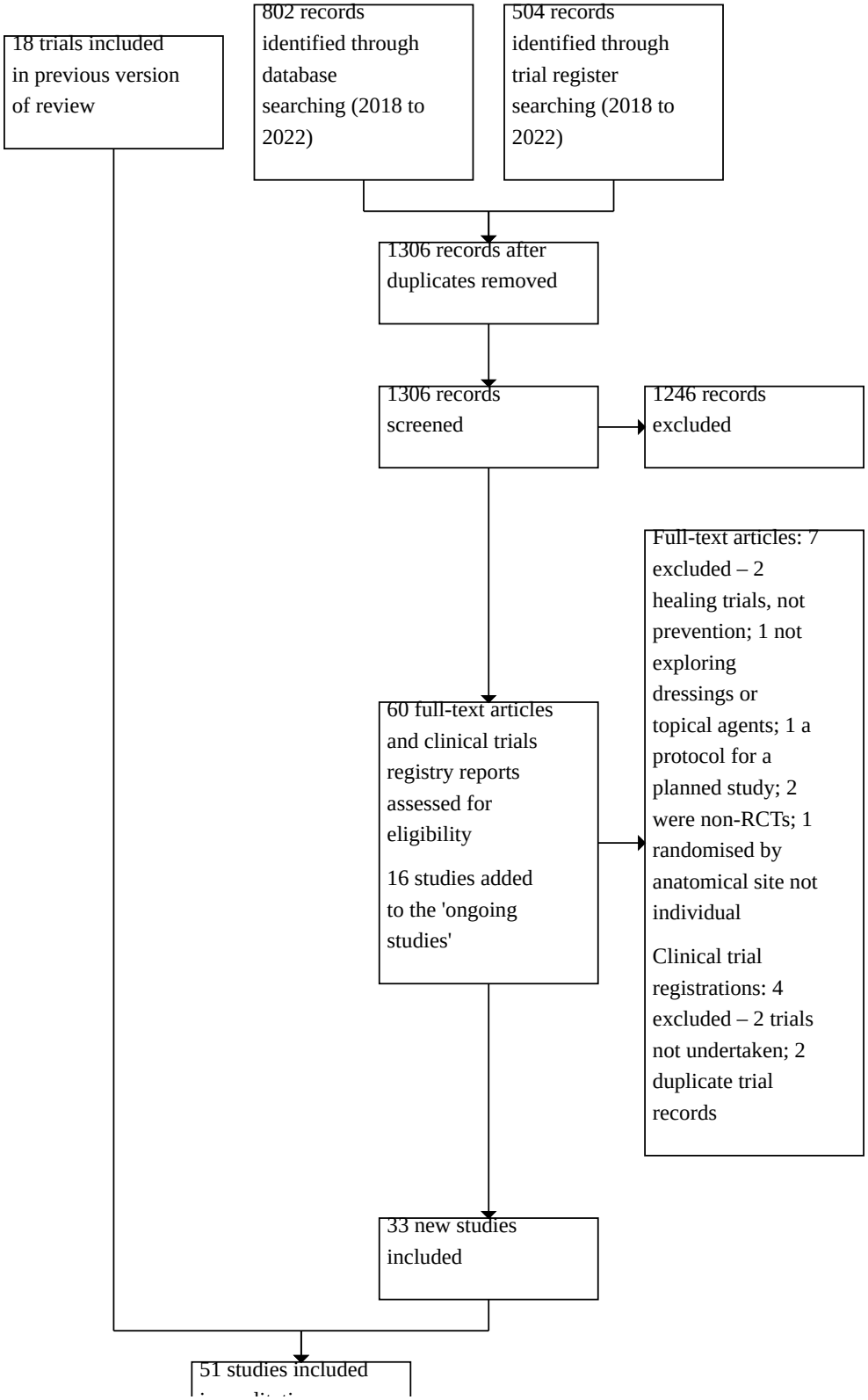
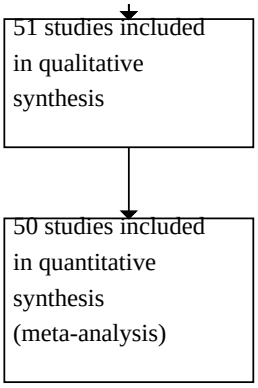


Figure 1. (Continued)



Data extraction and management

Two review authors independently extracted data from eligible trials using a data extraction sheet. Specifically, we extracted the following information:

- author, title, source;
- date of trial, trial's geographical location;
- funding source;
- care setting;
- inclusion/exclusion criteria;
- participant characteristics;
- balance of groups at baseline;
- trial design details;
- method of randomisation;
- allocation concealment;
- sample size calculation and sample size;
- intervention details; concurrent interventions;
- type of dressing and frequency of dressing change;
- use of additional dressing materials;
- participants' length of hospital stay;
- outcome measures;
- blinding (of the participants/outcome assessors);
- length of follow-up;
- loss to follow-up;
- results;
- intention-to-treat analysis; and
- conclusions as reported by the trial authors.

We resolved any differences in opinion by discussion and, where necessary, with reference to Cochrane Wounds editorial base. If data were missing from reports, we attempted to contact trial authors to obtain the missing information.

Assessment of risk of bias in included studies

Two review authors independently assessed the included trials using the original Cochrane risk of bias (RoB 1) tool for assessing risk of bias (Higgins 2011b). This tool addresses six specific domains: sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and other issues (e.g. extreme baseline imbalance). See Appendix 3 for details of the criteria on which our judgements were based. We assessed the overall risk of bias for each study.

Measures of treatment effect

For dichotomous outcomes, we calculated the risk ratio (RR) plus 95% confidence intervals (CI). For continuous outcomes, we calculated a mean difference (MD) plus 95% confidence intervals. We planned to analyse time-to-event data (e.g. time to ulceration) as survival data, using the appropriate analytical method (as per the *Cochrane Handbook for Systematic Reviews of Interventions*; Deeks 2011). If time-to-event data had been incorrectly presented as continuous data, we would have presented the data in a narrative format in the review. We planned to collect data only from those trials where scales had been validated and were self-reported or completed by an independent rater or relative (not the therapist or investigator). We planned to use the standardised mean difference as the summary statistic in any meta-analysis of such data (Deeks 2011).

Unit of analysis issues

Ideally, a trial would be designed with participant-level randomisation and analysis, and there would only be one pressure ulcer per participant (adjustment for clustering not necessary in this case). However, in pressure ulcer literature, it is not unusual to find trials that report outcomes for multiple pressure ulcers per randomised participant without adjusting for the cluster effect.

In such cases, we planned to contact the trial authors to attempt to obtain:

- participant-level data or results;
- data or results for one pressure ulcer per participant; or
- pressure ulcer-level data.

We then planned to perform multilevel regression to calculate the adjusted effect. We then would have combined the adjusted results in the meta-analysis with those of participant-level trials (using the generic-inverse method), and performed sensitivity analyses (Higgins 2011c). When we were unsuccessful in obtaining the additional data required, we assessed each study individually and determined whether to include the trial in the meta-analysis. We

took these studies into account in the risk of bias assessment when included.

Dealing with missing data

If there was evidence of missing data, we contacted the trial authors to request the information. Where trial authors could not provide missing data, we assessed the risk of bias in the missing data and decided if the missing data were of 'low' or 'high' risk of bias according to our risk of bias criteria (Higgins 2011b). Or, if we considered data to be missing at random, we analysed the available information. Where outcome data were missing, we used an available-case analysis, based on the numbers of participants for whom outcome data were known.

Assessment of heterogeneity

We explored clinical heterogeneity by examining potentially influential factors: for example, type of topical agent or dressing, care setting, or participant characteristics, such as level of mobility. We assessed statistical heterogeneity using the I^2 measure (Higgins 2003). This examines the percentage of total variation across trials due to clinical or methodological heterogeneity, or both, rather than to chance. Values of I^2 over 75% indicate a high level of heterogeneity.

Assessment of reporting biases

We assessed reporting bias according to guidelines in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). Reporting bias may occur for a number of reasons, including a greater likelihood of studies being published that report positive findings, and selective reporting of only those outcomes that favour the experimental intervention. We assessed reporting bias in each study as part of our risk of bias evaluation. To inspect for evidence of publication bias, we created a funnel plot for study data for two review outcomes (pressure ulcer incidence; pressure ulcer stage) in which we pooled the data from at least 10 trials.

Data synthesis

We conducted a structured narrative summary of the trials reviewed. We entered quantitative data into Review Manager (RevMan) (RevMan 2024), and conducted analyses using RevMan software. For dichotomous outcomes, we calculated risk ratios (RR) with 95% confidence intervals (CI). RR is the ratio of the risk of the event of interest (e.g. pressure ulcers developed) in the experimental group divided by the risk of this event in the control group and indicates the chances of pressure ulcer development for people in the experimental group compared with the control group (Deeks 2011). An RR of 1 means that there is no difference between two groups in terms of their risk of pressure ulcer development, whereas an RR of greater than 1, or of less than 1, usually means that use of a specific topical agent or dressing either increases (RR > 1) or decreases (RR < 1) the risk of pressure ulcer development (Deeks 2011). As, by definition, the risk of an event occurring in the control group is 1, then the RR reduction associated with using an experimental treatment is 1-RR. The RR indicates the relative benefit of a therapy, but not the actual benefit; that is, it does not take into account the number of people who would have developed a pressure ulcer anyway, without the intervention (Deeks 2011). For continuous outcomes, we calculated the mean difference (MD) with 95% confidence intervals. The MD is a standard statistic that measures the absolute difference between the mean value of two groups in a clinical trial. It estimates the amount by which the experimental intervention changes the outcome on average compared with the control. Interpretation of the results is the same as RR, except the point of no effect is 0 rather than 1 (Deeks 2011).

We carried out statistical pooling on groups of trials that we considered to be sufficiently similar (where populations, interventions, and methods were considered sufficiently similar). Where heterogeneity was absent or low (I^2 = 0% to 25%), we used a fixed-effect model. If there was evidence of heterogeneity (I^2 more than 25%), we used a random-effects model. If heterogeneity was very high (I^2 over 75%), we did not plan to pool trials.

Subgroup analysis and investigation of heterogeneity

We planned to conduct a subgroup analysis investigating the effects of any dressing or topical application on trials conducted in the community versus trials conducted in hospitals to compare effects due to differences in patient characteristics. However, we were unable to conduct this analysis as there were no comparisons which included both types of studies (i.e. those conducted in hospital versus in the community). No further subgroup analysis was conducted.

Sensitivity analysis

We did not consider any of the trials at low risk for our pre-defined key domains, so no sensitivity analyses were conducted.

Summary of findings and assessment of the certainty of the evidence

We have prioritised comparisons based on clinical and patient importance/relevance to current practice and have presented these in summary of findings tables. Summary of findings tables present key information concerning the certainty of the evidence, the magnitude of the effects of the interventions examined, and the sum of the available data for the main outcomes (Schünemann 2011a). Summary of findings tables also include an overall grading of the evidence related to each of the main outcomes using the GRADE approach (Schünemann 2011b). This approach defines the certainty of a body of evidence with regard to the extent to which one can be confident that an estimate of effect or association is close to the quantity of specific interest. To assess the overall body of evidence, we developed summary of findings tables using GRADEpro GDT 2024.

We included summary of findings tables for comparisons where:

- the intervention was similar, but controls differed, as long as there was no significant clinical or statistical heterogeneity between trials;
- the intervention and controls were similar between trials.

We assessed the certainty of the body of evidence against five principal domains: limitations in design and implementation (for example, we assessed blinding and completeness of outcome data); indirectness of evidence or generalisability of findings; inconsistency of results (for example, unexplained heterogeneity and inconsistent findings); imprecision of results where confidence intervals are wide; and publication bias (Schünemann 2011b). We used the following decision rules for downgrading the evidence for each of the five domains.

- If no serious concern existed, we did not downgrade evidence certainty from the baseline certainty (e.g. high for RCTs).
- If serious concern existed, we downgraded the evidence by one level (e.g. from high to moderate (- 1)).
- If very serious concern existed, we downgraded the evidence by two levels (e.g. from high to low (- 2)) (Ryan 2016).

We presented the following outcomes in the summary of findings tables:

- pressure ulcer incidence (the proportion of people developing any new pressure ulcer(s) of any stage);
- pressure ulcer stage;
- adverse events.

RESULTS

Description of studies

Results of the search

The original search identified 19 potentially relevant trials, nine of which we included in the review. The second updated search yielded 496 records and six additional records from other sources; from these, we selected nine additional studies for inclusion in the review. The review then included 17 published trials and one unpublished trial, yielding a total of 18 trials. For this third update, we identified 1306 records, which yielded a total of 60 trials potentially eligible for inclusion, based on screening of full texts, abstracts, trial registry records, and references identified from citation checking. From these, we included 33 new studies in the review (see Figure 1). Therefore, this version of the review now includes a total of 51 trials.

Included studies

The review includes results from 51 trials, with a total of 13,303 participants (mean: 665, standard deviation (SD): 1355) (Aloweni 2017; Alves 2020; Babamohamadi 2019; Beeckman 2021; Borzou 2020; Chang 2017; Chen 2020; Chiew 2010; da Silva Augusto 2019; De Wert 2019; Díaz-Valenzuela 2014; Díaz-Valenzuela 2019; Dutra 2015; Eberhardt 2021; Fallahi 2022; Ferrer Sola 2013; Forni 2018; Forni 2022; Gazineo 2020; Green 1974; Guerra 2017; Hahnel 2020; Han 2011; Hekmatpou 2018; Houwing 2008; Huang 2021; Imbulana 2018; Kalowes 2016; Karimi 2020; Lee 2019; Lovegrove 2022; Lupianez-Perez 2015; Madadi 2015; Nakagami 2007; Oe 2020; Otero 2017; Ozbudak 2020; Qiuli 2010; Saab 2015; Santamaria 2015; Smith 1985; Sonmez 2020; Stankiewicz 2019; Torra i Bou 2005; Van Der Cammen 1987; Verdu 2012; Walker 2015; Wang 2016; Yang 2020; Yanping 2018). Of these, three studies were cluster-RCTs (Houwing 2008; Santamaria 2018; Stankiewicz 2019). See Characteristics of included studies.

We attempted to contact 11 trial authors to seek additional information. We were unable to locate Green 1974, Chang 2017, and Yanping 2018. We received no response from Alves 2020, Han 2011, Qiuli 2010, Torra i Bou 2005, Van Der Cammen 1987, or Wang 2016. Two authors, from the Houwing 2008 and Kalowes 2016 studies, responded and provided answers to several questions.

Participants

The mean age of participants in 45 of the trials varied between 27.4 weeks (Imbulana 2018) and 86.6 years (Nakagami 2007). Participants' age was not reported in five trials (Chiew 2010; Han 2011; Otero 2017; Yanping 2018; Wang 2016).

Seven of the trials were conducted in Spain (Díaz-Valenzuela 2014; Díaz-Valenzuela 2019; Ferrer Sola 2013; Lupianez-Perez 2015; Otero 2017; Torra i Bou 2005; Verdu 2012); six in Australia (Imbulana 2018; Lovegrove 2022; Santamaria 2015; Santamaria 2018; Stankiewicz 2019; Walker 2015); seven in China (Chen 2020; Han 2011; Huang 2021; Qiuli 2010; Yang 2020; Yanping 2018; Wang 2016); six in Iran (Babamohamadi 2019; Borzou 2020; Fallahi 2022; Hekmatpou 2018; Karimi 2020; Madadi 2015); four in Italy (Forni 2018; Forni 2022; Gazineo 2020; Guerra 2017); three each in Singapore (Aloweni 2017; Chang 2017; Chiew 2010), Brazil (Eberhardt 2021; da Silva Augusto 2019; Dutra 2015), and the UK (Green 1974; Smith 1985; Van Der Cammen 1987); two each in Turkey (Sonmez 2020; Ozbudak 2020), Japan (Nakagami 2007; Oe 2020), the USA (Kalowes 2016; Saab 2015), and the Netherlands (Houwing 2008; De Wert 2019); and one each in Germany (Hahnel 2020), Portugal (Alves 2020), South Korea (Lee 2019), and Belgium (Beeckman 2021).

An inclusion criterion for 23 trials was that the participants were at high risk of pressure ulcer development according to the Braden pressure ulcer risk assessment scale (Bergstrom 1987) (these 23 studies were: Aloweni 2017; Babamohamadi 2019; Beeckman 2021; Borzou 2020; Chang 2017; da Silva Augusto 2019; Díaz-Valenzuela 2014; Díaz-Valenzuela 2019; Dutra 2015; Fallahi 2022; Ferrer Sola 2013; Forni 2022 ; Hekmatpou 2018; Houwing 2008; Kalowes 2016; Karimi 2020; Lee 2019 ; Lupianez-Perez 2015; Nakagami 2007; Torra i Bou 2005; Santamaria 2018;Sonmez 2020; Verdu 2012). For one trial, the individuals had a Norton pressure sore risk-assessment scale score of between five and 14 (Norton 1975), meaning high or very high risk (Van Der Cammen 1987). For a further three trials, the participants had a Waterlow score of 18 to 23 (Waterlow 1985), meaning high or very high risk (Qiuli 2010), a score of 10 and higher (Lovegrove 2022), or a score of 15+ (Walker 2015). In De Wert 2019, participants had to have a prePURSE (Prevention and Pressure Ulcer Risk Score Evaluation) score of 21 or higher, or a Braden score above 19. The remaining trials used other risk criteria. For example, Green 1974 used what was defined as a "clinical risk score"; Smith 2010 included elderly continuing care patients with "intact skin"; Chiew 2010 recruited elderly, high-risk orthopaedic patients; and Santamaria 2015 included high-risk people in intensive care units (ICU). In Forni 2018, participants were aged 65 years and older with a hip fragility fracture. In Otero 2017, participants were adults over the age of 18 years, with acute respiratory failure requiring non-invasive ventilation (NIV). In Wang 2016, participants were patients also requiring non-invasive ventilation. In Chen 2020, eligibility criteria specified children who were consecutively intubated with silicone nasotracheal tubes. In Eberhardt 2021, participants were hospitalised patients in the preoperative period of digestive or cardiac elective surgery. In Gazineo 2020, participants were hospitalised patients with a fragility hip fracture diagnosis. In Yang 2020, participants were people undergoing surgery, and in Huang 2021, participants were undergoing thoracolumbar surgery in the prone position. In Guerra 2017, participants were children aged three years and older who underwent surgery for flat foot. In Hahnel 2020, participants were adults in the ICU at high or very high pressure ulcer risk. In Imbulana 2018, participants were newborns under 30 weeks of gestation or with a birth weight under 1250 g, undergoing treatment with binasal prongs (either continuous positive airway pressure (CPAP) or nasal intermittent positive pressure ventilation). In Oe

2020, participants were hospital inpatients with persistent severe diarrhoea, fragile skin, or both. In Ozbudak 2020, participants were hospitalised adults with respiratory failure. In Stankiewicz 2019 and Madadi 2015, participants were adult ICU patients. In Alves 2020, Han 2011, Saab 2015, and Yanping 2018, the inclusion criteria were unclear.

Eleven studies were conducted in a general ICU (Alves 2020; Babamohamadi 2019; Borzou 2020; Fallahi 2022; Hahnel 2020; Hekmatpou 2018; Karimi 2020; Lee 2019; Madadi 2015; Sonmez 2020; Stankiewicz 2019), one in a paediatric ICU (Chen 2020), and one in a neonatal ICU (Imbulana 2018). Six studies were conducted in a medical/surgical/trauma intensive care unit, a cardiac intensive care unit (Dutra 2015; Kalowes 2016; Saab 2015; Santamaria 2015; Ozbudak 2020), or a high dependency unit (Otero 2017). Eighteen studies were conducted in an acute medical, surgical (Aloweni 2017; Chiew 2010; Eberhardt 2021; Forni 2022; Torra i Bou 2005; Walker 2015), orthopaedic (Guerra 2017; Gazineo 2020; Han 2011; Huang 2021; Forni 2018; Yang 2020), or general hospital setting (Chang 2017; da Silva Augusto 2019; De Wert 2019; Oe 2020; Yanping 2018; Van Der Cammen 1987). In Beeckman 2021, participants were drawn from three university or teaching hospitals and five general hospitals, including ICU and non-ICU wards. In Verdu 2012, participants were drawn from hospital and socio-sanitary centres in eight locations. Nine studies were conducted amongst elderly hospitalised or nursing home patients (Díaz-Valenzuela 2014; Díaz-Valenzuela 2019; Ferrer Sola 2013; Green 1974; Houwing 2008; Lovegrove 2022; Nakagami 2007; Smith 1985; Santamaria 2018). In Qiuli 2010, people with paralysis or coma were included, and participants in Lupianez-Perez 2015 were immobilised people living at home. In Wang 2016, the study setting was not stated.

Interventions

See Table 1 for the composition of the topical agents and dressings. In all the reported RCTs, both the control and intervention groups received standard pressure ulcer prevention, with the intervention groups additionally receiving either dressings or topical agents.

Dressings

A dressing was the intervention of interest in 31 included trials.

In Nakagami 2007, a dressing known as PPD (pressure ulcer preventive dressing) was applied in the intervention group. This consists of a skin adhesive layer (hydrocolloid) containing an intercellular lipid-ceramide, a support layer (urethane film) and an outer layer of multi-filament nylon fibres. They applied the dressing to either the right or left greater trochanter (depending on randomisation) of the participant. The dressing was replaced weekly. No dressing was applied in the control arm of the trial.

In Han 2011, a polyurethane film and foam dressing ("Kang' huier" transparent strip and foam dressing) was the intervention. They applied the dressing to the pressure areas of the participants during surgery. The control group did not have any dressings applied.

In Ferrer Sola 2013, the classic padded bandage was compared with a polyurethane foam heel.

In Dutra 2015, a transparent polyurethane film was compared to a group receiving a hydrocolloid dressing. They applied the dressings bilaterally to the trochanteric and sacral regions of the participants and changed them only if there was loss of adhesiveness, shear, excessive moisture, friction, presence of wrinkles, or the combination of these factors.

In Imbulana 2018, a hydrocolloid nasal barrier dressing applied during binasal CPAP therapy was compared to no barrier dressing.

In Yanping 2018, a foam dressing was compared with a transparent film on vulnerable pressure areas.

In da Silva Augusto 2019, a hydrocellular foam was compared with a hydrocolloid plate over the sacrum and trochanters.

In Chen 2020, a hydrocolloid dressing applied to the nasal columella of the ala was compared with a control group receiving usual care.

In Karimi 2020, olive oil-soaked gauze was compared with fish oil-soaked gauze applied to participants' heels.

The Ozbudak 2020 study compared a transparent film applied to participants before their oronasal mask was placed, with a control group receiving no dressing.

In Yang 2020, the comparison was a hydroactive dressing versus standard medical tape, applied to the nasal ala to which the nasotracheal tube was affixed.

In Alves 2020, Beeckman 2021, De Wert 2019, Eberhardt 2021, Forni 2018, Forni 2022, Gazineo 2020, Guerra 2017, Hahnel 2020, Kalowes 2016, Lee 2019, Lovegrove 2022, Oe 2020, Qiuli 2010, Saab 2015, Santamaria 2015, Santamaria 2018, Stankiewicz 2019, Walker 2015, and Wang 2016, multilayered polyurethane foam dressings were applied to the sacrum, coccyx, buttocks, heels, or nasal areas, and were compared with usual pressure ulcer prevention care.

Topical application and dressing

Both dressings and topical agents were the intervention of interest in four included trials.

In Otero 2017, participants were allocated into one of four groups; (1) a control group; (2) an adhesive thin polyurethane foam dressing (ATD) group; (3) an adhesive foam dressing (AFD) group; or (4) a group which received hyperoxygenated fatty acids (HOFA), gently applied without rubbing, on the chin, cheekbones, nasal bridge, and forehead. In groups 2 and 3, the dressings were placed over the nasal bridge and cheekbones.

In Aloweni 2017, participants were allocated to one of three groups: (1) silicone foam dressing to the sacrum, in addition to standard care; (2) fatty acid oil spray to the sacrum plus standard care; (3) standard care only.

In Chang 2017, participants were allocated to one of three groups: (1) multilayer silicone foam dressing in addition to standard care; (2) fatty acid oil spray on the sacrum in addition to standard care; (3) standard care only.

In Huang 2021, participants in the control group received a foam dressing applied to anatomical areas at risk of developing a pressure ulcer. In the intervention group, participants received Sanyrene cream applied to the anatomical areas at risk of developing a pressure ulcer, followed by application of a foam dressing.

Topical applications

We included 16 trials where a topical application was the intervention of interest.

In Green 1974, the intervention was a lotion described as "active", containing hexachlorophane 0.5%, saturated hydrocarbons (squalene (Cosbiol 3%) and glyoxyle diureide), allantoin 0.2%, antioxidants, lanolin, fatty acids, fatty acid esters, fatty alcohols, preservatives, and distilled water. For the control group, they applied a lotion described as "inert", containing lanolin, fatty acids, fatty acid esters, fatty alcohols, preservatives, distilled water, and mineral oils. They applied the lotions manually to pressure areas (sacral, trochanteric, heel, shoulder, and other areas, as indicated), and avoided excess friction. They inspected the participants' skin every two hours, and, if the participant was incontinent, they washed the skin with soap and water, then dried it and applied the relevant lotion. In the absence of incontinence, they carried out routine washing and reapplication of lotion every six hours.

In Smith 1985, Conotrane was the topical application for the intervention, which includes silicone cream, 20% dimethicone 350, and a broad spectrum antiseptic (0.05% hydrargaphen). They described the topical application in the control group as a bland cream known as Unguentum. For both groups, as part of the routine skin care regimen, they washed participants' skin when required, with water, then dried it thoroughly and applied the ointment.

In Van Der Cammen 1987, Prevasore was the topical application, which includes hexyl nicotinate, zinc stearate, isopropyl myristate, dimethicone 350, cetrimide, and glycol. In the control group, the topical application was Dermalex, which includes hexachlorophane, squalene, and allantoin. In both groups, they washed and dried the participants' buttocks and sacral areas, and applied the topical application at least twice daily, and again after changing, if the individual was wet or soiled.

In Torra i Bou 2005, Mepentol was the topical application for the intervention group, a hyperoxygenated fatty acid compound consisting of oleic acid, palmitic acid, stearic acid, palmitoleic acid, linoleic acid, gamma linoleic acid, arachidonic acid, and eicosenoic acid. The control group topical application was a compound consisting of triisostearin (99.4%) and perfume (0.6%). In both groups, they applied the topical application twice daily to at least three areas of the body: sacrum, trochanters, and heels.

In Houwing 2008, participants were allocated to one of three groups, as follows. (1) "DMSO-cream" was the intervention, which consists of 5% dimethyl sulfoxide in Vaseline-cetomacrogol cream; participants also had a 30° position change every six hours. (2) Placebo topical application was a three-minute massage of the buttock, heel, and ankle regions with an "indifferent" cream (Vaseline-cetomacrogol), combined with a 30° position change every six hours for four weeks. (3) Control group, in which no topical application was applied, but the participants had a 30° position change every six hours for four weeks.

In Chiew 2010, the intervention was a solution of 99% of hyperoxygenated glycerides of essential fatty acids (including linoleic acid 60%, linolenic acid, tocopherol, and vitamin E) and aniseed perfume 1%, known as Sanyrene, combined with two- to three-hourly changes of position in the intervention group. They applied the topical agent on the participants' sacrum, buttocks, and heels at every change of position from the day of admission. The control group received two- to three-hourly changes of position only.

In Verdu 2012, the intervention group received a new topical agent (IPARZINE-4A-SKR): the product was applied according to the following procedure: on at least 3 pressure ulcer risk areas; namely, sacrum, trochanters, and heels. Application frequency was every 12 hours. The control group received a placebo topical agent. The product was applied according to the following procedure: on at least 3 pressure ulcer risk areas; namely, sacrum, trochanters, and heels. Application frequency was every 12 hours.

In Díaz-Valenzuela 2014, a hyperoxygenated fatty acid compound, Mepentol, in the control group was compared with extra virgin olive oil (Oleicopiel) in the experimental group. They applied the topical treatments every 12 hours to risk areas of the skin.

In Lupianez-Perez 2015, a hyperoxygenated fatty acid product containing *Equisetum arvense*, *Hypericum perforatum,* and perfume in the intervention group, was compared with an olive oil product containing 97% extra virgin olive oil and 3% *Hypericum perforatum* and peppermint in the control group. They used two applications of the topical treatments on the skin areas of the sacrum, hips, and heels.

In Madadi 2015, the intervention group received a 15 cubic centimetre (cc) premium and standard formula olive oil. This oil was applied gently once a day on the following areas of the participants' bodies without any massaging: earlobes (0.5 cc each), shoulders (1.5 cc each), spine (1.5 cc), waist (1.5 cc), buttocks (1.5 cc each), iliac (1 cc), sacrum (1cc), elbows (0.5 cc each), heels (0.5 cc each), and ankles (0.5 cc each).

In Hekmatpou 2018, pure aloe vera gel was compared with placebo (water and starch) rubbed on the hips, sacrum, and heels twice a day (hours of 9 and 21), in addition to routine nursing care.

In Babamohamadi 2019, peppermint gel was compared with placebo gel, rubbed on the skin of areas at risk for pressure ulcers, including the participants' hip area, and bony prominences such as both elbows, knees, heels, and shoulder, three times daily.

In Díaz-Valenzuela 2019, a hyperoxygenated fatty acid product applied to pressure ulcer risk areas in addition to usual care procedures, twice a day, was compared with olive oil.

In Borzou 2020, participants were allocated to one of three groups: (1) sweet almond oil; (2) paraffin; (3) control.

In Sonmez 2020, extra virgin olive oil, applied to the sacrum, trochanteric regions, and heels, was compared with standard pressure ulcer prevention.

In Fallahi 2022, participants were allocated to one of four groups: (1) aloe vera gel; (2) olive oil; (3) compound aloe vera gel plus olive oil; (4) control.

None of the trials using topical applications applied any additional dressings. They applied the topical agent directly to the skin and the skin was then left bare.

Outcomes

All the trials included the development of a pressure ulcer as their primary outcome. Three used the European Pressure Ulcer

Advisory Panel (EPUAP) 1999 scale (Houwing 2008; Madadi 2015; Nakagami 2007). Three used the EPUAP/NPUAP (National Pressure Ulcer Advisory Panel) 2009 scale (Díaz-Valenzuela 2019; Forni 2022; Sonmez 2020). Nine used the EPUAP/National Pressure Injury Advisory Panel (NPIAP)/Pan Pacific Pressure Injury Alliance (PPPIA) 2014 scale (Aloweni 2017; Babamohamadi 2019; Borzou 2020; Gazineo 2020; Guerra 2017; Hahnel 2020; Lee 2019; Ozbudak 2020; Santamaria 2018). Six used the revised National Pressure Ulcer Advisory Panel Pressure Injury Staging System (2016) (Edsberg 2016; da Silva Augusto 2019; Fallahi 2022; Hekmatpou 2018; Oe 2020; Yang 2020). Six used the EPUAP/NPIAP/PPPIA 2019 scale (Díaz-Valenzuela 2014; Eberhardt 2021; Forni 2018; Huang 2021; Karimi 2020; Walker 2015). Han 2011 reported the use of an international measurement for pressure ulcers titled "WCET" (Black 2007). Green 1974 used a five-point scale. Smith 1985 used the Barbarel 1977 classification. Van Der Cammen 1987 used a five-point scale. Santamaria 2015 used the four-point staging system of the Australian Wound Management Association. Ferrer Sola 2013 and Otero 2017 used the GNEAUPP (Grupo Nacional para el Estudio y Asesoramiento en Úlceras por Presión y Heridas Crónicas) classification for pressure ulcer staging (García-Fernández 2014). Finally, 17 studies did not identify the classification system used (Alves 2020; Beeckman 2021; Chang 2017; Chiew 2010; De Wert 2019; Dutra 2015; Imbulana 2018; Kalowes 2016; Lovegrove 2022; Lupianez-Perez 2015; Qiuli 2010; Saab 2015; Stankiewicz 2019; Torra i Bou 2005; Verdu 2012; Wang 2016; Yanping 2018).

Ethics and consent

Nineteen studies did not provide any information about ethics approval or participant consent (Alves 2020; Borzou 2020; Chang 2017; Chen 2020; Chiew 2010; Eberhardt 2021; Ferrer Sola 2013; Forni 2022; Green 1974; Guerra 2017; Han 2011; Huang 2021; Kalowes 2016; Qiuli 2010; Saab 2015; Van Der Cammen 1987; Wang 2016; Yang 2020; Yanping 2018). The Santamaria 2015 and Smith 1985 studies had ethical approval, but they did not report participants' consent. The remaining trials provided information on ethics and consent (Aloweni 2017; Babamohamadi 2019; Beeckman 2021; da Silva Augusto 2019; Díaz-Valenzuela 2014; Díaz-Valenzuela 2019; Dutra 2015; Fallahi 2022; Forni 2018; Gazineo 2020; Hahnel 2020; Hekmatpou 2018; Houwing 2008; Imbulana 2018; Karimi 2020; Lee 2019; Lovegrove 2022; Lupianez-Perez 2015; Madadi 2015; Nakagami 2007; Otero 2017; Oe 2020; Ozbudak 2020; Santamaria 2018; Sonmez 2020; Stankiewicz 2019; Verdu 2012; Torra i Bou 2005; Walker 2015).

Funding

Fifteen studies reported receiving support from the manufacturers of the interventional product (da Silva Augusto 2019; Forni 2022; Gazineo 2020; Green 1974; Hahnel 2020; Han 2011; Kalowes 2016; Lee 2019; Lovegrove 2022; Nakagami 2007; Santamaria 2015; Santamaria 2018; Smith 1985; Torra i Bou 2005; Van Der Cammen 1987). Four studies did not provide any details about sponsorship (Chiew 2010; Otero 2017; Qiuli 2010; Saab 2015). Investigators in Nakagami 2007 were involved in developing the dressing used in the trial. The corresponding author in Van Der Cammen 1987 was an employee of the company producing the intervention product. The manufacturers provided the dressings in Forni 2018. Seventeen trials received funding from a non-commercial source (Aloweni 2017; Babamohamadi 2019; Beeckman 2021; Borzou 2020; Díaz-Valenzuela 2014; Díaz-Valenzuela 2019; Dutra 2015; Eberhardt 2021; Fallahi 2022; Guerra 2017; Hekmatpou 2018; Imbulana 2018; Karimi 2020; Lupianez-Perez 2015; Oe 2020; Verdu 2012; Walker 2015). Four studies did not receive any funding (Madadi 2015; Stankiewicz 2019; Ozbudak 2020; Sonmez 2020), and nine trials did not state whether funding was received (Alves 2020; Chang 2017; Chen 2020; Ferrer Sola 2013; Houwing 2008; Huang 2021; Wang 2016; Yang 2020; Yanping 2018).

Excluded studies

The previous version of this review excluded 16 trials (Moore 2018). In this third update, we excluded a further seven trials (Genc 2022; Guo 2015; Kim 2016; Lockwood 2022; Miraj 2020; Poursadra 2019; Yang TY 2020). Two of these trials related to interventions for treating pressure ulcers rather than for prevention of pressure ulcers. One study did not include a dressing or a topical agent; one was a protocol for a planned study; two were non-randomised studies; and one did not randomise individuals, instead they randomised sites (left/right chest). See Characteristics of excluded studies.

Ongoing studies

We identified 19 ongoing studies (ACTRN12619000763145; ACTRN12620000875909; ACTRN12621001072808; ACTRN12622000728730; ACTRN12622000793718; ACTRN12622001360707; ChiCTR2100050305; CTRI/2021/11/038231; IRCT20150519022320N20; IRCT20160110025929N23; IRCT20210317050732N1; IRCT20220110053683N1; JPRN-UMIN000024609; KCT0006781; NCT02565745; NCT04682925; NCT05198167; NCT05578638; RBR-4s8qjx). We contacted the investigators of five ongoing studies. We received no response from JPRN-UMIN000024609 and RBR-4s8qjx. In the three remaining studies, we learned that data collection is complete, but analysis is not yet available (KCT0006781; NCT04682925; NCT02565745). See Characteristics of ongoing studies.

Risk of bias in included studies

See Figure 2 for the risk of bias summary and Figure 3 for the risk of bias graph.

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

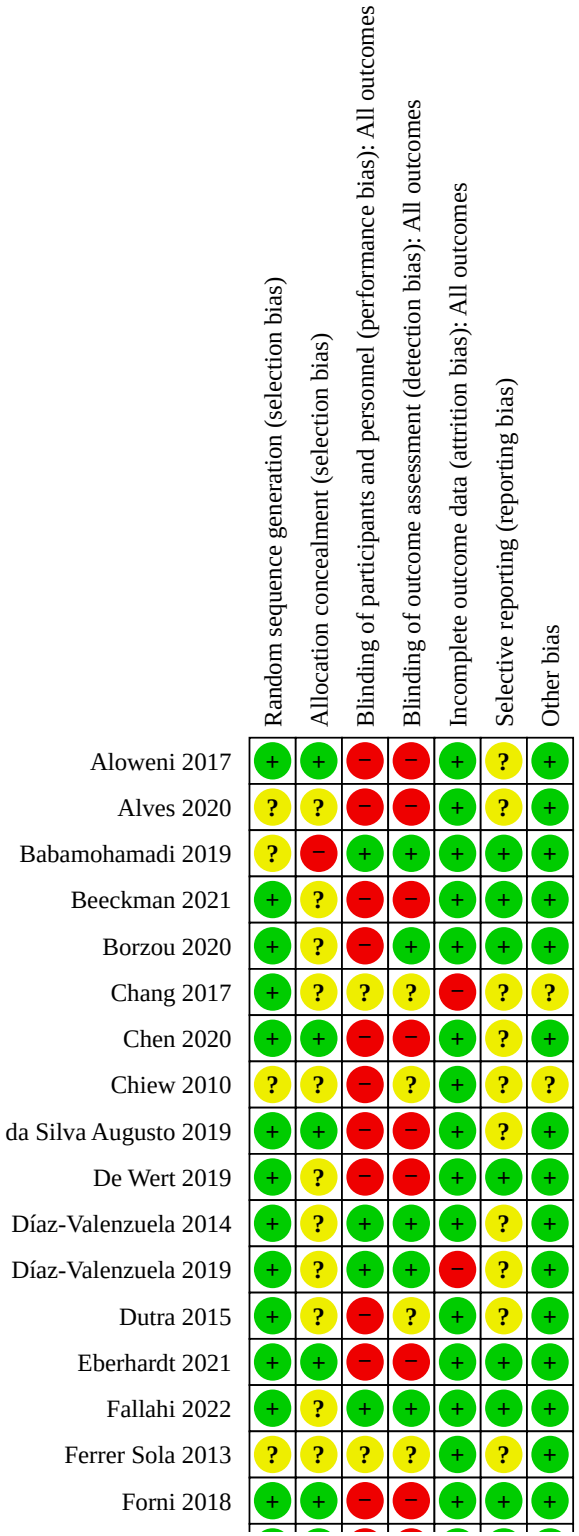


Figure 2. (Continued)

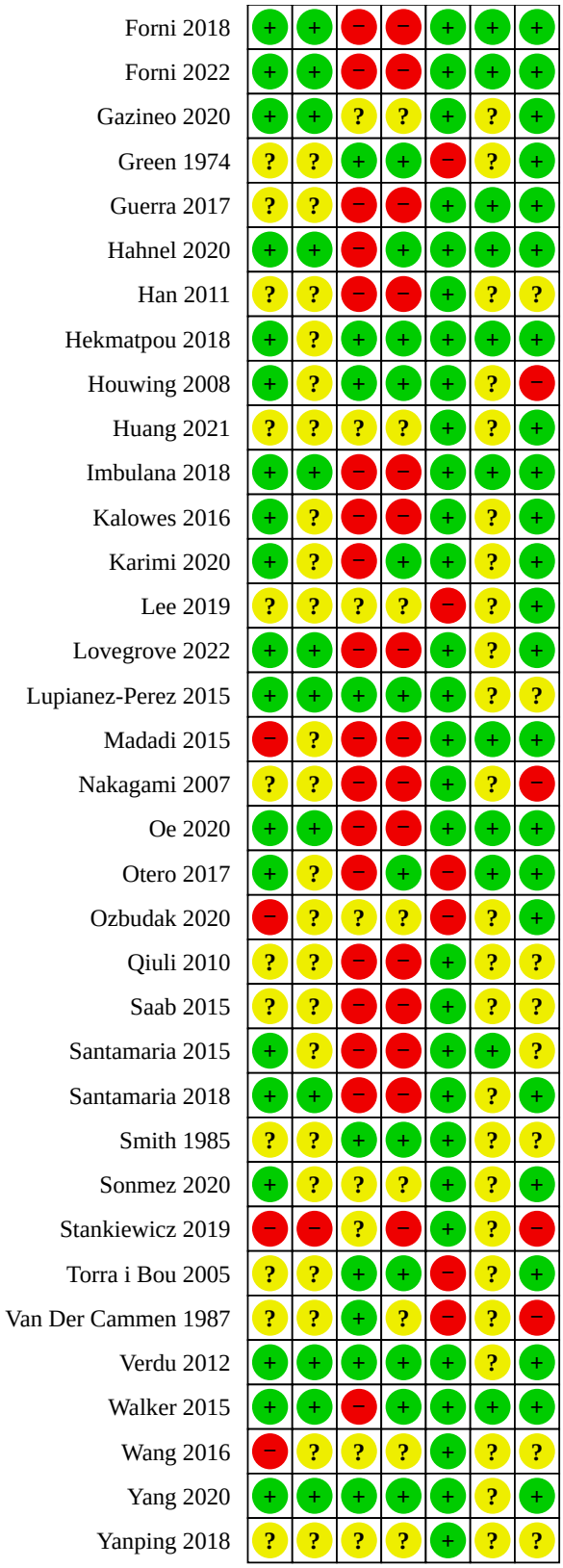
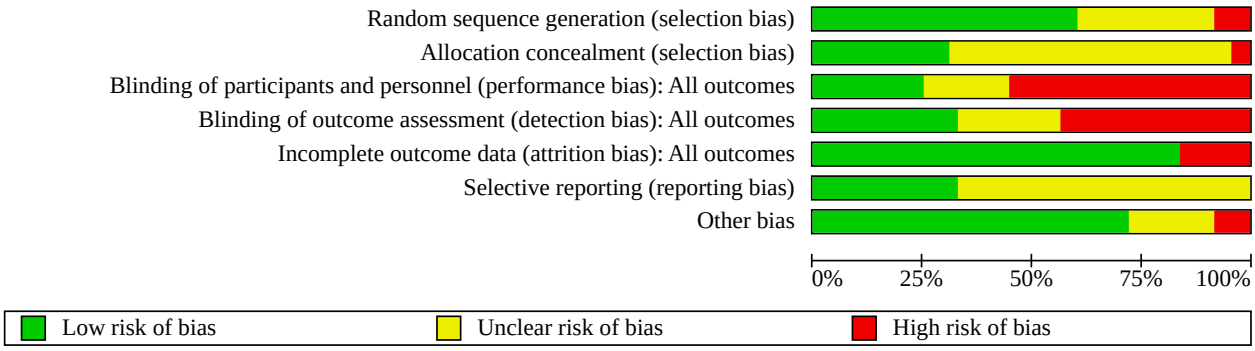


Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies



Allocation

Random sequence generation

Thirty-one trials provided details of appropriate methods used for generating the allocation sequence (Aloweni 2017; Beeckman 2021; Borzou 2020; Chang 2017; Chen 2020; da Silva Augusto 2019; De Wert 2019; Díaz-Valenzuela 2014; Díaz-Valenzuela 2019; Dutra 2015; Eberhardt 2021; Fallahi 2022; Forni 2018; Forni 2022; Gazineo 2020; Hahnel 2020; Hekmatpou 2018; Houwing 2008; Imbulana 2018; Kalowes 2016; Karimi 2020; Lovegrove 2022; Lupianez-Perez 2015; Oe 2020; Otero 2017; Santamaria 2015; Santamaria 2018; Sonmez 2020; Verdu 2012; Walker 2015; Yang 2020); we judged these to be at low risk of bias in this domain. Twenty-eight used a computer-generated list (Aloweni 2017; Beeckman 2021; Borzou 2020; Chang 2017; Chen 2020; da Silva Augusto 2019; De Wert 2019; Díaz-Valenzuela 2014; Díaz-Valenzuela 2019; Eberhardt 2021; Fallahi 2022; Forni 2018; Forni 2022; Gazineo 2020; Guerra 2017; Hahnel 2020; Hekmatpou 2018; Imbulana 2018; Karimi 2020; Lovegrove 2022; Lupianez-Perez 2015; Oe 2020; Santamaria 2015; Santamaria 2018; Sonmez 2020; Verdu 2012; Walker 2015; Yang 2020); one stated that they had used a lottery to generate the sequence (Dutra 2015); one trial used the throw of a die to generate the sequence (Houwing 2008); and one randomised individuals using specifically designed random number tables (Otero 2017). Four studies did not describe appropriate methods for generating the allocation sequence, and we judged these to be at high risk of bias in this domain (Madadi 2015; Ozbudak 2020; Stankiewicz 2019; Wang 2016). The remaining trials did not clearly state their method for sequence generation and were therefore judged at unclear risk of bias in this domain (Alves 2020; Babamohamadi 2019; Chiew 2010; Ferrer Sola 2013; Green 1974; Guerra 2017; Han 2011; Huang 2021; Lee 2019; Nakagami 2007; Qiuli 2010; Saab 2015; Smith 1985; Torra i Bou 2005; Van Der Cammen 1987; Yanping 2018).

Allocation concealment

Sixteen trials used adequate allocation concealment methods; we judged these to be at low risk of bias in this domain (Aloweni 2017; Chen 2020; da Silva Augusto 2019; Eberhardt 2021; Forni 2018; Forni 2022; Gazineo 2020; Hahnel 2020; Imbulana 2018; Lovegrove 2022; Lupianez-Perez 2015; Oe 2020; Santamaria 2018; Verdu 2012; Walker 2015; Yang 2020). Two studies did not describe appropriate methods for generating the allocation sequence, and we judged these to be at high risk of bias in this domain (Babamohamadi 2019; Stankiewicz 2019). We judged the remaining 33 trials to be at unclear risk of bias in this domain as their methods for concealing group allocation were unclear (Alves 2020; Beeckman 2021; Borzou 2020; Chang 2017; Chiew 2010; De Wert 2019; Díaz-Valenzuela 2014; Díaz-Valenzuela 2019; Dutra 2015; Fallahi 2022; Ferrer Sola 2013; Green 1974; Guerra 2017; Han 2011; Hekmatpou 2018; Houwing 2008; Huang 2021; Kalowes 2016; Karimi 2020; Lee 2019; Madadi 2015; Nakagami 2007; Otero 2017; Ozbudak 2020; Qiuli 2010; Saab 2015; Santamaria 2015; Smith 1985; Sonmez 2020; Torra i Bou 2005; Van Der Cammen 1987; Wang 2016; Yanping 2018).

Blinding

We assessed 12 studies as having a low risk of performance and detection bias as they were reported as double-blind (Babamohamadi 2019; Díaz-Valenzuela 2014; Díaz-Valenzuela 2019; Fallahi 2022; Green 1974; Hekmatpou 2018; Houwing 2008; Lupianez-Perez 2015; Smith 1985; Torra i Bou 2005; Verdu 2012; Yang 2020).

Five studies ensured blinding of the outcome assessors only (Borzou 2020; Hahnel 2020; Karimi 2020; Otero 2017; Walker 2015). Therefore, we judged these studies to be at low risk of detection bias, but high risk of performance bias.

We assessed 21 studies to be at high risk of performance and detection bias, as participants, carers, and outcome assessors were not blinded (Aloweni 2017; Alves 2020; Beeckman 2021; Chen 2020; da Silva Augusto 2019; De Wert 2019; Eberhardt 2021; Forni 2018; Forni 2022; Guerra 2017; Han 2011; Imbulana 2018; Kalowes 2016; Lovegrove 2022; Madadi 2015; Nakagami 2007; Oe 2020; Qiuli 2010; Saab 2015; Santamaria 2015; Santamaria 2018).

We assessed Chiew 2010 and Dutra 2015 as having a high risk of performance bias and unclear risk of detection bias. Stankiewicz 2019 had an unclear risk of performance bias, and a high risk of detection bias (no blinding of outcome assessment). For one study (Van Der Cammen 1987), there was low risk of performance bias and unclear risk of detection bias.

For the remaining trials, the authors did not state whether the studies were blinded, and thus, we judged these to be at unclear risk of performance and detection bias (Chang 2017; Ferrer Sola 2013; Gazineo 2020; Huang 2021; Lee 2019; Ozbudak 2020; Sonmez 2020; Wang 2016; Yanping 2018).

Incomplete outcome data

We judged that outcome data reporting for 43 trials was at low risk of attrition bias because either all participants randomised were analysed, or missing outcome data was balanced in numbers across intervention groups, with similar reasons for missing data cited across the study groups (Aloweni 2017; Alves 2020; Babamohamadi 2019; Beeckman 2021; Borzou 2020; Chen 2020; Chiew 2010; da Silva Augusto 2019; De Wert 2019; Díaz-Valenzuela 2014; Dutra 2015; Eberhardt 2021; Fallahi 2022; Ferrer Sola 2013; Forni 2018; Forni 2022; Gazineo 2020; Guerra 2017; Hahnel 2020; Han 2011; Hekmatpou 2018; Houwing 2008; Huang 2021; Imbulana 2018; Kalowes 2016; Karimi 2020; Lovegrove 2022; Lupianez-Perez 2015; Madadi 2015; Nakagami 2007; Oe 2020; Qiuli 2010; Saab 2015; Santamaria 2015; Santamaria 2018; Smith 1985; Sonmez 2020; Stankiewicz 2019; Verdu 2012; Walker 2015; Wang 2016; Yang 2020; Yanping 2018). In the remaining eight trials, the proportion of missing outcomes compared with observed event risk was enough to induce clinically relevant bias in the intervention effect estimate (Chang 2017; Díaz-Valenzuela 2019; Green 1974; Lee 2019; Otero 2017; Ozbudak 2020; Torra i Bou 2005; Van Der Cammen 1987); we judged these trials to be at high risk of attrition bias.

Selective reporting

We assessed 17 studies to be at low risk of reporting bias, as they reported all planned outcomes (Babamohamadi 2019; Beeckman 2021; Borzou 2020; De Wert 2019; Eberhardt 2021; Fallahi 2022; Forni 2018; Forni 2022; Guerra 2017; Hahnel 2020; Hekmatpou 2018; Imbulana 2018; Madadi 2015; Oe 2020; Otero 2017; Santamaria 2015; Walker 2015).

We judged the remaining 34 studies to be at unclear risk of reporting bias, as it was unclear whether all planned outcomes were reported (Aloweni 2017; Alves 2020; Chang 2017; Chen 2020; Chiew 2010; da Silva Augusto 2019; Díaz-Valenzuela 2014; Díaz-Valenzuela 2019; Dutra 2015; Ferrer Sola 2013; Gazineo 2020; Green 1974; Han 2011; Houwing 2008; Huang 2021; Kalowes 2016; Karimi 2020; Lee 2019; Lovegrove 2022; Lupianez-Perez 2015; Nakagami 2007; Ozbudak 2020; Qiuli 2010; Saab 2015; Santamaria 2018; Smith 1985; Sonmez 2020; Stankiewicz 2019; Torra i Bou 2005; Van Der Cammen 1987; Verdu 2012; Wang 2016; Yang 2020; Yanping 2018).

Other potential sources of bias

We assessed a total of 10 studies as having an unclear risk of bias for other potential sources of bias. For six of these studies, we had only limited information about the methods used, including in Han 2011 and Yanping 2018. Additionally, only abstracts from conference presentations were available for translation for Chang 2017, Chiew 2010, Saab 2015, and Wang 2016, so it is possible that there may have been biases about which we were unaware.

In the remaining four studies, there were either baseline imbalances or a lack of information about baseline characteristics. In Smith 1985, 33% more participants in the placebo group were incontinent for urine, and 25% more were incontinent for faeces, than in the treatment group, and they did not adjust for this in the analysis. The Qiuli 2010 study did not provide any baseline characteristics, so it is unclear if risks for the development of pressure ulcers were equal between groups. In Santamaria 2015, the sample size calculation was based on a control event rate of 4.0% (presumably this was known from existing hospital data). In the study, the control event rate was 13.1%, raising questions about the accuracy of pressure ulcer diagnosis in the control group during the study. In Lupianez-Perez 2015, there was an unequal number of participants allocated to each group and a 28% loss to follow-up in the olive oil group compared with 34% in the HOFA group.

We judged five studies to be at high risk for 'other' bias. In Houwing 2008, Santamaria 2018, and Stankiewicz 2019, the three cluster-randomised studies included in the review, authors analysed data at the level of the individual rather than by clusters.

The authors of Nakagami 2007 and Van Der Cammen 1987 were members of the groups that developed the intervention products, thus introducing a high risk of bias, such as risk of overestimating the treatment effect.

Effects of interventions

See: **Summary of findings 1** Silicone foam dressing versus no dressing; **Summary of findings 2** Foam dressing versus film dressing; **Summary of findings 3** Hydrocellular foam dressing versus hydrocolloid dressing; **Summary of findings 4** Silicone foam dressing type 1 versus silicone foam dressing type 2; **Summary of findings 5** Foam dressing versus fatty acid; **Summary of findings 6** Polyurethane film versus hydrocolloid dressing; **Summary of findings 7** Hydrocolloid dressing versus no dressing; **Summary of findings 8** Polyurethane foam dressing versus padded bandage; **Summary of findings 9** Fatty acid versus placebo; **Summary of findings 10** Fatty acid versus usual care; **Summary of findings 11** Cream versus fatty acid; **Summary of findings 12** Cream versus placebo; **Summary of findings 13** Cream versus usual care

We have presented results for dichotomous variables as risk ratios (RR) with 95% confidence intervals (CI). We generated 20 comparisons to report outcomes.

Comparison 1: silicone foam dressing versus no dressing (19 studies, 6029 participants)

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Analysis 1.1; Summary of findings 1

We were able to extract data from 18 studies for this outcome (Aloweni 2017; Beeckman 2021; Forni 2018; Forni 2022; De Wert 2019; Gazineo 2020; Guerra 2017; Hahnel 2020; Kalowes 2016; Lee 2019; Lovegrove 2022; Oe 2020; Otero 2017; Qiuli 2010; Saab 2015; Santamaria 2015; Santamaria 2018; Walker 2015). Otero 2017 had four trial arms and Aloweni 2017 had three trial arms. For this comparison, we used data from two study groups for Otero 2017 (silicone dressing group, with 74 participants; no-dressing group, with 39 participants), and two groups for Aloweni 2017 (silicone dressing group, with 129 participants; no-dressing group, with 202 participants).

Silicone foam dressings may reduce pressure ulcer incidence (any stage) compared to no dressing, but the evidence is very uncertain (silicone foam dressing group 180/3192, 5.6%; no-dressing group 281/2711, 10.4%; RR 0.50, 95% CI 0.33 to 0.77; 18 studies, 5903 participants; very low-certainty evidence: downgraded twice for high risk of bias, primarily performance, detection bias, and other bias, or unclear risk of bias, primarily selection bias; downgraded once for inconsistency (I^2 = 73%)).

In Wang 2016, although the authors reported that fewer pressure ulcers occurred in the silicone foam dressing group, they provided no details of the number of pressure ulcers that developed in each of the study groups. Therefore, we could not conduct any further analysis on the data from this study.

Secondary outcomes

Stage of any pressure ulcers

Analysis 1.2; Summary of findings 1

Eleven trials reported stage of any pressure ulcer (Forni 2018; Forni 2022; De Wert 2019; Gazineo 2020; Hahnel 2020; Kalowes 2016; Oe 2020; Qiuli 2010; Santamaria 2015; Santamaria 2018; Walker 2015).

Stage 1 pressure ulcer

Silicone foam dressings may reduce the incidence of stage 1 pressure ulcers compared to no dressing, but the evidence is very uncertain (silicone foam dressing group 15/904, 2%; no-dressing group 56/919, 6%; RR 0.32, 95% CI 0.13 to 0.79; 8 studies, 1823 participants; very low-certainty evidence: downgraded twice for high risk of bias or unclear risk of bias, primarily performance and detection bias; downgraded once for inconsistency (I^2 = 44%); downgraded once for imprecision due to a very wide 95% confidence interval; the risk ratio is large, but we did not upgrade as there is uncertainty around the effect size).

Stage 2 pressure ulcer

Silicone foam dressings may reduce the incidence of stage 2 pressure ulcers compared to no dressing (silicone foam dressing group 33/1426, 2%; no-dressing group 74/1447, 5%; RR 0.47, 95% CI 0.30 to 0.73; 10 studies, 2873 participants; very low-certainty evidence: downgraded twice for high risk of performance and detection bias and unclear risk of selection bias; downgraded once for inconsistency due to a very wide 95% confidence interval; the risk ratio is large, but we did not upgrade as there is uncertainty around the effect size).

Stage 3 pressure ulcer

Silicone foam dressings may have little to no effect on the incidence of stage 3 pressure ulcers compared to no dressing, but the evidence is very uncertain (silicone foam dressing group 1/355, 0.3%; no-dressing group 5/363, 1%; RR 0.45, 95% CI 0.06 to 3.21; 3 studies, 718 participants; very low-certainty evidence: downgraded twice for high risk of performance and detection bias; downgraded twice for very serious imprecision due to a small number of events and a very wide confidence interval which includes 1. The risk ratio is large, but we did not upgrade as there is uncertainty around the effect size).

Stage 4 pressure ulcer

Silicone foam dressings may have little to no effect on the incidence of stage 4 pressure ulcers compared to no dressing, but the evidence is very uncertain (silicone foam dressing group 0/299, 0%; no-dressing group 4/311, 1%; RR 0.21, 95% CI 0.02 to 1.77; 2 studies, 610 participants; very low-certainty evidence: downgraded twice for high risk of performance and detection bias; downgraded twice for very serious imprecision due to a small number of events and a very wide confidence interval which includes 1. The risk ratio is large, but we did not upgrade as there is uncertainty around the effect size).

Unstageable pressure ulcer

Silicone foam dressings may have little to no effect on the incidence of unstageable pressure ulcers compared to no dressing, but the evidence is very uncertain (silicone foam dressing group 0/184, 0%; no-dressing group 2/182, 1%; RR 0.20, 95% CI 0.01 to 4.09; 1 study, 366 participants; very low-certainty evidence: downgraded twice for high risk of performance and detection bias; downgraded twice for very serious imprecision due to a small number of events and a very wide confidence interval which includes 1. The risk ratio is large, but we did not upgrade as there is uncertainty around the effect size).

Deep tissue injury

Silicone foam dressings may have little to no effect on the incidence of deep tissue injury compared to no dressing, but the evidence is very uncertain (silicone foam dressing group 3/422, 0.7%; no-dressing group 11/418, 3%; RR 0.32, 95% CI 0.09 to 1.08; 3 studies, 840 participants; very low-certainty evidence: downgraded twice for high risk of performance and detection bias; downgraded twice for very serious imprecision due to a small number of events and a very wide confidence interval which includes 1. The risk ratio is large, but we did not upgrade as there is uncertainty around the effect size).

Time to pressure ulcer development

Four trials reported time to pressure ulcer development (Kalowes 2016; Forni 2022; Gazineo 2020; Hahnel 2020).

In Kalowes 2016, the survival analysis (Cox proportional hazards model) shows that the time to pressure ulcer development was slightly longer in the silicone foam dressing group, compared with the no-dressing group (hazard ratio (HR) 0.12, 95% CI 0.02 to 0.98; very low-certainty evidence: downgraded twice for high or unclear risk of bias across multiple domains; downgraded once for imprecision due to a wide confidence interval).

In Forni 2022, no standard deviations are provided with the mean time to pressure ulcer development. Therefore, we report the authors' results. The mean time to pressure ulcer development in the silicone group was 3.52 days, and 3.50 days in the no-dressing group (low-certainty evidence: downgraded twice for high or unclear risk of bias across multiple domains).

For the remaining studies, the follow-up time was not the same and, therefore, we did not undertake meta-analysis (Analysis 1.3). In Gazineo 2020, silicone foam dressings may have little to no effect on the mean time to pressure ulcer development compared to no dressing, but the evidence was very uncertain (mean time to pressure ulcer development, silicone foam dressing group: 5.9 days, SD 1.60; no-dressing group: 2.7 days, SD 0.96; MD 3.20, 95% CI 2.57 to 3.83; very low-certainty evidence: downgraded once for unclear risk of performance, detection, and selective reporting bias; downgraded twice for serious imprecision due to very few events and a small sample size).

In Hahnel 2020, silicone foam dressings may have little to no effect on the mean time to pressure ulcer development compared to no dressing, but the evidence is very uncertain (mean time to pressure ulcer development, silicone foam dressing group: 10.8 days, SD 10.1; no dressing group: 13.5 days, SD 13.86; MD -2.70, 95% CI -5.01 to -0.39; very low-certainty evidence: downgraded once for high risk

of performance bias; downgraded twice for serious imprecision due a small number of events and a very wide confidence interval).

Anatomical location of pressure ulcer development

Analysis 1.4

Five studies reported the anatomical location of pressure ulcer development: Beeckman 2021; De Wert 2019 (sacrum only); Hahnel 2020; Santamaria 2015; Santamaria 2018.

Sacral pressure ulcer

Silicone foam dressings may reduce the incidence of sacral pressure ulcer compared to no dressing, but the evidence is very uncertain (silicone foam dressing group 44/1690, 3%; no-dressing group 77/1178, 7%; RR 0.39, 95% CI 0.24 to 0.65; low-certainty evidence: downgraded twice for high risk of performance and detection bias).

Heel pressure ulcer

Silicone foam dressings may reduce the incidence of heel pressure ulcer compared to no dressing, but the evidence is very uncertain (silicone foam dressing group 23/1574, 1%; no-dressing group 39/1050, 4%; RR 0.44, 95% CI 0.21 to 0.95; low-certainty evidence: downgraded twice for high risk of performance and detection bias).

Cost of the intervention

Four studies reported the cost of the intervention (De Wert 2019; Hahnel 2020; Saab 2015; Santamaria 2015).

Santamaria 2015 provided cost estimates based on an assumption that participants would remain in hospital for 20 days and that costs for treating ulcers would not change during this time (see the secondary reference for this trial for cost-benefit analysis). The estimated average cost for the silicone foam dressing group was AUD 70.82 compared with the no-dressing group of AUD 144.56. In Saab 2015, the mean cost of the silicone foam dressing was USD 16.8 (SD 24.5) per patient stay. In De Wert 2019, overall prevention costs were calculated, which included repositioning, mattresses, and dressings. However, given that there were no dressings used in the control group, we have not extracted any data for costs from this trial. Finally, Hahnel 2020 reported that the total additional direct costs of pressure ulcer prevention in the silicone dressing group were EUR 31,972.42 with an average cost of EUR 150.81 per patient (see the secondary reference for this trial for cost-benefit analysis).

Quality of life (measured by any validated scale)

One study reported quality of life (De Wert 2019), and measured this outcome using the EuroQol visual analogue scale (VAS) of 0 to 100, with higher scores indicating a higher quality of life (EuroQol Group 1990). The authors report a median score of 70.0 (interquartile range (IQR) 0 to 100) versus 70.0 (IQR 0 to 98) in the dressing and control groups, respectively, at baseline, and 70.0 (IQR 0 to 98) versus 68.5 (IQR 0 to 100) in the silicone foam dressing and control groups, respectively, at discharge.

Pain at dressing change (measured by any validated scale)

Two studies reported pain at dressing change (De Wert 2019; Guerra 2017). Both studies assessed pain using a numeric rating scale, with values from 0 to 10, with a higher score indicating higher pain levels. In Guerra 2017, in the silicone foam dressing group, 68.4% (26/38) had pain and in the no-dressing group, 59.5% (25/42) had pain. In De Wert 2019, the median VAS score for total pain (days 3 to 8) was 2.1 (IQR 0 to 9.6) in the silicone foam dressing group and 1.8 (IQR 0 to 7.7) in the no-dressing group. The median VAS score for sacral pain (days 3 to 8) was 0.05 (IQR 0 to 4.8) in the silicone foam dressing group and 0.03 (IQR 0 to 7.9) in the no-dressing group.

Acceptability of/satisfaction with the intervention (with respect to participants' comfort)

Two trials reported acceptability of/satisfaction with the intervention (De Wert 2019; Walker 2015).

In Walker 2015, participants were asked to rate the comfort of the dressing on 131 occasions. On six (4.6%) occasions, participants found the dressing uncomfortable. No further analysis was carried out.

In De Wert 2019, discomfort was assessed using a numeric rating scale, with values from 0 to 10, with a higher score indicating greater discomfort. The median VAS score (days 3 to 8) for total discomfort was 2.2 (IQR 0 to 9.5) in the silicone foam dressing group and 2.4 (IQR 0 to 9.1) in the no-dressing group, and for sacral discomfort (days 3 to 8) the median VAS score was 0.05 (IQR 0 to 4.1) in the silicone foam dressing group and 0.07 (IQR 0 to 9.1) in the no-dressing group.

Adverse events

Three studies reported adverse events (Beeckman 2021; De Wert 2019; Santamaria 2015).

In Santamaria 2015, silicone foam dressings may have little to no effect on the incidence of adverse events compared to no dressing, but the evidence is very uncertain (silicone foam dressing group: 0%, 0/220; no-dressing group: 0%, 0/220; very low-certainty evidence: downgraded twice for high risk of performance and detection bias and unclear risk of selection bias; downgraded once for very high imprecision due to no events).

In Beeckman 2021, adverse events were related to the device used in the trial. Silicone foam dressings may have little to no effect on the incidence of adverse events, but the evidence is very uncertain (silicone foam dressing group: 3%, 33/1087; no-dressing group, n = 547: unknown; very low-certainty evidence: downgraded twice for high risk of performance and detection bias; downgraded once for very high imprecision due to no adverse events measured in the control group).

In De Wert 2019, adverse events were related to the device used in the trial. Silicone foam dressings may have little to no effect on the incidence of adverse events, but the evidence is very uncertain (silicone foam dressing group: 50%, 58/117; no-dressing group: n = 127: unknown; very low-certainty evidence: downgraded twice for high risk of performance and detection bias; downgraded once for very high imprecision due to no adverse events measured in the control group).

Length of hospital stay

Not reported.

Funnel plots

We assessed funnel plots for the outcomes of pressure ulcer incidence (any stage) (Figure 4), and pressure ulcer stage (Figure 5).

Figure 4. Funnel plot: silicone dressing versus no dressing, outcome: 1.1 Any pressure ulcer

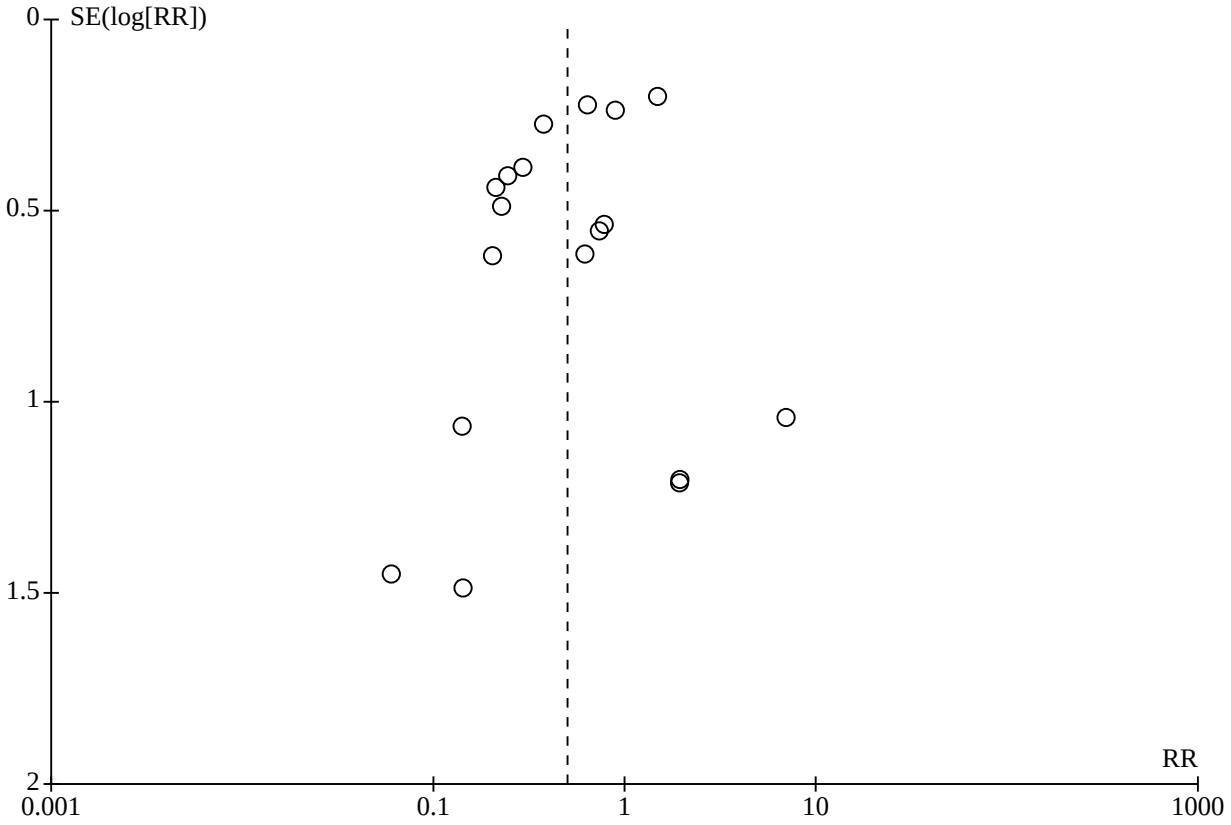
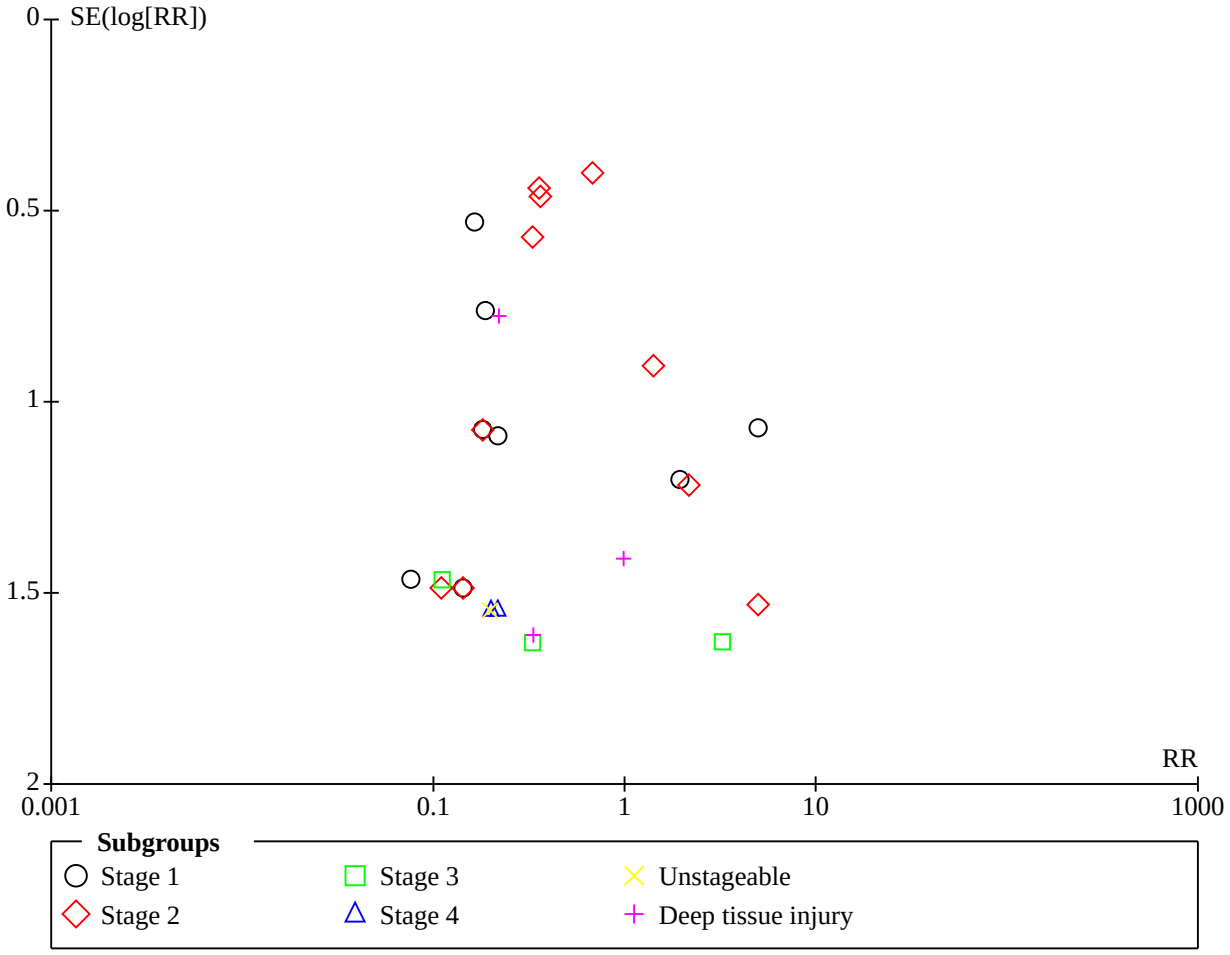


Figure 5. Funnel plot: silicone dressing versus no dressing, outcome: 1.2 Pressure ulcer stage



Comparison 2: foam dressing versus film dressing (3 studies, 569 participants)

Three trials compared a foam dressing with a transparent film dressing (Alves 2020; Eberhardt 2021; Yanping 2018).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Analysis 2.1; Summary of findings 2

Even though the populations, interventions, and comparators in these studies were similar, there was substantial heterogeneity (I^2 = 76%), so we used a random-effects model for the meta-analysis.

Foam dressings may have little to no effect on the incidence of pressure ulcers compared to film dressings, but the evidence is very uncertain (foam dressing group 46/285, 16%; film dressing group 75/284, 26.4%; RR 0.72, 95% CI 0.20 to 2.67; 3 studies, 569 participants; very low-certainty evidence: downgraded twice for high or unclear risk of performance and detection bias and unclear risk of selection bias and reporting bias; downgraded once for inconsistency (I^2 = 76%); downgraded once for imprecision due to a wide confidence interval which includes 1).

Secondary outcomes

Stage of any pressure ulcers

Analysis 2.2; Summary of findings 2

One trial (270 participants) reported stage of pressure ulcer (Eberhardt 2021).

Stage 1 pressure ulcer

Foam dressings may reduce stage 1 pressure ulcer incidence compared to film dressings, but the evidence is very uncertain (foam dressing group 33/135, 24.4%; film dressing group 59/135, 43.7%; RR 0.56, 95% CI 0.39 to 0.80; very low-certainty evidence: downgraded twice for high risk of performance and detection bias, and once for imprecision due to a small sample size).

Stage 2 pressure ulcer

Foam dressings may have little to no effect on the incidence of stage 2 pressure ulcers compared to film dressings, but the evidence is very uncertain (foam dressing group 1/135, 0.7%; film dressing group 1/135, 0.7%; RR 1.00, 95% CI 0.06 to 15.82; very low-certainty evidence: downgraded twice for high risk of performance and detection bias, and twice for imprecision due to a small sample

size, a small number of events, and a very wide confidence interval which includes 1).

Deep tissue injury

Foam dressings may have little to no effect on the incidence of deep tissue injury compared to film dressings, but the evidence is very uncertain (foam dressing group 2/135, 1.5%; film dressing group 3/135, 2.2%; RR 0.67, 95% CI 0.11 to 3.93; very low-certainty evidence: downgraded twice for high risk of performance and detection bias; downgraded twice for imprecision due to small sample size, a small number of events, and a very wide confidence interval which includes 1).

Remaining review outcomes

None of the studies included in this comparison reported any of our remaining secondary outcomes of interest (i.e. time to pressure ulcer development; anatomical location; cost of interventions; quality of life; pain at dressing change; acceptability/satisfaction; adverse events; length of hospital stay).

Comparison 3: hydrocellular foam dressing versus hydrocolloid dressing (1 study, 80 participants)

One study compared a foam dressing with a transparent film dressing (da Silva Augusto 2019).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Analysis 3.1; Summary of findings 3

Hydrocellular foam dressings may have little to no effect on the incidence of pressure ulcers compared to hydrocolloid dressings, but the evidence is very uncertain (hydrocellular foam dressing group 0/40, 0%; hydrocolloid dressing group 0/40, 0%; RR not estimable; very low-certainty evidence: downgraded once for high risk of performance and detection bias; downgraded twice for serious imprecision due to no events and a small sample size).

Secondary outcomes

The da Silva Augusto 2019 study did not report any of our secondary outcomes of interest (i.e. stage of any pressure ulcers; time to pressure ulcer development; anatomical location; cost of interventions; quality of life; pain at dressing change; acceptability/satisfaction; adverse events; length of hospital stay).

Comparison 4: silicone foam dressing type 1 versus silicone foam dressing type 2 (2 studies, 376 participants)

Two studies compared two different types of silicone foam dressings (Otero 2017; Stankiewicz 2019). There were four study groups in Otero 2017, and we used data from two groups for this comparison: the silicone foam dressing type 1 group (n = 35) and the silicone foam dressing type 2 group (n = 39).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Analysis 4.1; Summary of findings 4

Silicone foam dressing type 1 may have little to no effect on the incidence of pressure ulcers compared to silicone foam dressing type 2, but the evidence is very uncertain (silicone foam dressing 1, 22/164, 13.4%; silicone foam dressing 2, 31/212, 14.6%; RR 0.80, 95% CI 0.56 to 1.15; 2 studies, 376 participants; very low-certainty evidence: downgraded twice for high risk of selection, performance, detection, and attrition bias, and unclear risk of performance, reporting bias, and other bias; downgraded twice for serious imprecision due to a small number of events and a very wide confidence interval).

Secondary outcomes

Cost of interventions

Only Stankiewicz 2019 assessed the cost of interventions, reporting that there was a dressing cost difference per patient: AUD 10.29 for silicone foam dressing 1 and AUD 28.84 for silicone foam dressing 2.

Remaining review outcomes

Neither of the two studies included in this comparison reported any of the other secondary outcomes of interest (i.e. stage of any pressure ulcers; time to pressure ulcer development; anatomical location; quality of life; pain at dressing change; acceptability/satisfaction; adverse events; length of hospital stay).

Comparison 5: foam dressing versus fatty acid (2 studies, 300 participants)

Two studies compared a foam dressing with fatty acid (Chang 2017; Otero 2017). In this comparison, we used data from two of the four study arms in Otero 2017: foam (n = 74) and fatty acid (n = 39).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Analysis 5.1; Summary of findings 5

Foam dressings may have little to no effect on the incidence of pressure ulcers compared to fatty acid, but the evidence is very uncertain (foam dressing 52/160, 32.5%; fatty acid 15/140, 8%; RR 1.67, 95% CI 0.49 to 5.72; 2 studies, 300 participants; very low-certainty evidence: downgraded twice for high risk of performance, detection, and attrition bias, and unclear risk of reporting bias; downgraded once for inconsistency (I^2 = 70%); downgraded twice for imprecision due to the wide confidence interval and the small sample size. The risk ratio is very large, but we did not upgrade as there is a lot of uncertainty around the effect size).

Secondary outcomes

Neither of the two studies included in this comparison reported any of our secondary outcomes of interest (i.e. stage of any pressure ulcers; time to pressure ulcer development; anatomical location; cost of interventions; quality of life; pain at dressing change; acceptability/satisfaction; adverse events; length of hospital stay).

Comparison 6: polyurethane film versus hydrocolloid dressing (1 study, 160 participants)

One trial compared a polyurethane film dressing with a hydrocolloid dressing (Dutra 2015).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Analysis 6.1; Summary of findings 6.

Polyurethane film dressing may have little to no effect on the incidence of pressure ulcers compared to hydrocolloid dressing, but the evidence is very uncertain (polyurethane film 7/80, 9%;

hydrocolloid 12/80, 15%; RR 0.58, 95% CI 0.24 to 1.41; 1 study, 160 participants; very low-certainty evidence: downgraded once for high risk of performance bias and unclear risk of selection, detection, and reporting bias; downgraded twice for very serious imprecision due to a small number of events and a wide confidence interval which includes 1).

Secondary outcomes

Dutra 2015 did not report any of our secondary outcomes of interest (i.e. stage of any pressure ulcers; time to pressure ulcer development; anatomical location; cost of interventions; quality of life; pain at dressing change; acceptability/satisfaction; adverse events; length of hospital stay).

Comparison 7: hydrocolloid dressing versus no dressing (2 studies, 230 participants)

Two trials compared a hydrocolloid dressing with no dressing (Chen 2020; Imbulana 2018).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Analysis 7.1; Summary of findings 7

Even though the populations, interventions, and comparators were similar in the two studies, there was substantial heterogeneity (I^2 = 93%), so we used a random-effects model for the meta-analysis.

Hydrocolloid dressings may reduce pressure ulcer incidence compared to no dressing, but the evidence is very uncertain (hydrocolloid dressing 44/113, 38.9%; no dressing 76/117, 65%; RR 0.60, 95% CI 0.46 to 0.78; 2 studies, 230 participants; very low-certainty evidence: downgraded twice for high risk of performance and detection bias and unclear risk of reporting bias; downgraded once for imprecision due to a small sample size).

Secondary outcomes

Stage of any pressure ulcers

Analysis 7.2; Summary of findings 7

One trial provided data for this outcome (Imbulana 2018).

Pressure ulcer stage 1

Hydrocolloid dressings may reduce stage 1 pressure ulcer incidence compared to no dressing, but the evidence is very uncertain (hydrocolloid dressing 13/53, 25%; no dressing 25/55, 45%; RR 0.54, 95% CI 0.31 to 0.94; 1 study, 108 participants; very low-certainty evidence: downgraded once for high risk of performance and detection bias; downgraded twice for serious imprecision due to small number of events and a small sample size).

Pressure ulcer stage 2

Hydrocolloid dressings may have little to no effect on the incidence of stage 2 pressure ulcers compared to no dressing, but the evidence is very uncertain (hydrocolloid dressing 5/53, 9%; no dressing 6/55, 10%; RR 0.86, 95% CI 0.28 to 2.66; 1 study, 108 participants; very low-certainty evidence: downgraded once for high risk of performance and detection bias; downgraded twice for serious imprecision due to a small number of events, a small sample size, and a wide confidence interval which includes 1).

Cost of interventions

Only Imbulana 2018 provided data for this outcome, reporting that the average total cost of barrier dressings was AUD 68.65 per infant.

Remaining review outcomes

Neither of the two studies included in this comparison reported any of the remaining secondary outcomes of interest (i.e. time to pressure ulcer development; anatomical location; quality of life; pain at dressing change; acceptability/satisfaction; adverse events; length of hospital stay).

Comparison 8: Kang' huier dressing versus no dressing (1 study, 100 participants)

One trial compared a Kang' huier dressing with no dressing (Han 2011).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Analysis 8.1; Table 2

It is very uncertain whether a Kang' huier dressing makes any difference to pressure ulcer incidence compared to routine care (Kang' huier 2/49, 4%; routine care 5/51, 10%; RR 0.42, 95% CI 0.08 to 2.05; very low-certainty evidence: downgraded once for high risk of performance and detection bias, and unclear risk of selection, reporting, and other bias; downgraded twice for very serious imprecision due to a small number of events and a very wide confidence interval which includes 1).

Secondary outcomes

Han 2011 did not report any of our secondary outcomes of interest (i.e. stage of any pressure ulcers; time to pressure ulcer development; anatomical location; cost of interventions; quality of life; pain at dressing change; acceptability/satisfaction; adverse events; length of hospital stay).

Comparison 9: silicone foam dressing versus silicone foam dressing and Sanyrene (1 study, 150 participants)

One trial compared a silicone foam dressing with a topical agent, Sanyrene, with a silicone foam dressing (Huang 2021).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Analysis 9.1; Table 3

A silicone foam dressing with Sanyrene may reduce pressure ulcer incidence compared to a silicone foam dressing alone, but the evidence is very uncertain (silicone foam dressing 18/75, 24%; silicone foam dressing and Sanyrene 7/75, 9%; RR 2.57, 95% CI 1.14 to 5.79; very low-certainty evidence: downgraded once for unclear risk of selection, performance, detection, and reporting bias; downgraded twice for imprecision due to a small number of events, a small sample size, and a very wide confidence interval).

Secondary outcomes

Stage of any pressure ulcers

Analysis 9.2; Table 3

One trial provided data for this outcome (Huang 2021).

Pressure ulcer stage 1

A silicone foam dressing with Sanyrene may reduce stage 1 pressure ulcer incidence compared to a silicone foam dressing alone, but the evidence is very uncertain (silicone foam dressing 15/75, 20%; silicone foam dressing and Sanyrene 6/75, 8%; RR 2.50, 95% CI 1.03 to 6.09; very low-certainty evidence: downgraded once for unclear risk of selection, performance, detection, and reporting bias; downgraded twice for imprecision due to a small number of events, a small sample size, and a very wide confidence interval).

Pressure ulcer stage 2

A silicone foam dressing with Sanyrene may have little to no effect on the incidence of pressure ulcer stage 2 compared to a silicone foam dressing alone, but the evidence is very uncertain (silicone foam dressing 3/75, 4%; silicone foam dressing and Sanyrene 1/75, 1.3%; RR 3.00, 95% CI 0.32 to 28.19; very low-certainty evidence: downgraded once for unclear risk of selection, performance, detection, and reporting bias; downgraded twice for imprecision due to a small number of events, a small sample size, and a very wide confidence interval which includes 1).

Remaining review outcomes

Huang 2021 did not report any of the remaining secondary outcomes of interest (i.e. time to pressure ulcer development; anatomical location; cost of interventions; quality of life; pain at dressing change; acceptability/satisfaction; adverse events; length of hospital stay).

Comparison 10: pressure ulcer preventative dressing versus no dressing (1 study, 74 participants)

One trial compared a pressure ulcer preventive dressing (PPD) dressing with no dressing (Nakagami 2007).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Analysis 10.1; Table 4

In Nakagami 2007, no pressure ulcers developed in either arm of the trial. However, the trial authors reported the presence of persistent erythema in both groups. We have interpreted the presence of persistent erythema as a stage 1 pressure ulcer. Pressure ulcer preventative dressings (PPD) may have little to no effect on the incidence of pressure ulcer compared to no dressing, but the evidence is very uncertain (PPD 2/37, 5%; no dressing 11/37, 29%; RR 0.18, 95% CI 0.04 to 0.76; very low-certainty evidence: downgraded once for high risk of performance, detection, and other bias, and unclear risk of selection and reporting bias; downgraded twice for very serious imprecision due to a small number of events, a small sample size, and a wide confidence interval).

Secondary outcomes

Nakagami 2007 did not report any of our secondary outcomes of interest (i.e. stage of any pressure ulcers; time to pressure ulcer development; anatomical location; cost of interventions; quality of life; pain at dressing change; acceptability/satisfaction; adverse events; length of hospital st

Comparison 11: polyurethane foam dressing versus padded bandage (1 study, 409 participants)

One trial compared a polyurethane foam dressing with a padded bandage (Ferrer Sola 2013).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Analysis 11.1; Table 5

Polyurethane foam dressings may have little to no effect on the incidence of pressure ulcers compared to padded bandages, but the evidence is very uncertain (polyurethane foam dressing group 3/208, 2.4%; padded bandage group 7/201, 3.5%; RR 0.41, 95% CI 0.11 to 1.58; very low-certainty evidence: downgraded once for unclear risk of selection, performance, detection, and reporting bias; downgraded twice for very serious imprecision due to a small number of events and a very wide confidence interval which includes 1).

Secondary outcomes

Ferrer Sola 2013 did not report any of our secondary outcomes of interest (i.e. stage of any pressure ulcers; time to pressure ulcer development; anatomical location; cost of interventions; quality of life; pain at dressing change; acceptability/satisfaction; adverse events; length of hospital stay).

Comparison 12: gauze soaked in olive oil versus gauze soaked in fish oil (1 study, 100 participants)

One trial compared gauze soaked in olive oil with gauze soaked in fish oil (Karimi 2020).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Analysis 12.1; Table 6

In Karimi 2020, no participant developed a pressure ulcer in either study group. Gauze soaked in olive oil may have little to no effect on the incidence of pressure ulcers compared to gauze soaked in fish oil, but the evidence is very uncertain (gauze soaked in olive oil 0/50, 0%; gauze soaked in fish oil group 0/50, 0%; RR not estimable; very low-certainty evidence: downgraded once for high risk of performance bias, and unclear risk of selection and reporting bias; downgraded once for serious imprecision due to no events and a very small sample size).

Secondary outcomes

Adverse events

In Karimi 2020, no adverse reactions due to the use of dressings soaked in olive oil or fish oil were observed in the participants' heels in the two groups. Gauze soaked in olive oil may have little to no effect on the incidence of adverse events compared to gauze soaked in fish oil, but the evidence is very uncertain (gauze soaked in olive oil group: 0%, 0/50; gauze soaked in fish oil group: 0%, 0/50, RR not estimable; very low-certainty evidence: downgraded once for high risk of performance bias and unclear risk of reporting bias; downgraded twice for serious imprecision due to no events and a small sample size).

Remaining review outcomes

Karimi 2020 did not report any of the remaining secondary outcomes of interest (i.e. stage of any pressure ulcers; time to pressure ulcer development; anatomical location; cost of interventions; quality of life; pain at dressing change; acceptability/satisfaction; length of hospital stay).

Comparison 13: hydroactive dressings versus tape (1 study, 450 participants)

One trial compared a hydroactive dressing with tape (Yang 2020).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Analysis 13.1; Table 7

Hydroactive dressings may reduce pressure ulcer incidence compared to tape, but the evidence is very uncertain (hydroactive dressing group 10/225, 4.4%; tape group 32/225, 14.2%; RR 0.31, 95% CI 0.16 to 0.62; very low-certainty evidence: downgraded once for high risk of attrition bias; downgraded twice for very serious imprecision due to a small number of events and a wide confidence interval).

Secondary outcomes

Yang 2020 did not report any of our secondary outcomes of interest (i.e. stage of any pressure ulcers; time to pressure ulcer development; anatomical location; cost of interventions; quality of life; pain at dressing change; acceptability/satisfaction; adverse events; length of hospital stay).

Comparison 14: fatty acid versus placebo (6 studies, 2201 participants)

Six studies compared fatty acid to placebo (Borzou 2020; Díaz-Valenzuela 2014; Díaz-Valenzuela 2019; Green 1974; Lupianez-Perez 2015; Torra i Bou 2005). There were three study groups in Borzou 2020, and we used data from two of the study groups in this comparison: the fatty acid group (n = 36) and the placebo group (n = 36).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Analysis 14.1; Summary of findings 9

Fatty acid may have little to no effect on pressure ulcer incidence compared to placebo, but the evidence is very uncertain (fatty acid group 80/1075, 7%; placebo group 100/1126, 9%; RR 0.86, 95% CI 0.54 to 1.36; 6 studies, 2201 participants; very low-certainty evidence: downgraded once for high risk of performance and attrition bias and unclear risk of selection, reporting, and other bias; downgraded once for inconsistency (I^2 = 57%); downgraded once for serious imprecision due to a wide confidence interval which crosses 1).

Secondary outcomes

Time to pressure ulcer development

One trial reported this outcome (Green 1974). Ulcers appeared approximately one day later in the fatty acid group than in the placebo group (fatty acid 9.8 days versus placebo 8.7 days), but the trial report did not state whether these were mean or median values.

Anatomical location of pressure ulcer development

Analysis 14.2. Two trials reported this outcome (Borzou 2020; Díaz-Valenzuela 2019).

Sacral pressure ulcer

Fatty acid may have little to no effect on sacral pressure ulcer incidence compared to placebo, but the evidence is very uncertain (fatty acid 11/319, 3%; placebo 7/324, 2%; RR 1.56, 95% CI 0.63 to 3.86; 2 studies, 643 participants; very low-certainty evidence: downgraded once for high risk of attrition bias and unclear risk of selection and reporting bias; downgraded twice for serious imprecision due to the small number of events and an extremely wide confidence interval, which includes 1).

Heel pressure ulcer

Fatty acid may have little to no effect on heel pressure ulcer incidence compared to placebo, but the evidence is very uncertain (fatty acid 6/319, 2%; placebo 5/324, 2%; RR 1.20, 95% CI 0.39 to 3.69; 2 studies, 643 participants; very low-certainty evidence: downgraded once for high risk of performance and attrition bias and unclear risk of selection and reporting bias; downgraded twice for serious imprecision due to the small number of events and an extremely wide confidence interval, which includes 1).

Shoulder pressure ulcer

Fatty acid may have little to no effect on shoulder pressure ulcer incidence compared to placebo, but the evidence is very uncertain (fatty acid 2/36, 5%; placebo 3/36, 8%; RR 0.67, 95% CI 0.12 to 3.75; 1 study, 72 participants; very low-certainty evidence: downgraded once for high risk of attrition bias and unclear risk of selection bias; downgraded twice for serious imprecision due to the small number of events and an extremely wide confidence interval, which includes 1).

Adverse events

Analysis 14.3; Summary of findings 9

Three trials reported adverse effects (Díaz-Valenzuela 2014; Díaz-Valenzuela 2019; Green 1974).

Fatty acid may have little to no effect on the incidence of adverse events compared to placebo, but the evidence is very uncertain (fatty acid 3/481, 0.6%; placebo group 0/486, 0%; RR 4.38, 95% CI 0.50 to 38.30; 3 studies, 967 participants; very low-certainty evidence: downgraded once for high risk of attrition bias and unclear risk of reporting bias; downgraded twice for serious imprecision due to the small number of events and an extremely wide confidence interval which includes 1. The risk ratio is very large, but we did not upgrade as there is a lot of uncertainty around the effect size).

Remaining review outcomes

None of the studies included in this comparison reported data for the remaining secondary outcomes (i.e. stage of any pressure ulcers; cost of interventions; quality of life; pain at dressing change; acceptability/satisfaction; length of hospital stay).

Comparison 15: fatty acid versus usual care (7 studies, 1058 participants)

Seven studies compared fatty acid to usual care (Aloweni 2017; Borzou 2020; Chang 2017; Chiew 2010; Fallahi 2022; Madadi 2015; Sonmez 2020).

Aloweni 2017, Borzou 2020, and Chang 2017 each had three study groups. We only included data from a fatty acid group and a control group for each of these studies: Aloweni 2017: fatty acid group n = 310, control group n = 383; Borzou 2020: fatty acid group n = 36, control group n = 36; Chang 2017: fatty acid group n = 101, control group n = 159. There were four study groups in Fallahi 2022, and we used data from two of these: fatty acid (olive oil) group (n = 60) and the control group (n = 60).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Analysis 15.1; Summary of findings 10

All seven studies included in this comparison provided data for this outcome (Aloweni 2017; Borzou 2020; Chiew 2010; Chang 2017; Fallahi 2022; Madadi 2015; Sonmez 2020). Fatty acid may reduce pressure ulcer incidence compared to usual care, but the evidence is very uncertain (fatty acid: 10.9%, 52/476; usual care: 15.6%, 91/582; RR: 0.62, 95% CI 0.46 to 0.84; 7 studies, 1058 participants; very low-certainty evidence: downgraded twice for high risk of selection, performance, detection, and attrition bias; downgraded once for imprecision due to a relatively small sample size).

Secondary outcomes

Stage of any pressure ulcers

Analysis 15.2; Summary of findings 10

Two trials reported this outcome (Fallahi 2022; Madadi 2015).

Pressure ulcer stage 1

Fatty acid may have little to no effect on pressure ulcer incidence stage 1 compared to usual care, but the evidence is very uncertain (fatty acid 13/90, 14.4%; usual care 13/90, 14.4%; RR 1.00, 95% CI 0.49 to 2.03; 2 studies, 180 participants; very low-certainty evidence: downgraded twice for high risk of selection, performance, and detection bias; downgraded twice for serious imprecision due to a small sample size, a small event size, and a wide confidence interval which crosses 1).

Pressure ulcer stage 2

The evidence suggests fatty acid results in a large reduction in stage 2 pressure ulcer development compared to usual care (fatty acid: 4.4%, 4/90; usual care: 23.3%, 21/90; RR 0.19, 95% CI 0.07 to 0.53; 2 studies, 180 participants; low-certainty evidence). We downgraded twice for high risk of selection, performance, detection, and attrition bias, and once for imprecision due to a small sample size. The risk ratio is large, and while the confidence interval is slightly wide, the limits fall almost entirely within a range considered to indicate a large effect. Thus, we upgraded the evidence certainty by one level.

Time to pressure ulcer development

One study reported time to pressure ulcer development (Sonmez 2020). Fatty acid may increase the mean time to pressure ulcer development compared to usual care, but the evidence is very uncertain (fatty acid: 10.45, SD 5.20; usual care: 7.50, SD 5.43; MD 2.95, 95% CI 1.11 to 4.79; very low-certainty evidence: downgraded once for unclear risk of selection, performance, detection, and reporting bias; downgraded twice for imprecision due to a small sample size and a wide 95% CI; Analysis 15.3).

Anatomical location of pressure ulcer development

Analysis 15.4; Summary of findings 10

Three trials reported this outcome (Borzou 2020; Fallahi 2022; Madadi 2015).

Sacral pressure ulcer

Fatty acid may reduce sacral pressure ulcer incidence compared to usual care, but the evidence is very uncertain (fatty acid 7/126, 5%; usual care 23/126, 18%; RR 0.32, 95% CI 0.15 to 0.69; 3 studies, 252 participants; very low-certainty evidence: downgraded twice for high risk of selection, performance, detection, and attrition bias; downgraded twice for imprecision due to a small sample size and a small number of events. The risk ratio is large, but we did not upgrade as there is uncertainty around the effect size) (Borzou 2020; Fallahi 2022; Madadi 2015).

Buttock pressure ulcer

Fatty acid may have little to no effect on buttock pressure ulcer incidence compared to usual care, but the evidence is very uncertain (fatty acid 6/90, 6.7%; usual care 10/90, 11.1%; RR 0.60, 95% CI 0.23 to 1.58; 2 studies, 180 participants; very low-certainty evidence: downgraded twice for high risk of selection, performance, and detection bias; downgraded twice for imprecision due to a small sample size, a small event size, and a wide confidence interval which crosses 1) (Fallahi 2022; Madadi 2015).

Iliac pressure ulcer

Fatty acid may have little to no effect on iliac pressure ulcer incidence compared to usual care, but the evidence is very uncertain (fatty acid 2/90, 2.2%; usual care 2/90, 2.2%; RR 1.00, 95% CI 0.18 to 5.66; 2 studies, 180 participants; very low-certainty evidence: downgraded twice for high risk of selection, performance, and detection bias; downgraded twice for imprecision due to a small sample size, a small event size, and a wide confidence interval which crosses 1) (Fallahi 2022; Madadi 2015).

Shoulder pressure ulcer

Fatty acid may have little to no effect on shoulder pressure ulcer incidence compared to usual care, but the evidence is very uncertain (fatty acid 3/66, 5%; usual care 3/66, 5%; RR 1.00, 95% CI 0.21 to 4.77; 2 studies, 132 participants; very low-certainty evidence: downgraded twice for high risk of selection, performance, detection, and attrition bias; downgraded twice for imprecision due to a small sample size, a small event size, and a wide confidence interval which crosses 1) (Borzou 2020; Madadi 2015).

Earlobe pressure ulcer

Fatty acid may have little to no effect on earlobe pressure ulcer incidence compared to usual care, but the evidence is very uncertain (fatty acid 0/30, 0%; usual care 1/30, 3.3%; RR 0.33, 95%

CI 0.01 to 7.87; 1 study, 60 participants; very low-certainty evidence: downgraded twice for high risk of selection, performance, and detection bias; downgraded twice for imprecision due to a small sample size, a small event size, and a wide confidence interval which crosses 1. The risk ratio is large, but we did not upgrade as there is uncertainty around the effect size) (Madadi 2015).

Heel pressure ulcer

Fatty acid may have little to no effect on heel pressure ulcer incidence compared to usual care, but the evidence is very uncertain (fatty acid 0/36, 0%; usual care 2/36, 5%; RR 0.20, 95% CI 0.01 to 4.03; 1 study, 72 participants; very low-certainty evidence: downgraded once for attrition bias; downgraded twice for imprecision due to a small sample size, a small event size, and a wide confidence interval which crosses 1) (Borzou 2020).

Adverse events

One trial reported this outcome (Madadi 2015). The authors reported no adverse events in the fatty acid group.

Remaining review outcomes

None of the seven studies included in this comparison reported data for the remaining secondary outcomes (i.e. cost of interventions; quality of life; pain at dressing change; acceptability/satisfaction; length of hospital stay).

Comparison 16: cream versus fatty acid (1 study, 120 participants)

One trial compared a cream to fatty acid (Van Der Cammen 1987).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Analysis 16.1; Summary of findings 11

Cream may have little to no effect on pressure ulcer incidence compared to fatty acid, but the evidence is very uncertain (cream 3/60, 2%; fatty acid 1/60, 5%; RR 3.00, 95% CI 0.32 to 28.03; very low-certainty evidence: downgraded twice for high risk of attrition and other bias and unclear risk of selection, detection, and reporting bias; downgraded twice for serious imprecision due to a small number of events and a very wide confidence interval which includes 1).

Secondary outcomes

Van Der Cammen 1987 did not report any of our secondary outcomes of interest (i.e. stage of any pressure ulcers; time to pressure ulcer development; anatomical location; cost of interventions; quality of life; pain at dressing change; acceptability/satisfaction; adverse events; length of hospital stay).

Comparison 17: cream versus placebo (3 studies, 513 participants)

Three trials compared a cream to placebo (Houwing 2008; Smith 1985; Verdu 2012). There were three study groups in Houwing 2008. For this comparison, we used data from two of these: the cream group (n = 29) and the placebo group (n = 32).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Analysis 17.1; Summary of findings 12

Even though the populations, interventions, and comparators were similar, there was substantial heterogeneity (I^2 = 76%), so we used a random-effects model for the meta-analysis.

Cream may have little to no effect on pressure ulcer incidence compared to placebo, but the evidence is very uncertain (cream group 62/257, 24.1%; placebo group 64/256, 25%; RR 1.18, 95% CI 0.59 to 2.36; 3 studies, 513 participants; very low-certainty evidence: downgraded once for high risk of other bias and unclear risk of selection and reporting bias; downgraded once for inconsistency (I^2 = 76%); downgraded twice for very serious imprecision due to a small sample size and a confidence interval which crosses 1).

Secondary outcomes

Stage of any pressure ulcers

Analysis 17.2; Summary of findings 12

One trial reported data for this outcome (Smith 1985).

Pressure ulcer stage 3

Cream may have little to no effect on the incidence of stage 3 pressure ulcer compared to placebo, but the evidence is very uncertain (cream group 5/129, 3.9%; placebo group 4/129, 3.1%; RR 1.25, 95% CI 0.34 to 4.55; 1 study, 258 participants; very low-certainty evidence: downgraded once for unclear risk of selection, reporting, and other bias; downgraded twice for very serious imprecision due to a small sample and event size, and a very wide confidence interval which crosses 1).

Pressure ulcer stage 4

Cream may have little to no effect on the incidence of stage 4 pressure ulcer compared to placebo, but the evidence is very uncertain (cream group 0/129, 0%; placebo group 1/129, 0.7%; RR 0.33, 95% CI 0.01 to 8.11; 1 study, 258 participants; very low-certainty evidence: downgraded once for unclear risk of selection, reporting and other bias; downgraded twice for very serious imprecision due to a small sample and event size, and a very wide confidence interval which crosses 1).

Remaining review outcomes

None of the three studies included in this comparison reported data for the remaining secondary outcomes (i.e. time to pressure ulcer development; anatomical location of pressure ulcer development; cost of interventions; quality of life; pain at dressing change; acceptability/satisfaction; adverse events; length of hospital stay).

Comparison 18: cream versus usual care (1 study, 47 participants)

One trial compared a cream with usual care (Houwing 2008). There were three study groups in Houwing 2008. For this comparison, we used data from two: cream group (n = 29) and usual care group (n = 18).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage

Analysis 18.1; Summary of findings 13

Cream may have little to no effect on the incidence of pressure ulcer compared to usual care, but the evidence is very uncertain

(cream group: 62%, 18/29; usual care group: 39%, 7/18; RR 1.60, 95% CI 0.84 to 3.04; very low-certainty evidence: downgraded once for unclear risk of selection bias and other bias, where the effect of the clustering was not accounted for in the analysis; downgraded twice for imprecision due to a small number of events and a small sample size).

Secondary outcomes

Houwing 2008 did not report any of our secondary outcomes of interest (i.e. stage of any pressure ulcers; time to pressure ulcer development; anatomical location; cost of interventions; quality of life; pain at dressing change; acceptability/satisfaction; adverse events; length of hospital stay).

Comparison 19: aloe vera versus aloe vera and oil (1 study, 120 participants)

One trial compared aloe vera with aloe vera and oil (Fallahi 2022). There were four study groups in Fallahi 2022. For this comparison, we used data from two: aloe vera group (n = 60) and aloe vera plus oil group (n = 60).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Analysis 19.1; Table 8

Aloe vera may increase the incidence of pressure ulcer compared to aloe vera and oil, but the evidence is very uncertain (aloe vera group 20/60, 33%; aloe vera and oil group 10/60, 16.7%; RR 2.00, 95% CI 1.02 to 3.91; very low-certainty evidence: downgraded three times for extremely serious imprecision due to a small sample size, a small number of events, and a wide confidence interval).

Secondary outcomes

Stage of any pressure ulcers

Analysis 19.2; Table 8

Pressure ulcer stage 1

Aloe vera may have little to no effect on the incidence of stage 1 pressure ulcer compared to aloe vera and oil, but the evidence is very uncertain (aloe vera group 13/60, 21.7%; aloe vera and oil group 8/60, 13.3%; RR 1.63, 95% CI 0.73 to 3.63; very low-certainty evidence: downgraded three times for extremely serious imprecision due to a small sample size, a small number of events, and a wide confidence interval which crosses 1).

Pressure ulcer stage 2

Aloe vera may have little to no effect on the incidence of stage 2 pressure ulcer compared to aloe vera and oil, but the evidence is very uncertain (aloe vera group 7/60, 11.7%; aloe vera and oil group 2/60, 3.3%; RR 3.50, 95% CI 0.76 to 16.17; very low-certainty evidence: downgraded three times for extremely serious imprecision due to a small sample size, a small number of events, and a wide confidence interval which crosses 1).

Anatomical location of pressure ulcer development

Sacral pressure ulcer

Aloe vera may have little to no effect on the incidence of sacral pressure ulcer compared to aloe vera and oil, but the evidence is very uncertain (aloe vera group 9/60, 15%; aloe vera and oil group 3/60, 5%; RR 3.00, 95% CI 0.85 to 10.54; very low-certainty evidence: downgraded three times for extremely serious imprecision due to a small sample size, a small number of events, and a wide confidence interval which crosses 1; Analysis 19.3).

Buttock pressure ulcer

Aloe vera may have little to no effect on the incidence of buttock pressure ulcer compared to aloe vera and oil, but the evidence is very uncertain (aloe vera group 6/60, 10%; aloe vera and oil group 6/60, 10%; RR 1.00, 95% CI 0.34 to 2.93; very low-certainty evidence: downgraded three times for extremely serious imprecision due to a small sample size, a small number of events, and a wide confidence interval which crosses 1; Analysis 19.3).

Iliac pressure ulcer

Aloe vera may have little to no effect on the incidence of iliac pressure ulcer compared to aloe vera and oil, but the evidence is very uncertain (aloe vera group 5/60, 8.3%; aloe vera and oil group 1/60, 1.7%; RR 5.00, 95% CI 0.60 to 41.53; very low-certainty evidence: downgraded three times for extremely serious imprecision due to a small sample size, a small number of events, and a wide confidence interval which crosses 1; Analysis 19.3).

Remaining review outcomes

Fallahi 2022 did not report data for the remaining secondary outcomes (i.e. time to pressure ulcer development; cost of interventions; quality of life; pain at dressing change; acceptability/satisfaction; adverse events; length of hospital stay).

Comparison 20: gel versus placebo (2 studies, 217 participants)

Two trials compared a gel with a placebo (Babamohamadi 2019; Hekmatpou 2018).

Primary outcome: pressure ulcer incidence (proportion of participants developing any new pressure ulcer(s) of any stage)

Table 9

Gel probably results in a large reduction in pressure ulcer development compared to placebo (gel group: 17.4%, 19/109; placebo group: 11%, 66/108; RR 0.29, 95% CI 0.19 to 0.44; 2 studies, 217 participants; moderate-certainty evidence; Analysis 20.1). We downgraded once for high risk or unclear risk of selection bias, and once for imprecision due to a small number of events and a small sample size. However, the risk ratio is large, based on data from two RCTs, and the range of the confidence interval is relatively narrow, and so we upgraded the evidence by one level.

Secondary outcomes

Neither of the two studies included in this comparison reported any of our secondary outcomes of interest (i.e. stage of any pressure ulcers; time to pressure ulcer development; anatomical location; cost of interventions; quality of life; pain at dressing change; acceptability/satisfaction; adverse events; length of hospital stay).

DISCUSSION

Summary of main results

This systematic review examined the evidence from 51 trials, with a total of 13,303 participants, on the effects of interventions aimed at

reducing the incidence of pressure ulcers amongst at-risk persons. Thirty-one trials explored the use of a dressing; in four trials, both dressings and topical agents were the intervention of interest; and sixteen trials explored the use of a topical application. We generated 20 comparisons to report outcomes: 13 comparisons were related to dressings and seven comparisons were related to topical agents. This is the third update of the review, with the previous version including 18 trials (Moore 2018).

Dressings

Primary outcome: development of new pressure ulcers

We evaluated the effectiveness of dressings in relation to pressure ulcer incidence, making a total of 13 comparisons with 9027 participants. We present seven prioritised comparisons in the summary of findings (SoF) tables as follows:

- silicone foam dressing versus no dressing (18 trials, 5903 participants);
- foam dressing versus film dressing (3 trials, 569 participants);
- hydrocellular foam dressing versus hydrocolloid dressing (1 trial, 80 participants);
- silicone foam dressing type 1 versus silicone foam dressing type 2 (2 trials, 376 participants);
- foam dressing versus fatty acid (2 trials, 300 participants);
- polyurethane film versus hydrocolloid dressing (1 trial, 160 participants);
- hydrocolloid dressing versus no dressing (2 trials, 230 participants).

Apart from the comparison of silicone foam dressing versus no dressing, all other comparisons have very few trials (mean = 2), and very few participants (mean = 285). All comparisons were associated with low- or very low-certainty evidence. The main reasons for this relate to the risk of bias and imprecision (see Quality of the evidence). Thus, the evidence is uncertain about the effect of dressings on pressure ulcer development.

For the comparison of silicone foam dressing versus no dressing, there were 19 trials and 6029 participants. For the primary outcome, we analysed data from 18 trials, with 5903 participants. Despite the number of trials in this comparison, it is also affected by some elements of risk of bias and imprecision in the study results, and we downgraded the certainty of the evidence for these reasons (see Quality of the evidence). Thus, although silicone foam dressings may reduce pressure ulcer incidence compared to no dressing, the evidence is very uncertain.

Secondary outcomes

Pressure ulcer stage was reported in the three following comparisons.

- Silicone foam dressing versus no dressing:
  - pressure ulcer stage 1 (8 trials, 1823 participants;
  - pressure ulcer stage 2 (10 trials, 2873 participants);
  - pressure ulcer stage 3 (3 trials, 718 participants);
  - pressure ulcer stage 4 (2 trials, 610 participants);
  - unstageable pressure ulcer (1 trial, 366 participants);
  - Deep tissue injury (3 trials, 840 participants).
- Foam dressing versus film dressing:
  - pressure ulcer stage 1, 2, 3 (1 trial, 270 participants).
- Hydrocolloid dressing versus no dressing:
  - pressure ulcer stage 1, 2 (1 trial, 108 participants).

In one comparison, adverse events were reported (silicone foam dressing versus no dressing; 3 trials, 2317 participants), in addition to the time to pressure ulcer development (4 trials, 1059 participants), the anatomical location of pressure ulcer development (5 trials, 2871 participants), the cost of the interventions (4 trials, 1267 participants), quality of life (1 trial, 244 participants), pain (2 trials, 324 participants), and acceptability (2 trials, 321 participants). Two additional comparisons explored costs associated with the intervention: silicone foam dressing 1 versus silicone foam dressing 2 (1 trial, 302 participants), and polyurethane film versus hydrocolloid dressing (1 trial, 108 participants). All comparisons were associated with low- or very low-certainty evidence. The main reasons for this relate to the risk of bias and imprecision (see Quality of the evidence). Therefore, the evidence is uncertain about the effect of dressings on any of the secondary outcomes outlined.

Summary

We assessed the body of evidence from the included trials as being of low or very low certainty. Therefore, it is very uncertain whether any of the dressings included in this review make any difference to the incidence of pressure ulcer development, adverse events, stage of pressure ulcer, time to pressure ulcer development, or anatomical location of the pressure ulcer. There is limited evidence pertaining to the cost, pain, and acceptability of the dressings, and just one study reported on quality of life.

Topical agents

Primary outcome: development of new pressure ulcers

We evaluated the effectiveness of topical agents in relation to pressure ulcer incidence, making a total of seven comparisons in our analysis, with 4276 participants. We present five prioritised comparisons in the SoF tables as follows:

- fatty acid versus placebo (6 trials, 2201 participants);
- fatty acid versus usual care (7 trials, 1058 participants);
- cream versus fatty acid (1 trial, 120 participants);
- cream versus placebo (3 trials, 513 participants);
- cream versus usual care (1 trial, 47 participants).

All comparisons were associated with very low certainty evidence. The main reasons for this relate to the risk of bias and imprecision (see Quality of the evidence). In all the comparisons, it is, therefore, very uncertain whether the interventions make any difference to pressure ulcer development.

Secondary outcomes

Two comparisons reported pressure ulcer stage: fatty acid versus usual care (pressure ulcer stage 1: 2 trials, 180 participants; pressure ulcer stage 2: 2 trials, 180 participants), and cream versus placebo (pressure ulcer stage 3: 1 trial, 258 participants; pressure ulcer stage 4: 1 trial, 258 participants). One comparison reported adverse events: fatty acid versus placebo (3 trials, 967 participants). One comparison reported time to pressure ulcer development: fatty acid versus placebo (1 trial, 167 participants). Finally, two comparisons reported the anatomical location of pressure ulcer

development: fatty acid versus placebo (2 trials, 643 participants), and fatty acid versus usual care (3 trials, 252 participants).

All comparisons were associated with low- or very low-certainty evidence. The main reasons for this relate to the risk of bias and imprecision (see Quality of the evidence). It is, therefore, uncertain whether the interventions make a difference to any of the secondary outcomes outlined.

Summary

It is uncertain whether any of the topical agents included in this review make any difference to pressure ulcer incidence, pressure ulcer stage, adverse events, time to pressure ulcer development, or anatomical location of pressure ulcer development when compared to control/placebo.

Overall completeness and applicability of evidence

Participants recruited to the trials exploring the use of dressings and new pressure ulcer development were representative of at-risk individuals. Participants included neonates, infants and children, adults, and older people. Most of the dressing trials were conducted in hospital clinical settings that report high pressure ulcer incidence rates, including critical and intensive care, emergency departments, operating room, medical and surgical units. Few dressing trials were conducted in geriatric and long-term care facilities, hence further investigation into this population and setting is warranted.

We separated results for pressure ulcer stage. However, in most clinical pressure ulcer prevention trials, severe categories, including stages 3 and 4, rarely occur. Therefore, though we were interested in the effect on all stages of pressure ulcer development, it is important to emphasise this clinical reality, especially when considering the impact on overall pressure ulcer incidence.

The trials exploring topical agents mainly included at-risk adults and older people in hospitals, geriatric medicine, and nursing homes. Thus, topical agents require greater investigation across other patient populations and clinical settings.

Economic and cost-effectiveness analyses were reported in four dressing trials: three in adults and one in infants. There were no economic data on topical agents. Three trials reported intervention-related adverse events: Beeckman 2021 and De Wert 2019 reported dressing-related adverse events for the intervention group, while Santamaria 2015 reported no dressing adverse events.

Scant evidence exists on participants' satisfaction with dressings for pressure ulcer prevention (De Wert 2019; Walker 2015), and pain experienced (De Wert 2019; Guerra 2017), with more research needed on these issues. Just one of the dressing trials measured the impact on participants' quality of life (De Wert 2019).

Potential conflicts of interest and bias are noted. Fifteen (29.0%) trials reported receiving support from manufacturers, either financial (n = 14) or product (n = 1). Furthermore, one group of investigators were developers of the dressing they subsequently evaluated in their trial, and one author in another study was an employee of the product manufacturer. Another 17 (33%) trials received non-commercial funding. The trials in this review were conducted across 16 countries, with most located in Europe, Asia, and the Pacific region.

Quality of the evidence

Limitations in trial design and implementation

In this third update of the review, we continued to include only RCTs to enable a thorough assessment of risk of bias for each trial. Most trials provided details of appropriate random sequence allocation, which resulted in an overall low risk of bias. However, we judged several trials as having an unclear or high risk of bias due to a lack of detail regarding sequence generation. Broadly speaking, we assessed most studies as having an unclear or high risk of bias for allocation concealment and blinding of participants and personnel. While some trials of topical agents had success in blinding participants and personnel, most of the dressing trials were not able to blind participants and personnel (a somewhat expected result). However, one dressing trial was able to blind outcome assessment using photography (Walker 2015). Outcome data were generally well reported. However, a few trials did not analyse participants randomised to the intervention, and we therefore judged these to be at high risk of attrition bias. Selective reporting and other potential sources of bias were also evident to some extent, but we judged most trials as having a low or unclear risk of bias in these domains (Figure 3).

Of the three cluster-RCTs, the Stankiewicz 2019 trial allocated participants to one dressing type, alternating between silicone dressing 1 and silicone dressing 2, in three monthly cycles. The Houwing 2008 trial randomised participants by ward, not individual. In Santamaria 2018, each facility included in the study (rather than individuals within the facility) was randomised to either the intervention or control group. Participants in the Nakagami 2007 trial acted as their own control; that is, no dressing was applied to the opposite trochanter, thereby increasing the risk of unit of analysis error.

In terms of assessment of the certainty of the evidence using GRADE criteria, in the comparison of fatty acid to usual care, we upgraded the evidence certainty by one level for the outcome 'pressure ulcer stage 1', because the risk ratio was large, and although the confidence interval was slightly wide, the limits fall almost entirely within a range considered as indicating a large effect. However, we also downgraded the evidence for high risk of selection, performance, detection, and attrition bias, as well as for imprecision due to a small sample size. For the remaining comparisons, we downgraded the evidence for outcomes to low or very low certainty. Reasons for downgrading included concerns over the risk of bias across multiple domains (as summarised above), and imprecision. Other reasons included serious imprecision, a small number of events, wide confidence intervals, and small sample sizes.

Indirectness of evidence

Although the review was limited by variations in both the experimental and the control interventions, we did not downgrade the evidence for indirectness as it covers the population, intervention, and outcomes stipulated in the protocol.

Imprecision of results

As summarised above, the low number of events and small sample sizes resulted in wide confidence intervals in most of the pooled estimates of outcomes. However, in the analyses of silicone dressing versus no dressing, confidence intervals were narrower

and results statistically significant for any pressure ulcer, and stage 1 and stage 2 pressure ulcers. Where there were wide confidence intervals, precision was reduced and created uncertainty around the estimate of effect for both topical agents and dressings trials.

Publication bias

In this update, we attempted to obtain additional information from three trial authors, but without success. This reflects the difficulties we experienced in trying to contact authors for information whilst developing the previous versions of the review. As summarised above, reporting of trial information was done reasonably well with few issues related to selective reporting. However, we acknowledge that statistically significant findings are more likely to be published (particularly from studies with smaller sample sizes). As such, there is a possibility 'negative results' were not reported, which may lead to a spurious positive effect, favouring the intervention (Schünemann 2013).

Potential biases in the review process

To limit potential biases in the review process, we implemented systematic and rigorous methods that were transparent and reproducible (Lefebvre 2022). The broad electronic database literature searches included studies published in any language and setting, and without date limiters. The first update of this review included Han 2011, a Chinese publication requiring a translator to aid with data extraction. In this second review, the newly added trials were all published in English. As noted above, we attempted to contact three trial authors to seek additional information, but without success. We acknowledge that it is possible that trials published in journals outside our search strategy may have been missed. Whilst participants and staff can be blinded to the use of topical agents, this is almost impossible in relation to prophylactic dressings; thus, most dressing trials are unavoidably at risk of performance bias.

Agreements and disagreements with other studies or reviews

Pressure ulcer prevention is a significant patient safety issue and, as such, there are several recent pressure ulcer prevention systematic reviews that include dressings, topical agents, or both. For example, Fulbrook 2019 undertook a systematic review exploring the effectiveness of prophylactic sacral protective dressings. From the six studies included in the meta-analysis, an overall effect in favour of the prophylactic dressing was identified. In a systematic review of 21 papers on multicomponent pressure ulcer prevention programmes in the intensive care unit (ICU) setting, Lin and colleagues included two quality improvement studies that had incorporated prophylactic dressings as one component of the intervention, with both showing that the multicomponent intervention reduced pressure ulcers (Lin 2020). Another review of 14 nursing interventions for pressure ulcer prevention in ICU patients included four studies of prevention bundles that incorporated prophylactic dressings (Alshahrani 2021), with various beneficial effects associated with bundle use. In their systematic review, Gaspar and colleagues assessed 26 studies that focused on the effectiveness of pressure ulcer prevention strategies, six of which were specifically on prophylactic dressings (Gaspar 2019). They found five of the six dressing studies demonstrated statistically significant decreases in pressure ulcers. In the sixth study, a gel mattress was compared to a multilayered foam dressing, with no statistically significant differences in sacral pressure ulcers between the two groups. Finally, Tezcan and colleagues carried out a systematic review of studies investigating pressure ulcer treatment in healthcare workers arising from their use of protective equipment during the COVID-19 pandemic (Tezcan 2022). This review included six studies exploring the use of prophylactic dressings and assessed various outcomes. Studies that included pressure ulcers as an outcome generally found dressings were effective. To the best of our knowledge, this Cochrane review is the only systematic review that assesses dressings and topical agents for pressure ulcer prevention.

AUTHORS' CONCLUSIONS

Implications for practice

Pressure ulcers are a relatively common acquired complication that occurs in community dwellers and across all care settings. Their prevention is a priority for healthcare providers, yet this review of 51 trials found that many uncertainties exist in the evidence for the use of dressings and topical agents for the prevention of pressure ulcers. While several dressing types were used in the trials we evaluated and were assessed against a variety of comparators (including no dressing, a placebo, or alternative dressing), the main type was silicone (18 studies, 5903 participants). Three of the recent studies on silicone dressings we reviewed showed evidence of benefit (Beeckman 2021; Forni 2022; Hahnel 2020). While all of these studies were at high risk of bias on some criteria, this was often because blinding of participants (and sometimes outcome assessors) was not undertaken. Thus, while silicone foam dressings may reduce pressure ulcer incidence (any stage) compared to no dressing, the evidence is very uncertain.

The trials we assessed tested a vast array of topical agents, with fatty acid being the most common agent – tested in 13 trials and a total of 3259 participants. These trials were at high risk of bias and the body of evidence was very uncertain. The trials of other topical agents were also at high risk of bias in numerous domains. Overall, topical agents may have little to no effect on pressure ulcer incidence, but the evidence is very uncertain.

Implications for research

There are numerous topical agents and dressings advocated for pressure ulcer prevention. However, as yet we do not clearly know whether any of the products make any difference to pressure ulcer development. Given the plethora of products available, future studies should engage with patients, the public, and decision-makers to determine priority interventions to test in future research. Once these priorities are identified, there needs to be a very clear and detailed description of the intervention. Given that dressing costs vary, adequately powered, high-quality head-to-head trials of different types of dressings, such as silicone versus foam, is one potential area to pursue. Associated with this, we found only a few studies that examined crude costs and found no cost-effectiveness research, clearly an important consideration for decision-makers. Planning for a cost-effective analysis a priori, led by an experienced health economist, should be considered in future trials. Furthermore, researchers undertaking future trials should register their trial in a World Health Organization (WHO) International Clinical Trials Registry Platform member registry, prior to recruitment of the first participant.

There are other issues trialists should address. Many studies we reviewed did not blind outcome assessors. However, one-third of studies included in the review were able to achieve this (17/51; 33%). Determining the target population to study is an important consideration as many of the dressings trials focused on people in intensive care or in hospital. There was much less research on aged care residents or individuals living in the community, although several studies of topical agents were undertaken on the elderly, either those accessing community health care or residing in nursing homes/long-term care facilities. Thus, the extent to which dressings and topical agents have benefit in a wider variety of populations should be considered. Further, given many of the studies we reviewed had small samples, it is important that accurate sample size calculations are completed for the particular target population to avoid undertaking an underpowered trial. Finally, the recent advances in determining a core outcome set for pressure ulcer research provides future researchers with opportunities to standardise and justify their choice of outcome measures (Lechner 2022). For example, three outcomes specified in this work include the acceptability and comfort of the intervention, adherence or compliance, and adverse events or safety. All of these outcomes may be important for trials of dressings, given dressings can 'malfunction' and can result in blistering.

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The following people conducted the editorial process for this article:

- Sign-off Editor (final editorial decision): Emma Sydenham, Cochrane;
- Managing Editor (selected peer reviewers, provided editorial guidance to authors, edited the article): Luisa Fernandez Mauleffinch, Cochrane Central Editorial Service;
- Editorial Assistant (conducted editorial policy checks, collated peer-reviewer comments and supported editorial team): Sara Hales-Brittain, Cochrane Central Editorial Service;
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- Peer-reviewers (provided comments and recommended an editorial decision): Prof Dr Jan Kottner, Charité-Universitätsmedizin Berlin, Germany (clinical/content review); Rujan Shrestha, Infectious Diseases Data Observatory (IDDO), University of Oxford, Old Road Campus, Oxford, UK (consumer review); Jennifer Hilgart, Cochrane (methods review); Gemma Villanueva, Cochrane Response (methods/content review); Jo Platt, Central Editorial Information Specialist (search review); and Michael Clark, Birmingham City University (clinical/content review).

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Aloweni 2017

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: yes **Follow-up period**: 14 days **Sample size estimate**: yes, a total of 494 participants would be needed **ITT analysis**: yes; **number randomised:** 461 **number analysed**: 461 **Funding**: SingHealth Foundation Research Grant 2012 (SHF/HSR061/2012)
Participants	**Inclusion criteria**: • ≥ 21 years of age (the study venue was an adult-focused health facility) • Without pre-existing pressure injuries • Assessed as being at high risk of developing pressure injuries (scoring less than or equal to 14 using the Braden Scale) **Exclusion criteria**: • Existing sacral pressure injury • Allergy to fatty acid oil or silicone dressing • Faecal incontinence at the time of hospital admission **Pretreatment**: • Age: 87% (n = 401/461) aged 60 to 99 years • Gender not provided • 58% Braden score ≥ 13
Interventions	**Intervention group 1**: • Standard care plus a multilayer soft silicone foam dressing applied to the sacrum • Dressing changed every 7 days or when soiled **Intervention group 2**: • Standard care plus fatty acid oil applied to the sacrum three times a day **Control group**: • Standard care Study group 1 and control group included in comparison 1; study group 2 and control group included in comparison 15
Outcomes	PU incidence

Aloweni 2017 *(Continued)*

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Unit of measure**: numbers
- **Direction**: lower is better
- **Data value**: endpoint

Identification	**Sponsorship source**: not stated **Country**: Singapore **Setting**: 8 medical-surgical wards **Comments: n**one **Author's name**: Lim Mei Ling **Institution**: Nursing Division, Singapore General Hospital **Email**: lim.mei.ling@sgh.com.sg **Address**: Bowyers Block B Level 2, 31 Third Hospital Avenue, Singapore 168753
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Using a computer-generated table of simple random sampling (ratio 1:1:2)
Allocation concealment (selection bias)	Low risk	The allocation list was performed by a research coordinator who was not involved in the study. Opaque sealed envelopes were used to maintain allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	The participants were assessed by the registered nurses who cared for them.
Blinding of outcome assessment (detection bias) All outcomes	High risk	A study investigator also assessed participants.
Incomplete outcome data (attrition bias) All outcomes	Low risk	An intention-to-treat (ITT) analysis approach was adopted to include all participants who were recruited and randomised in this study, regardless of protocol violations
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Low risk	None detected

Alves 2020

Study characteristics

Methods	**Trial design**: RCT

Alves 2020 *(Continued)*

Trial grouping: parallel - participants' heels were either control or intervention

Ethics and informed consent: unclear
Follow-up period: unclear

Sample size estimate: unclear

ITT analysis: yes; **number randomised:** 92 **number analysed:** 92

Funding: unclear

Participants	**Inclusion criteria**: • High and very high risk patients **Exclusion criteria**: • Unclear **Pretreatment**: • Age: 54.4 years (SD: 18.7) • Gender: male: 56.5% (n = 52)
Interventions	**Intervention group**: multilayer soft silicone foam dressing. No further details are provided. **Control group**: polyurethane film. No further details are provided.
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** not stated **Country**: Portugal **Setting**: ICU wards **Comments:** information obtained from published abstract **Author's name**: Paulo Alves **Institution**: Universidade Católica Portuguesa **Email**: pjpalves@gmail.com **Address**: Palma de Cima, Edifício Reitoria, 1649-023 Lisboa, Portugal
Notes	We attempted to contact the authors to seek additional information, but received no response.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised clinical trial but method of randomisation not described in sufficient detail
Allocation concealment (selection bias)	Unclear risk	Not stated

Alves 2020 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Without blinding
Blinding of outcome assessment (detection bias) All outcomes	High risk	Without blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	92 randomised and 92 analysed
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Low risk	None detected

Babamohamadi 2019

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: yes **Follow-up period**: while participants stayed in the ICU, for a maximum 14 days **Sample size estimate**: yes; the sample size was estimated to be 54 cases for each group **ITT analysis:** no; **number randomised:** 150; **number analysed:** 140 **Funding**: funded by a grant from the Semnan University of Medical Sciences (grant number: 600)
Participants	**Inclusion criteria** • Admitted to the ICU because of head trauma, endotracheal tube on admission to the intensive care unit • At risk of moderate to severe bedsores according to Braden scoring tool and scored less than 13–14 • Lack of systematic diseases such as diabetes, heart failure, kidney failure and cancer advanced phase • Lack of sensitivity to the mint family of plants • Absence of PI on admission • Glasgow Coma Scale of 8 and less on admission • Limit of changes in body position with multiple injuries **Exclusion criteria** • Death or patient transmission less than 48 hours after admission to the ICU • Unwillingness of family to cooperate, natural-conscious state in less than 48 hours after inclusion • Sensitivity to mint gel after use on a patient's forearm (area of 2 × 2 cm), This area was evaluated for the presence of redness, swelling and warmth within 45 min. **Pretreatment** • Age: intervention group: 34.06 years; control group: 38.20 years • Gender: 81.3% of participants in the experimental group and 78.7% in the control group were male

Babamohamadi 2019 *(Continued)*

Interventions	**Intervention group** • "Peppermint gel was rubbed three times during the skin care as a layer on the skin at areas at risk for PIs, including the patient's hip area, and bony prominences such as both elbows, knees, heels and shoulder" **Control group** • All measures were similar to the intervention groups, except that a placebo gel was applied in this group.
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** not stated **Country**: Iran **Setting**: 2 hospitals - ICU wards **Comments**: no comments **Author's name**: Hassan Babamohamadi **Institution**: Nursing Care Research Center, Semnan University of Medical Sciences **Email**: babamohamadi@semums.ac.ir **Address**: 5 Kilometers of Damghan Road, Education and Research Campus, Semnan University of Medical Sciences, Faculty of Nursing and Midwifery, Postal Code: 3513138111, Semnan, Iran
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random sequence allocation was carried out using sealed envelopes, but method of randomisation not clearly described
Allocation concealment (selection bias)	High risk	Envelopes not described as opaque
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants and relatives were blinded to the assigned intervention.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors and statistician were blinded to the assigned intervention.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.

Babamohamadi 2019 *(Continued)*

Selective reporting (reporting bias)	Low risk	All outcomes listed in the trial registry measured (Iranian Registry of Clinical Trials IRCT201402098665N3)
Other bias	Low risk	None detected

Beeckman 2021

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: yes **Follow-up period**: maximum 14 days **Sample size estimate**: yes; 1578 participants in total **ITT analysis:** no; **number randomised:** 1633; **number analysed:** 1605 **Funding:** Belgian Health Care Knowledge Centre (KCE) via the KCE Trials Programme (study ID KCE16012)
Participants	**Inclusion criteria** • Aged > 18 years who gave written informed consent (patient or proxy) • At risk for PU development based on Braden risk assessment (Braden score < 17) • Admitted to the hospital within the previous 48 hours • Had no PU of category 2 or worse present on the sacrum • No clinically relevant incontinence-associated dermatitis or other skin condition that would be a contraindication for application of the study devices **Exclusion criteria** • Aged < 18 years • Length of stay counting from first day of admission in one or (if the participant was transferred to another ward) more participating wards is < 7 days • Both heels amputated • Previously known/documented allergy for substances used in the devices under study • A clinical condition not allowing participation in a clinical study • Participation in another interventional clinical trial • Patients who exceptionally receive or are planned to receive a dressing for the prevention of pressure ulcers at sacrum, heels, and trochanters based on best medical judgement and outside the surgery setting **Pretreatment** • Age: median (IQR) Intervention group 1: 83.1 (74.7–88.2); Intervention group 2: 83.1 (72.6–88.3); Control group: 82.7 (73.4–87.5) • Gender F/M: Intervention group 1: 320/222; Intervention group 2: 302/243; Control group: 319/227
Interventions	**Intervention groups 1 and 2 combined** • Standard hospital protocols for prevention of pressure ulcers in addition to silicone adhesive multilayer foam dressings applied to the sacrum, heel right/left, greater trochanter right/left. • Dressings were maintained on the treatable skin sites throughout the conduct of the trial and changed if they became soiled or dislodged.

Beeckman 2021 *(Continued)*

- The skin beneath the dressing was inspected daily.

Control group

- Standard hospital protocols for prevention of pressure ulcers
- The skin on the sacrum, heel right/left, trochanter right/left were inspected daily.

Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Adverse events • **Outcome type**: dichotomous outcome • **Reporting**: partially reported • **Unit of measure**: numbers • **Direction**: lower stage is better • **Data value**: endpoint Anatomical location of pressure ulcer development • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** not stated **Country**: Belgium **Setting**: eight hospitals (three university or teaching hospitals and five general hospitals, including ICU and non-ICU wards **Comments**: no comments **Author's name**: Dimitri Beeckman **Institution**: Skin Integrity Research Group (SKINT) **Email**: Dimitri.Beeckman@UGent.be **Address**: University Centre for Nursing and Midwifery, Department of Public Health and Primary Care, Ghent University
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were centrally randomised to study groups based on a 1 : 1: 1 allocation.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not clearly described

Beeckman 2021 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants, caregivers, and study personnel were not blinded to the study procedures.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Study personnel were not blinded to the study procedures.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.
Selective reporting (reporting bias)	Low risk	All outcomes listed in the trial registry measured (ClinicalTrials.gov: NCT03442777)
Other bias	Low risk	None detected

Borzou 2020

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: not reported **Follow-up period**: 7 days **Sample size estimate**: yes; 36 per group **ITT analysis:** no; **number randomised:** 138; **number analysed:** 108 **Funding**: "Financial support for this work was provided by the vice chancellor for research and technology, Hamadan University of Medical Sciences, Hamadan, Iran (grant no. 960921587)"
Participants	**Inclusion criteria** • Ages 18 to 85 years • No history of skin allergies (rash, hives, redness) or skin diseases such as atopic dermatitis (eczema), shingles (herpes zoster), hives (urticaria), and contact dermatitis • Absence of pressure injury • Had indwelling urinary catheters • No recent application of lotion, topical ointments, or oil such as almond or fish oils, zinc oxide, or Vaseline to the skin sites being studied • No sensitivity to almond oil and its related products • No diabetes as this places participants at greater risk of developing pressure injuries • Able to provide written informed consent or consent by legal guardian • Braden Scale score of 18 or below indicating high risk for pressure injury **Exclusion criteria** • Being quadriplegic or paraplegic • On complete bed rest • Impending transfer out of the unit **Pretreatment**

Borzou 2020 *(Continued)*

- Age (mean; SD): Intervention group 1: 52.83 (20.5); Intervention group 2: 52.58 (18.55); Control: 53.19 (20.01)
- Gender (F/M): Intervention group 1: 7/29; Intervention group 2: 14/22; Control: 9/27

Interventions	**Intervention group 1** • Group A - received a topical application of sweet almond oil in addition to routine care • The product was applied once a day, for 7 days, by hand in circular motions without pressure for approximately 5 seconds to 5 areas prone to pressure: the posterior of each shoulder and sacrum and each heel. **Intervention group 2** • Group B received a commercially available liquid paraffin placebo in addition to routine care • Paraffin was applied to the same areas using the same procedure as for almond oil. **Control group**: • Received routine care only Study groups 1 and 2 included in comparison 14; study group 1 and control group included in comparison 15.
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** not stated **Country**: Iran **Setting**: 1 hospital - ICU ward **Comments**: no comments **Author's name**: Seyed Reza Borzou **Institution**: Department of Nursing, Chronic Diseases (Home Care) Research Center, School of Nursing & Midwifery, Hamadan University of Medical Sciences, Hamadan, Iran **Email**: sheller.amiri5115@gmail.com **Address**: Research Center, School of Nursing & Midwifery, Hamadan University of Medical Sciences, Hamadan, Iran
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A permuted block randomisation method
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not clearly described

Borzou 2020 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Single blind
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessor blinded to study group
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.
Selective reporting (reporting bias)	Low risk	Trial registered and planned outcomes were measured (Iranian Registry of Clinical Trials (IRCT) # RCT20171128037657N1)
Other bias	Low risk	None detected

Chang 2017

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: not reported **Follow-up period**: 14 days **Sample size estimate**: not reported **ITT analysis:** no; **number randomised:** 400; **number analysed:** 346 **Funding**: not stated
Participants	**Inclusion criteria** • Braden score ≤ 14 • No pressure ulcer on recruitment **Exclusion criteria:** not stated **Pretreatment** • Age (Mean; SD): 76; 14.2 years • 51% female
Interventions	**Intervention group 1** • Group A: multilayer dressing to the sacrum (details of application not provided) with standard care **Intervention group 2** • Group B: fatty acid oil spray to the sacrum (details of application not provided) with standard care **Control group** • Standard care alone

Chang 2017 *(Continued)*

	Study group 1 and 2 included in comparison 5; study group 2 and control group included in comparison 15
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: end point
Identification	**Sponsorship source**: not stated **Country**: Singapore **Setting**: 1 hospital - in patient wards **Comments**: no comments **Author's name**: Yee Yee Chang **Institution**: Singapore General Hospital **Email**: not provided **Address**: Singapore
Notes	We attempted to contact the authors to seek additional information. We were unable to locate them.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Simple randomisation with an allocation ratio of 1:1:2
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	High risk	13.5% of participants dropped out of the study and the numbers per group are not provided.
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Unclear risk	As the data have been extracted from an abstract, it is unclear if there are any other sources of bias.

Chen 2020

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: not reported **Follow-up period**: not reported **Sample size estimate**: yes; 35 participants for each group **ITT analysis**: no; **number randomised**: 130; **number analysed:** 125 **Funding**: not reported
Participants	**Inclusion criteria:** children who were consecutively intubated with silicone nasotracheal tubes **Exclusion criteria** • Nasal skin injuries, skin rash • Allergy to the dressing **Pretreatment** • Age (Months, median and IQR): Intervention: 16 (5.25 to 45.75); Control: 12 (3 to 36) • Gender F/M: Intervention: 23/37; Control 24/38
Interventions	**Intervention group** • Hydrocolloid dressing to cover the area from the nasal columella to the ala • Generally, the dressing was changed daily or more frequently when excessive exudate, mucous secretion, or sweat saturated the dressing **Control group:** usual Care
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Adverse events • **Outcome type**: dichotomous outcome • **Reporting**: partially reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** not stated **Country**: China **Setting**: 1 hospital PICU **Comments**: no comments **Author's name**:Jie Chen **Institution**:Pediatric Intensive Care Unit, Guangzhou Women and Children's Medical Center

Chen 2020 *(Continued)*

Email: chen.j.cn@hotmail.com

Address: Pediatric Intensive Care Unit, Guangzhou Women and Children's Medical Center, Guangzhou Medical University, Guangzhou, China

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomly allocated to the control group and the experimental group in a 1:1 ratio by using Microsoft Excel to generate a randomisation list.
Allocation concealment (selection bias)	Low risk	The allocation sequence was concealed in an individual opaque envelope.
Blinding of participants and personnel (performance bias) All outcomes	High risk	The nurses and physicians could notice the intervention during the process of this study.
Blinding of outcome assessment (detection bias) All outcomes	High risk	The nurses and physicians could notice the intervention during the process of this study.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data balanced in numbers across intervention groups
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Low risk	None detected

Chiew 2010

Study characteristics

Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: not reported **Follow-up period**: not reported **Sample size estimate**: not reported **ITT analysis**: yes; **number randomised:** 109; **number analysed:** 109 **Funding**: not reported
Participants	**Inclusion criteria:** people > 60 years (mean age not reported by group), with traumatic hip fractures who had a surgical intervention **Exclusion criteria:** not stated

Chiew 2010 *(Continued)*

	Pretreatment: Most of the participants were female (71.6%), 76 years old and above (58.7%), and community ambulant (57.8%) prior to the hip fracture
Interventions	**Intervention group** • Sanyrene solution and 2–3 hourly change of position • The topical agent was applied on the participant's sacrum, buttocks, and heels at every change of position from day of admission **Control group:** 2–3 hourly change of position only
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Stage of PUs • **Outcome type**: dichotomous outcome • **Reporting**: partially reported • **Unit of measure**: numbers • **Direction**: lower stage is better • **Data value**: endpoint Location of PUs • **Outcome type**: dichotomous outcome • **Reporting**: partially reported • **Unit of measure**: numbers • **Direction**: none • **Data value**: endpoint
Identification	**Sponsorship source:** not stated **Country**: Singapore **Setting**: orthopaedic ward **Comments**: no comments **Author's name**: Chiew SF **Institution**: Department of Orthopaedic Surgery, Singapore General Hospital, Singapore **Email**: not stated **Address**: not stated
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Although block randomisation was mentioned, the method of sequence generation was not (i.e. computer generated; random numbers list; toss of coin, etc).

Chiew 2010 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	The method of allocation concealment was not reported.
Blinding of participants and personnel (performance bias) All outcomes	High risk	The nature of the intervention would make blinding of participants and personnel impossible.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reported the incidence of PUs for all those enroled in the study
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Unclear risk	As the data have been extracted from an abstract, it is unclear if there are any other sources of bias.

da Silva Augusto 2019

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: yes **Follow-up period**: 30 days or until pressure ulcer onset **Sample size estimate**: no **ITT analysis:** no; **number randomised:** 80; **number analysed:** 62 **Funding**: financial support for this study was provided by Smith & Nephew, Inc (Hull, United Kingdom)
Participants	**Inclusion criteria:** people at risk for pressure injuries, according to the Braden Scale for Predicting Pressure Sore Risk (Braden Scale) who had intact skin over the sacrum and trochanters **Exclusion criteria:** people with scars, changes in skin colour, or desquamation in the sacral and trochanteric regions **Pretreatment** • 35 (56.5%) were women • 40 (64.5%) were 60 years of age or older (mean, 62.2 years)
Interventions	**Intervention group** • Hydrocellular foam polyurethane dressing applied to the sacrum and trochanters • Dressings were changed weekly or when they became damp, loosened, or soiled • Preventive interventions followed the study institution's prevention protocol for pressure injuries **Control group**

da Silva Augusto 2019 *(Continued)*

- Hydrocolloid dressing applied to the sacrum and trochanters
- Dressings were changed weekly or when they became damp, loosened, or soiled
- Preventive interventions followed the study institution's prevention protocol for pressure injuries

Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Discomfort during dressing removal • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** financial support for this study was provided by Smith & Nephew, Inc (Hull, United Kingdom) **Country**: Brazil **Setting**: 1 hospital **Comments**: no comments **Author's name**: Fabiana da Silva Augusto **Institution**: Graduate Program in Translational Surgery, Federal University of São Paulo (UNIFESP) **Email**: fabianasaugusto@gmail.com **Address**: São Paulo, Brazil
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The allocation sequence was generated using a computer-generated randomisation chart.
Allocation concealment (selection bias)	Low risk	The participants and nursing team were blinded to group assignment until the moment of intervention.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded
Blinding of outcome assessment (detection bias) All outcomes	High risk	The investigators were not blinded to group assignment.
Incomplete outcome data (attrition bias)	Low risk	Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.

da Silva Augusto 2019 *(Continued)*
All outcomes

Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Low risk	None detected

De Wert 2019

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: yes **Follow-up period**: 6 weeks **Sample size estimate**: yes, a total of 870 participants would be needed **ITT analysis:** no; **number randomised:** 253; **number analysed:** 244 **Funding**: Kootstra Talent Fellowship, Maastricht University Medical Centre
Participants	**Inclusion criteria** • A prePURSE score ≥ 2121 or a Braden score < 19 (prePURSE: prevention and Pressure Ulcer Risk Score Evaluation) • Expected to be immobile (bed- or chair-bound) for 3 days or more **Exclusion criteria** • Age < 18 years, pre-existing sacral pressure ulcer • Pre-existing trauma to the sacrum • Inability to speak Dutch • Mentally disabled people • Patients who went directly to the ICU after hospital admission **Pretreatment** • Age in years: mean (SD): Intervention: 71.9 ± 10.9; Control: 70.9 ± 9.8 • Male: number (%): Intervention: 66 (54.1); Control: 83 (63.4) • PrePURSE: score mean (SD): Intervention: 23.6 ± 3.8; Control: 23.9 ± 4.4 • Braden: score mean (SD): Intervention: 20.8 ± 3.0; Control: 21.1 ± 2.9
Interventions	**Intervention** • Five-layered soft silicone self-adherent sacral dressing • The dressing was replaced at least every four days or more frequently when necessary in cases when the dressing was soiled, displaced, curled or not in the right place • Plus standard care **Control:** standard care (no dressing)
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported

De Wert 2019 *(Continued)*

- **Unit of measure**: numbers
- **Direction**: lower is better
- **Data value**: endpoint

Pain

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Unit of measure**: numbers
- **Direction**: lower is better
- **Data value**: endpoint

Discomfort

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Unit of measure**: numbers
- **Direction**: lower is better
- **Data value**: endpoint

Health-related quality of life

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Unit of measure**: numbers
- **Direction**: lower is better
- **Data value**: endpoint

Identification	**Sponsorship source:** Maastricht University Medical Centre **Country**: Netherlands **Setting**: 1 hospital **Comments**: no comments **Author's name**: Luuk Albert de Wert **Institution**: Maastricht University Medical Centre **Email**: l.dewert@maastrichtuniversity.nl **Address**: NUTRIM School of Nutrition and Translational Research in Metabolism, Maastricht University, Universiteitssingel 50, P.O. Box 616, 6200 MD Maastricht, The Netherlands
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation of participants "was performed online via TENALEA in a 1:1 ratio"
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not clearly described
Blinding of participants and personnel (performance bias)	High risk	Neither participants nor members of the research team were blinded.

De Wert 2019 *(Continued)*

All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	High risk	Neither participants nor members of the research team were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data balanced in numbers across intervention groups
Selective reporting (reporting bias)	Low risk	Trial registered and planned outcomes measured (ClinicalTrials.gov NCT01640418)
Other bias	Low risk	None noted

Díaz-Valenzuela 2014

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: yes **Follow-up period**: 30 days **Sample size estimate**: yes (560 people required) **ITT analysis:** no; **number randomised:** 247; **number analysed:** 229 **Funding**: Ministry of Health of the Government of Andalusia, in the call for Research Biomedical and Health Sciences in Andalusia 2010 with No. of record PI- 0772-2010
Participants	**Inclusion criteria:** people living in nursing homes with moderate or high risk of PUs (≥ 14 on the Braden scale) **Exclusion criteria:** people with an existing PU; those with vascular disease or those with an extremely poor medical condition **Pretreatment** • Mean age: olive oil group: 84.06 years; fatty acid group: 81.7 years • Mean Braden score: olive oil: 12.06; fatty acid: 12.09 • Men: olive oil: 19%; fatty acid: 27.8% • Incontinent urine: olive oil: 6.6%; fatty acid: 11.9% • Incontinent mixed: olive oil: 83.4%; fatty acid: 88.1% • Repositioning; olive oil: 33.1%; fatty acid: 27.8% • Pressure redistribution mattresses: olive oil: 43.0%; fatty acid: 32.5% • Local pressure redistribution devices: olive oil: 38.8%; fatty acid: 39.7% • Nutritional supplements: olive oil: 8.3%; fatty acid: 3.28% • Both groups were equivalent at baseline
Interventions	**Intervention group:** application of extra virgin olive oil (Oleicopiel) every 12 h to risk areas **Control group:** application of HOFAs (Mepentol) every 12 h to risk areas
Outcomes	PU incidence

Díaz-Valenzuela 2014 *(Continued)*

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Unit of measure**: numbers
- **Direction**: lower is better
- **Data value**: endpoint

Time to onset of the PU

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Unit of measure**: survival analysis
- **Direction**: higher is better
- **Data value**: endpoint

Identification	**Sponsorship source:** not stated **Country**: Spain **Setting**: nursing homes in the province of Córdoba **Comments**: no comments **Author's name**: Antonio Díaz Valenzuela **Institution**: Hospital de Alta Resolución de Puente Genil **Email**: adiaz@ephag.es **Address**: Miguel Quintero Merino, 14500 Puente Genil (Córdoba)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer software (Epidat 3.1) was used to generate random number sequence (ratio 1:1)
Allocation concealment (selection bias)	Unclear risk	Not mentioned
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Double-blind
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Double-blind
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Low risk	Baseline characteristics were similar and there were no other obvious risks of bias.

Díaz-Valenzuela 2019

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: yes **Follow-up period**: not reported **Sample size estimate**: yes; 267 participants were required per treatment group **ITT analysis:** no; **number randomised:** 571; **number analysed:** 537 **Funding**: Fundación Progreso y Salud, Consejería deSalud de la Junta de Andalucía (Spain), Grant/ Award Number: PI-0772-2010
Participants	**Inclusion criteria:** nursing home residents at risk of PU onset (Braden Scale score < 14 points) **Exclusion criteria** • Presence of PUs (any category) • Non-healed skin lesion • Active vascular disease • Expected failure to complete the follow-up study (e.g. due to very poor health status or planned transfer to another centre) **Pretreatment** • Gender: female 47 (34.8%), male 88 (65.2%) • Age: mean (years) 59.5 ± 12.9 (18 to 82) • NB: data are for the intervention group only
Interventions	**Intervention group** • An extra-virgin olive oil solution was applied to PU-risk areas in addition to usual care procedures. • The attending nurses applied two sprays to each risk area every 12 hours using an atomiser and their fingers to gently spread the product without rubbing. **Control group** • Hyperoxygenated fatty acid was applied to PU-risk areas in the same manner as in the intervention group. • The participants also received usual care procedures.
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Adverse events • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better

Díaz-Valenzuela 2019 *(Continued)*

- **Data value**: endpoint

Identification	**Sponsorship source:** not stated **Country**: Spain **Setting**: nursing home **Comments**: no comments **Author's name**: Antonio Díaz-Valenzuela **Institution**:Hospital Alta Resolución de Puente Genil **Email**: antonioxdixva@gmail.com **Address**: C/Miguel Quintero Merino S/N. Puente Genil. C.P: 14500, Córdoba, Andalusia, Spain.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomly assigned (1:1) using a list of random numbers generated
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not clearly described
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The study was double-blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The study was double-blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	Missing outcome data not balanced in numbers across intervention groups
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Low risk	None detected

Dutra 2015

Study characteristics

Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: yes **Follow-up period**: 30 days or until the participant was discharged, transferred, or died **Sample size estimate**: no

Dutra 2015 *(Continued)*

	ITT analysis: yes; **number randomised**: 160; **number analysed**: 160 **Funding**: trial authors state: no conflict of interest and no external funding
Participants	**Inclusion criteria** • Adults of both sexes, without PUs • Hospitalised in the adult ICU, CCU, or medical clinic of the institution • Moderate and high risk of PUs, according to the Braden assessed 48 hours after admission **Exclusion criteria** • People with PUs • Those hospitalised for < 48 hours, or were diagnosed as brain-dead • Those who dropped out, declined or whose family members declined to participate in the study **Pretreatment** • The mean age was 65.15 and 64.13 years in the foam and hydrocolloid groups, respectively. • In both groups, most participants were men (foam n = 44, 55%; hydrocolloid n = 47, 58.8%) • White ethnicity (foam n = 65, 81.2%; hydrocolloid n = 73, 91.2%) • Smokers (foam n = 64, 80%; hydrocolloid n = 56, 70%) • Ethnicity differed between groups with more white people in the hydrocolloid group and more people of mixed race in the foam group. • More participants in the hydrocolloid group had psychomotor agitation, were unconscious, and fasting. • Participants in the hydrocolloid group had lower risk scores on the Braden scale (indicating higher risk of PU development).
Interventions	**Intervention group** • Transparent polyurethane film was applied bilaterally to the trochanteric and sacral regions and was changed only if there was loss of adhesiveness, shear, excessive moisture, friction, presence of wrinkles, or the combination of these factors. **Control group**: • Hydrocolloid was applied bilaterally to the trochanteric and sacral regions and was changed only if there was loss of adhesiveness, shear, excessive moisture, friction, presence of wrinkles, or the combination of these factors.
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Performance of dressings • **Outcome type**: continuous outcome • **Reporting**: fully reported • **Unit of measure**: mean frequency of dressing changes • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** none stated **Country**: Brazil

Dutra 2015 *(Continued)*

Setting: study was conducted in the ICU, CCU and Medical Clinic

Comments: no comments

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Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomly assigned by lottery"
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	High risk	The nature of the intervention would make blinding of participants and personnel impossible.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcomes reported for all those enroled
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Low risk	None noted

Eberhardt 2021

Study characteristics

Methods

Trial design: RCT

Trial grouping: parallel

Ethics and informed consent: unclear
Follow-up period: 72 hours

Sample size estimate: yes; sample size of 116 individuals

ITT analysis: no; **number randomised**: 308; **number analysed**: 270

Funding: Coordenaçao de Aperfeiçoamento dePessoal de Nível Superior, Grant/AwardNumber: 001 Fundaçao de Amparo àPesquisa do Estado do Rio Grande doSulHospital Universitário de SantaMari-

Eberhardt 2021 *(Continued)*

aMölnlycke Health CareABUniversidade Federal de SantaMariaUniversidade Católica Portuguesa /Centro de Investigaçao Interdisciplinar emSaúde (CIIS) - FCT Financiamento BaseUIDB 04279/202

Participants	**Inclusion criteria** • People in hospital during the preoperative period of digestive or cardiac elective surgery • Expected postoperative hospitalisation ≥ 48 hours • Age equal to or above 18 years **Exclusion criteria** • Amputation of lower limb • Fracture in one of the lower limbs using skeletal traction or external fixation, plaster, dressing that would prevent access to the heels • Presence of trans-operative PI in the heels, before the beginning of the surgical procedure • Impaired verbal communication without companion • Altered level of consciousness and without a companion **Pretreatment** • Gender: female 47 (34.8%), male 88 (65.2%) • Age: mean (years) 59.5 ± 12.9 (18 to 82) • NB: data are for the intervention group only
Interventions	**Intervention group** • The heel was cleaned with 0.9% saline and gauze, then dried with another gauze, then the group received multilayered heel silicone foam dressing **Control group** • Received a transparent polyurethane film heel dressing
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint PU stage • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** not stated **Country**: Brazil **Setting**: operating room in one hospital **Comments**: none **Author's name**: Teixeira Soares, 817, Centro, Passo Fundo, RS, Brazil. 99010-080 **Institution**: Departamento de Enfermagem **Email**: thaiseberhardt@gmail.com

Eberhardt 2021 *(Continued)*

	Address: eixeira Soares, 817, Centro, Passo Fundo, RS, Brazil. 99010-080
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A computerised random number generator was used.
Allocation concealment (selection bias)	Low risk	The number sequence was extracted from the computerised programme, and was placed inside numbered, opaque and sealed envelopes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.
Selective reporting (reporting bias)	Low risk	Outcomes listed in trial registration presented in paper (Brazilian Registry of Clinical Trials (ReBEC), RBR- 5GKNG5
Other bias	Low risk	None detected

Fallahi 2022

Study characteristics

Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: Yes **Follow-up period**: 30 days **Sample size estimate**: yes; total 240; 60 per group **ITT analysis**: yes; **number randomised**: 240; **number analysed**: 240 **Funding**: funded by Kermanshah University of Medical Sciences (Grant NO. 96620)
Participants	**Inclusion criteria** • Hospitalisation in the ICU without PU on the 1st day of hospitalisation • Stability of haemodynamic status • Having a Foley catheter • Obtaining a score of 9 to 14 on Braden Scale • No diarrhoea

Fallahi 2022 *(Continued)*

- Serum albumin above 3.5 g/dL
- No oedema
- Consented to participate in the study
- No sensitivity to olive oil and aloe vera gel
- No autoimmune diseases, renal failure, and diabetes
- No use of immunosuppressive drugs
- No vascular disease
- Age over 18 years
- Non-smoker

Exclusion criteria

- Reluctance to continue co-operation
- Need for surgery
- Scoring 19 and above on Braden Scale during wound examination
- Discharge
- Death

Pretreatment

- 50.8% of the participants (n = 122) were female
- The mean age of the sample was 56.26 years ± 13.24
- The mean BMI and Braden scores were 26.96 ± 1.72 kg/m^2 and 11.29 ± 1.16, respectively.

Interventions

Intervention group 1

- 94% aloe vera gel applied at a rate of 10 to 15 mL on the pressure areas of the body three times a day AND routine pressure ulcer prevention

Intervention group 2

- 100% pure olive oil applied at a rate of 10 to 15 mL on the pressure areas of the body three times a day AND routine pressure ulcer prevention

Intervention group 3

- Aloe vera gel-olive oil combination applied in a ratio of 3 to 2 at a rate of 10 to 15 mL on the pressure areas of the body three times a day AND routine pressure ulcer prevention

Control group:

- Routine pressure ulcer prevention

Study group 2 and control group included in comparison 15; study groups 1 and 3 included in comparison 19

Outcomes

PU incidence

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Unit of measure**: numbers
- **Direction**: lower is better
- **Data value**: endpoint

PU stage

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Unit of measure**: numbers
- **Direction**: lower is better

Fallahi 2022 *(Continued)*

- **Data value**: endpoint

PU location

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Unit of measure**: numbers
- **Direction**: lower is better
- **Data value**: endpoint

Identification	**Sponsorship source:** funded by Kermanshah University of Medical Sciences (Grant NO. 96620) **Country**: Iran **Setting**: ICU **Comments**: none **Author's name**: Mrs. Somayeh Mahdavikian **Institution**: School of Nursing and Midwifery, Kermanshah University of Medical Science **Email**: smahdavikia@gmail.com **Address**: School of Nursing and Midwifery, Kermanshah University of Medical Sciences, Kermanshah, Iran
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A parallel design and 1:1 allocation ratio in the experimental (three intervention groups) and control groups.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not clearly described
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Double-blind
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Double-blind
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up
Selective reporting (reporting bias)	Low risk	All planned outcomes measured (study was registered at the Iranian Registry of Clinical Trials IRCT20181105041563N4)
Other bias	Low risk	None detected

Ferrer Sola 2013

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: unclear **Follow-up period**: 15 days **Sample size estimate**: unclear **ITT analysis:** yes; **number randomised:** 409; **number analysed:** 409 **Funding**: not reported
Participants	**Inclusion criteria:** no PU but had a risk of PU according to the Braden Scale or clinical judgement **Exclusion criteria** • Patients who did not consent • Those with contraindications to the heel protection **Pretreatment** • Mean age of 80.5 years • 59.1% women • 78% had Barthel score ≤ 30 • 28.6% dementia • 37.6% delirium • 27.6% diabetes • 19.6% other pressure ulcer
Interventions	**Intervention group:** polyurethane foam **Control group:** classic padded bandage
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** not stated **Country**: Spain **Setting**: long stay setting **Comments**: no comments **Author's name**: Marta Ferrer Solàa **Institution**: Hospital de la Santa Creu **Email**: mferrer@hsc.chv.cat **Address**: Vic, Barcelona, Espagna
Notes	

Ferrer Sola 2013 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Participants were randomised, but the exact process not described
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Low risk	409 people randomised, 409 people analysed
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Low risk	None detected

Forni 2018

Study characteristics

Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: unclear **Follow-up period**: 8 days **Sample size estimate**: yes (359 people required) **ITT analysis**: yes; **number randomised**: 359; **number analysed**: 359 **Funding**: sponsored by the Istituto Ortopedico Rizzoli; ClinicalTrials.gov identifier: NCT02692482
Participants	**Inclusion criteria** • People aged ≥ 65 years with hip fragility fracture without NPUAP scale stage ≥ 2 PU • People or legal guardians who gave their consent to take part in the study **Exclusion criteria** • People with known allergy to the product being tested or dermatological diseases that prevent the use of topical products • People with periprosthetic or pathological fractures • People with diaphyseal or distal femoral fractures **Pretreatment**

Forni 2018 *(Continued)*

- Age: mean (SD): intervention group: 84.3 (7.7); control group: 83.2 (7.7)
- Female: n (%): intervention group: 144 (81.4%); control group: 145 (79.7%)

Interventions	**Intervention group** • Application of a multilayered dressing incorporating hydrocellular foam, hyper-absorber lock-away core with a silicone wound contact layer over the sacral region within 24 hours of admission and replaced when detached, wet, or dirty, in addition to standard pressure ulcer prevention care **Control group** • Standard pressure ulcer prevention care
Outcomes	PU incidence in the sacral anatomical location • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint PU incidence in other anatomical location • **Outcome type**: dichotomous outcome • **Reporting**: not reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint PU severity • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Adverse events: skin irritation/damage • **Outcome type**: dichotomous outcome • **Reporting**: not reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source**: Istituto Ortopedico Rizzoli **Country**: Italy **Setting**: elderly population admitted for fragility hip fractures **Comments**: no comments **Author's name**: Cristiana Forni **Institution**: Istituto Ortopedico Rizzoli **Email**: cristiana.forni@ior.it **Address**: Bologna, Italy, 40136

Forni 2018 *(Continued)*

Notes	Sponsor: Insituto Ortopedico Rizzoli

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization list in blocks of ten was generated by computer"
Allocation concealment (selection bias)	Low risk	Quote: "Opaque envelopes were used to contain the type of treatment (new polyurethane foam multilayer dressing or standard care) according to the sequence indicated by the list; the envelopes were numbered and tied in blocks of ten".
Blinding of participants and personnel (performance bias) All outcomes	High risk	Open-label
Blinding of outcome assessment (detection bias) All outcomes	High risk	Open-label
Incomplete outcome data (attrition bias) All outcomes	Low risk	All those randomised included in the final analysis
Selective reporting (reporting bias)	Low risk	All planned outcomes reported (The study protocol was registered on www.ClinicalTrials.gov: NCT02692482).
Other bias	Low risk	None noted

Forni 2022

Study characteristics

Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: Yes **Follow-up period**: 7 days **Sample size estimate**: the planned sample size was 280 participants per area for a total of 840 participants (420 per arm). **ITT analysis**: yes; **number randomised**: 711; **number analysed**: 709 (2 participants did not receive the intervention) **Funding**: Smith & Nephew signed an agreement to supply the dressings free of charge for all participants in the study.
Participants	**Inclusion criteria** • ≥ 18 years • At risk for PU development as measured with the Braden scale (scores ≤ 16) • Intact skin

Forni 2022 *(Continued)*

- Life expectancy greater than 72 hours as per clinical judgment
- Participants had to be enrolled within 24 hours from hospital admission and expected to remain hospitalised for at least 72 hours

Exclusion criteria

- Any known allergy to foam dressing
- Refusal to participate in the study

Pretreatment

- Mean age (SD): Intervention: 77.5 (13.6); Control: 78.2 (13.0)
- Male gender: Intervention: 157/351 (44.7%); Control: 156/357 (43.6%)

Interventions

Intervention group

- Standard care plus the application of the multilayered, silicone-adhesive polyurethane foam dressing to the sacrum
- The dressing was lifted, but not changed, daily for routine skin assessment and changed every time it happened to be soiled or dislodged.

Control group: standard care

Outcomes

Primary outcome: PU incidence

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Unit of measure**: numbers
- **Direction**: lower is better
- **Data value**: endpoint

Anatomical location of PU development

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Unit of measure**: numbers
- **Direction**: lower is better
- **Data value**: endpoint

Time to PU development

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Unit of measure**: numbers
- **Direction**: higher is better
- **Data value**: endpoint

Identification

Sponsorship source: Smith & Nephew signed an agreement to supply the dressings free of charge for all participants in the study.

Country: Italy
Setting: medical, surgical, and intensive care units of 12 Italian hospitals

Comments: no comments

Author's name: Elisa Ambrosi

Institution: Department of Diagnostics and Public Health, University of Verona

Email: elisa.ambrosi_01@univr.it

Forni 2022 *(Continued)*

	Address: Verona, Italy. Strada le Grazie 8 Verona, 37134
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A randomly permuted block design with 1:1 allocations of patients within randomly selected blocks of 10, stratified by units to ensure balanced groups, was used. The ordering of patients within each block was also randomly assigned using a computerised research randomiser (WWW. randomization.com). The randomisation list was generated by the principal investigator at the research centre outside the hospitals."
Allocation concealment (selection bias)	Low risk	Quote: "The allocation sequence was concealed from the research nurse enrolling and evaluating participants in sequentially numbered opaque, sealed, and stapled envelopes."
Blinding of participants and personnel (performance bias) All outcomes	High risk	The participants and the healthcare professionals were not blinded due to the nature of the intervention.
Blinding of outcome assessment (detection bias) All outcomes	High risk	The skin imprint after the foam removal made it impossible to blind the outcome assessor.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All those who received the intervention were analysed.
Selective reporting (reporting bias)	Low risk	All planned outcomes were measured (Trial registered: NCT03900455).
Other bias	Low risk	None noted

Gazineo 2020

Study characteristics

Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: Yes **Follow-up period**: 8 days **Sample size estimate**: yes; a target sample size of 180 participants (90 per group) was determined **ITT analysis**: yes; **number randomised**: 68; **number analysed**: 68 **Funding**: Smith & Nephew signed an agreement to supply the dressings free of charge for all participants in the study.
Participants	**Inclusion criteria**

Gazineo 2020 *(Continued)*

- 65 years and older, admitted to the hospital from the emergency department (ED) with a diagnosis of fragility hip fracture
- Provided written informed consent to participate in the study

Exclusion criteria

- Pre-existing sacral PIs, as assessed using the NPUAP classification
- A periprosthetic or pathologic fracture, diaphyseal and distal femoral fracture
- Known allergy to the foam dressing being studied
- Skin diseases on admission

Pretreatment

- Mean age (SD) Intervention: 83.8 (6.3); Control: 84.5 (6.9)
- Gender: Female: Intervention 24; Control: 20

Interventions

Intervention group

- Standard pressure ulcer prevention and a multilayered polyurethane foam dressing
- The dressing was lifted daily for routine skin assessment and was changed every 7 days or when it became soiled or dislodged by the ward nurses

Control group: standard pressure ulcer prevention

Outcomes

PU incidence

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Unit of measure**: numbers
- **Direction**: lower is better
- **Data value**: endpoint

Time to PU development

- **Outcome type**: continuous outcome
- **Reporting**: fully reported
- **Unit of measure**: numbers
- **Direction**: longer is better
- **Data value**: endpoint

Anatomical location of PU development

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Unit of measure**: numbers
- **Direction**: lower is better
- **Data value**: endpoint

Adverse events

- **Outcome type**: dichotomous outcome
- **Reporting**: fully reported
- **Unit of measure**: numbers
- **Direction**: lower is better
- **Data value**: endpoint

Identification

Sponsorship source: Smith & Nephew signed an agreement to supply the dressings free of charge for all participants in the study.

Gazineo 2020 *(Continued)*

Country: Italy
Setting: General hospital - hip fracture patients

Comments: no comments

Author's name: Elisa Ambrosi

Institution: Department of Medical and Surgical Sciences,

Email: elisaambrosi1983@gmail.com

Address: University of Bologna, Via Massarenti 9, 40138 Bologna, Italy

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomly permuted block design with 1:1 allocations of patients within randomly selected blocks of 10. The ordering of patients within each block was also randomly assigned using a computerized research randomiser. The randomization list was generated by the principal investigator at the research center outside the hospital."
Allocation concealment (selection bias)	Low risk	Quote: "The allocation sequence was concealed from the research nurse enroling and evaluating participants in sequentially numbered opaque, sealed, and stapled envelopes."
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Low risk	All those randomised were analysed.
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Low risk	None detected

Green 1974

Study characteristics

Methods

Trial design: RCT

Trial grouping: parallel

Ethics and informed consent: unclear
Follow-up period: 3 weeks

Green 1974 *(Continued)*

	Sample size estimate: no **ITT analysis**: no; **number randomised**: 319; **number analysed**: 167 **Funding**: sponsored by Dermalex Co
Participants	**Inclusion criteria** • Geriatric patients • People at risk of PUs **Exclusion criteria** • Those with existing PUs • Those not at risk of PU development • Those with severe and terminal illness **Pretreatment** • 40 men, 127 women with a mean age of 81.5 years • Baseline characteristics were represented within the 2 groups within acceptable sampling limits (i.e. 5% sampling limits)
Interventions	**Intervention group** • Active lotion containing: hexachlorophane 0.5%, saturated hydrocarbons (squalene (Cosbiol 3%) and glyoxyle diureide), allantoin 0.2%, antioxidants, lanolin, fatty acids, fatty acid esters, fatty alcohols, preservatives and distilled water. • The lotion was applied with fingers to pressure areas (sacral, trochanteric, heel, shoulder, and other areas as indicated). Excess friction avoided • Skin inspected every 2 hours, participant turned and changed if soiled, washed with soap and water, skin dried and lotion applied after each cleansing. In the absence of incontinence, routine washing and reapplication of lotion was carried out every 6 hours. • Bed cradles used for all participants to keep the weight of the bedding off the feet and lower legs. • Participants with a score of ≤ 10 (clinical at-risk score) were nursed on a large cell alternating pressure mattress. **Control group** • Inert lotion containing: lanolin, fatty acids, fatty acid esters, fatty alcohols, preservatives, distilled water and mineral oils • The lotion was applied with fingers to pressure areas (sacral, trochanteric, heel, shoulder, and other areas as indicated). Excess friction avoided • Skin inspected every 2 hours, participant turned and changed if soiled, washed with soap and water, skin dried and lotion applied after each cleansing. In the absence of incontinence, routine washing and reapplication of lotion was carried out every 6 hours. • Bed cradles used for all participants to keep the weight of the bedding off the feet and lower legs. • Participants with a score of ≤ 10 (clinical at-risk score) were nursed on a large cell alternating pressure mattress.
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source**: Dermalex Co

Green 1974 *(Continued)*

	Country: UK **Setting**: geriatric participants from 6 geriatric units in the UK **Comments**: no comments **Author's name**: MF Green **Institution**: Royal Free Hospital **Email**: none provided **Address**: Pond Street, London, NW3 2QG
Notes	We attempted to contact the authors to seek additional information. We were unable to locate them.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not stated
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "The active and inert lotions were similar in appearance and texture. They were randomly dispensed in identical plastic squeeze bottles to avoid possible bias of application, or other nursing procedures"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The active and inert lotions were similar in appearance and texture. They were randomly dispensed in identical plastic squeeze bottles to avoid possible bias of application, or other nursing procedures, and of the research nurses observations"
Incomplete outcome data (attrition bias) All outcomes	High risk	ITT not conducted, 152 participants excluded
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Low risk	None detected

Guerra 2017

Study characteristics

Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: unclear **Follow-up period**: unclear **Sample size estimate**: yes, a sample size of 36 participants for each group was required

Guerra 2017 *(Continued)*

	ITT analysis: yes; **number randomised**: 80; **number analysed**: 80 **Funding**: not stated
Participants	**Inclusion criteria** • Children aged > 3 years undergoing surgery for flat foot • Children with intact skin at the heel **Exclusion criteria** • Caregivers who cannot speak Italian • Those who refuse to give their consent to take part in the study • Children with lower limb casts after surgery **Pretreatment**: • Age: mean (SD); Intervention: 11.79 (1.27); Control: 11.64 (1.44) • Gender - Female/Male: Intervention: 15/23; Control: 16/26
Interventions	**Intervention group:** application of the polyurethane foam dressing at the heel in the immediate post-operative period before applying the leg-foot splint (Walker) **Control group:** no dressing
Outcomes	PU incidence (heels) • **Outcome type**: dichotomous outcome • **Unit of measure**: numbers • **Reporting**: fully reported • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source: Not stated** **Country**: Italy **Setting**: hospital setting **Comments**: no comments **Author's name**: Caterina Guerra **Institution**: Istituto Ortopedico Rizzoli, Italy **Email**: cristiana.forni@ior.it **Address**: Via Giulio Cesare Pupilli, 1, 40136 Bologna BO, Italy
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Just states: "randomised"
Allocation concealment (selection bias)	Unclear risk	Not stated

Guerra 2017 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Open-label
Blinding of outcome assessment (detection bias) All outcomes	High risk	Open-label
Incomplete outcome data (attrition bias) All outcomes	Low risk	All randomised children were analysed.
Selective reporting (reporting bias)	Low risk	All planned outcomes measured (Trial registered: NCT03039179)
Other bias	Low risk	None noted

Hahnel 2020

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: yes **Follow-up period**: 12.6 days (SD:12.7) **Sample size estimate**: yes **ITT analysis**: yes; **number randomised**: 475; **number analysed**: 432 (some excluded after randomisation because of no consent) **Funding:** supported by Molnlycke Health Care AB (Gothenburg, Sweden)
Participants	**Inclusion criteria** • ICU patients aged 18 years or older • Within 6 hours of admission to an ICU • At high or very high PU risk • An expected minimum length of stay of at least 3 days **Exclusion criteria** • ICU patients who were at the end of life • With existing PUs at any stage according to the National and European Pressure Ulcer Advisory Panels (NPUAP/EPUAP) 2014 classification system • Trauma at the heels and sacrum • Known allergies to the preventive dressings were excluded **Pretreatment** • The mean (SD) age of ICU patients was 63.5 years (15.4) • The majority of the ICU patients were male (65%) • The mean BMI (SD) was 26.5 kg/m^2 (4.9) • Most ICU patients had a Fitzpatrick skin photo type of II (75%)

Hahnel 2020 *(Continued)*

	• 171 ICU patients (40%) were affected by diabetes mellitus and 10 patients (24%) had tetraplegia
Interventions	**Intervention group** • Standard care and a multilayered silicone foam dressing on the sacral area • The dressings were renewed every 3 days and the skin underneath the dressings was checked daily. • In cases where dressings became soiled or dislodged, they were changed immediately. **Control group:** standard of care
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Stage of pressure ulcer • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Time to pressure ulcer development • **Outcome type**: continuous • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: higher is better • **Data value**: endpoint Anatomical location of pressure ulcer • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** supported by Molnlycke Health Care AB (Gothenburg, Sweden) **Country**: Germany **Setting**: hospital setting, ICU **Comments**: no comments **Author's name**: Jan Kottner **Institution**:Department of Biometry and Clinical Epidemiology, **Email**: E-mail: jan.kottner@charite.de **Address**: Charite – Universitatsmedizin Berlin, Berlin, Germany
Notes	

Hahnel 2020 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A simple randomisation with a 1: 1 allocation as per computer-generated randomisation table was used.
Allocation concealment (selection bias)	Low risk	The randomisation table was created independently from the study team. Sequentially numbered, opaque, sealed envelopes containing the group assignment were prepared and used.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Owing to the nature of the intervention, caregivers and the study team were not blinded.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The data manager was blinded throughout the study.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Some participants were excluded after randomisation because they did not consent to participation, but they did not receive any intervention or have any data collected.
Selective reporting (reporting bias)	Low risk	Planned outcomes were measured (trial registered: NCT02295735)
Other bias	Low risk	None detected

Han 2011

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: unclear **Follow-up period**: 3 days **Sample size estimate**: no **ITT analysis**: yes; **number randomised**: 100; **number analysed**: 100 **Funding**: sponsored by manufacturers of the interventional product
Participants	**Inclusion criteria** • People admitted for posterior spinal surgery **Exclusion criteria** • People with previous skin disease, • Those undergoing emergency surgery • Those with operation time of < 3 hours **Pretreatment**

Han 2011 *(Continued)*

	• Not stated
Interventions	**Intervention group:** Kang' huier transparent strip and foam dressing **Control group:** routine operating room protective measures
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source**: Shandong Province Higher Education Reform Project **Country**: China **Setting**: spinal surgery **Comments**: no comments **Author's name**: MF Green **Institution**: a third-grade class-A hospital of Qingdao city **Email**: none provided **Address**: Nursing College of Medical College of Qingdao University, Shandong 266021 China
Notes	Authors state that the 2 PUs in the intervention group occurred outside the treated area. We attempted to contact the authors to seek additional information, but received no response.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described; states only that participants were randomly grouped. Authors did not explain how the sequence was generated.
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding impossible due to the nature of the intervention
Blinding of outcome assessment (detection bias) All outcomes	High risk	Blinding impossible due to the nature of the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	100 participants enroled and all accounted for in the results.
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.

Han 2011 *(Continued)*

Other bias	Unclear risk	We had only the most important data interpreted. It is possible that there may have been biases of which we are unaware.

Hekmatpou 2018

Study characteristics

Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: yes **Follow-up period**: 10 days **Sample size estimate**: yes; 80 participants assigned to two groups (control and intervention) with 40 participants in each **ITT analysis**: no; **number randomised**: 80; **number analysed**: 77 **Funding**: Arak University of Medical Sciences
Participants	**Inclusion criteria** • Willingness to participate in research • Lack of skin diseases (such as psoriasis, fungal illness, freckles) • Age over 18 and under 65 years • At risk of moderate to severe bedsores according to nursing diagnosis and Braden scoring tool and scored less than 13 to 14 • Lack of pressure ulcers on admission • Probability of length of stay should have been above 10 days; their admission should have been within previous 24 hours; had not already been hospitalised in another part of the hospital • Lack of systemic diseases such as diabetes, bleeding from trauma, heart failure, kidney failure, and cancer advanced phase • Systolic blood pressure of 10 mmHg or higher • Not using vasoactive drugs • No drug addiction • No fever (body temperature higher than 38.8) • Haemoglobin level higher than 12 **Exclusion criteria** • Not wanting to continue to participate in the study • Death • Decrease in haemoglobin levels during the study to less than 12 mg/dL in men and less than 10 mg/dL in women • Receiving vasoactive medications • Anaemia • Reduced pressure, and hyperthermia during the study **Pretreatment** • Age (Mean ± SD): Intervention: 11.50 ± 41.71; Control: 42.34 ± 12.19 • Sex (Male %): Intervention: 71.8%; Control: 73.7%
Interventions	**Intervention group**

Hekmatpou 2018 *(Continued)*

	• Routine pressure ulcer prevention • Aloe vera rubbed on the skin of the patient twice daily (at 9 and 21 o'clock) on pressure points (hip, sacrum, heels) **Control group** • Routine pressure ulcer prevention • Placebo (gel of water and starch) using the same application method as the intervention group
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source**: not stated **Country**: Iran **Setting**: hospital setting, ICU **Comments**: No comments **Author's name**: Davood Hekmatpou **Institution**: Nursing and Midwifery Faculty, Arak University of Medical Sciences, **Email**: dr_hekmat@arakmu.ac.ir; hekmatpou@yahoo.com **Address**: Basij Sq., Payambar-e-Azam Educational Complex, Arak, Iran
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomly assigned into intervention and control groups based on blocking sampling method.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not clearly described
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Triple-blind
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Triple-blind
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.
Selective reporting (reporting bias)	Low risk	Planned outcomes were measured (trial registered: IRCT ID: IRCT2016051027825N1)

Hekmatpou 2018 *(Continued)*

Other bias	Low risk	None detected

Houwing 2008

Study characteristics

Methods

Trial design: RCT

Trial grouping: cluster

Ethics and informed consent: yes
Follow-up period: 4 weeks

Sample size estimate: no

ITT analysis: yes; **number randomised**: 79; **number analysed**: 79

Funding: not stated

Participants

Inclusion criteria

- Written informed consent was obtained from each participant. If the mental capability of the participant to decide on participation was uncertain, the legal representative of the participant was asked for consent.
- Participants had to be able to participate for an evaluation for 4 weeks
- Participants had to rest on an anti-PU mattress
- Participants had to be at high risk of developing PU according to the Braden scale using a cut-off point of 20

Exclusion criteria

- Patients who were treated with another, unrelated ointment or cream
- People who were to undergo or had undergone surgery < 2 weeks prior
- People with existing PU
- People with dark skin because of difficulty in assessment

Pretreatment

- Men: 27.7% control; 25% placebo; 37.9% DMSO
- Not incontinent: 16.7% control; 6.3% placebo; 0% DMSO
- Age (median): 81.5 years control; 85 years placebo; 80.5 years DMSO
- No significant differences in participant characteristics

Interventions

Intervention group 1

- Massage using a "DMSO-cream"; this cream consisted of 5% dimethyl sulfoxide in Vaseline-cetomacrogol cream, combined with a 30° position change
- This procedure was repeated every 6 hours for 4 weeks

Intervention group 2

- 3-minute massage of the buttock, heel, and ankle regions with an "indifferent" cream (Vaseline-cetomacrogol) combined with a 30° position change
- This procedure was repeated every 6 hours for 4 weeks

Control group

- 30° position change, repeated every 6 hours for 4 weeks

Houwing 2008 *(Continued)*

	Study groups 1 and 2 included in comparison 17; study group 1 and control group included in comparison 18.
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source**: not stated **Country**: the Netherlands **Setting**: 8 nursing homes **Comments**: no comments **Author's name**: R Houwing **Institution**: Department Dermatology, Deventer Ziekenhuis **Email**: houwingr@dz.nl **Address**: Department Dermatology, Deventer Ziekenhuis, the Netherlands
Notes	We attempted to contact the author to seek additional information. The author responded and provided answers to several questions.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Throw of a dice (additional information from the study author)
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Stated as double-blind
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinded; quote: "presence of a pressure ulcer confirmed by two external observers"
Incomplete outcome data (attrition bias) All outcomes	Low risk	None excluded
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	High risk	There is no indication that the cluster design was accounted for in the analysis.

Huang 2021

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: not stated **Follow-up period**: unclear **Sample size estimate**: not stated **ITT analysis**: yes; **number randomised**: 150; **number analysed**: 150 **Funding**: unclear
Participants	**Inclusion criteria:** people undergoing thoracolumbar surgery and in prone position more than 4 hours **Exclusion criteria:** unclear **Pretreatment** • Age (Mean ± SD): Intervention: 53.63 ± 10; Control: 51.31 ± 8 • Sex: Male: Intervention: 43%, Control: 48%
Interventions	**Intervention** • Sanyrene cream applied to high-risk areas for the development of pressure injuries followed by the application of Mepilex Border dressing **Control** • Mepilex Border dressing applied to high-risk areas for the development of pressure injuries
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Stage of PU development • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source**: not stated **Country**: China **Setting**: surgical department **Comments**: no comments **Author's name**: Huang Mingliang **Institution**: Operation room, First Affiliated Hospital of Guangxi University of Chinese Medicine **Email**: 280997149@qq. com

Huang 2021 *(Continued)*

	Address: Nanning, Guangxi, 530023
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not stated
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Low risk	All randomised participants were analysed.
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Low risk	None detected

Imbulana 2018

Study characteristics

Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: yes **Follow-up period**: 36 weeks **Sample size estimate**: yes; 206 infants **ITT analysis**: yes; **number randomised**: 108; **number analysed**: 108 **Funding**: Royal Women's Hospital Neonatal Services department funded the equipment used in the trial.
Participants	**Inclusion criteria** • Born < 30 weeks of gestation or with birth weight < 1250 g • Expected to require treatment with binasal prongs (either continuous positive airway pressure (CPAP) or nasal intermittent positive pressure ventilation) for more than 4 hours **Exclusion criteria**

Imbulana 2018 *(Continued)*

- Had commenced CPAP ≥ 30 weeks of postmenstrual age (PMA) or at a weight ≥ 1250 g
- Had received 48 hours or more of CPAP prior to randomisation
- Had nasal injury documented prior to enrolment
- Had facial features that might preclude treatment with binasal CPAP (e.g. cleft lip or palate, Pierre Robin sequence, choanal atresia)

Pretreatment

- Gestational age (weeks) (Mean/SD): Intervention: 27.4 (1.7); Control: 27.5 (1.9)
- Sex (Male %): Intervention: 27%, Control: 25%

Interventions	**Intervention group:** hydrocolloid dressing with an optional Velcro strap to secure the CPAP interface to the dressing **Control group:** no barrier dressing
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Stage of PU development • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Costs • **Outcome type**: continuous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source**: not stated **Country**: Australia **Setting**: hospital setting, neonatal intensive care unit **Comments**: no comments **Author's name**: Brett J. Manley **Institution**: Newborn Research Center, The Royal Women's Hospital **Email**: brett.manley@thewomens.org.au **Address**: Level 7, 20 Flemington Rd, Parkville, VIC 3052, Australia
Notes	
Risk of bias	

Imbulana 2018 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised using computer-generated block randomisation with variable block sizes.
Allocation concealment (selection bias)	Low risk	Sequentially numbered, sealed, opaque envelope were used.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of the intervention was not possible.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Blinding of the intervention was not possible.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All randomised infants were analysed.
Selective reporting (reporting bias)	Low risk	Planned outcomes were measured (trial registered: ACTRN12616000438459)
Other bias	Low risk	None noted

Kalowes 2016

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: ethics approval obtained; exemption from consent obtained **Follow-up period**: participants were followed by the research team until discharged from the ICU (range 4 to 14 days). Information about subsequent PU development was retrieved from electronic medical records. **Sample size estimate**: yes, estimated as requiring 185/group **ITT analysis**: yes; **number randomised**: 366; **number analysed**: 366 **Funding**: not declared in the published paper, but a report of a conference presentation declared support for the study by Molnlycke, manufacturer of the intervention product
Participants	**Inclusion criteria** • All critically ill people admitted to an ICU in a large Level 2 Magnet hospital • ≥ 18 years • Braden score ≤ 13 • Intact skin **Exclusion criteria** • Braden score ≥ 14 • Existing PU

Kalowes 2016 *(Continued)*

- Moisture-related skin damage
- Receiving end-of-life care

Pretreatment

- Age, mean (SD): intervention: 64.6 (17.7) years; control: 67.3 (16.2) years
- Women, n (%): intervention: 81 (44.0); control: 82 (45.1)
- Braden score, mean (SD): intervention: 11.8 (1.3); control: 11.9 (1.4)
- ≥ 4 comorbid conditions, n (%): intervention: 66 (35.9); control: 67 (36.8)
- APACHE III (Acute Physiology and Chronic Health Evaluation) score, mean (SD): intervention: 58.6 (29.3); control: 49.5 (23.6)
- Baseline characteristics did not differ significantly between the groups

Interventions	**Intervention group** • Silicone dressing was applied within 24 hours of admission • Dressing changed every 3 days or when soiled or dislodged • Usual care was also provided **Control group:** usual care (no dressing)
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Stage of PUs • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Location of PUs • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: none • **Data value**: endpoint
Identification	**Sponsorship source**: Molnlycke **Country**: USA **Setting**: medical/surgical/trauma ICU and a cardiac ICU **Comments**: no comments **Author's name**: Peggy Kalowes **Institution**: Memorial Care Health System **Email**: p.kalowes@memorialcare.org

Kalowes 2016 *(Continued)*

	Address: Longbeach Memorial, 2801 Atlantic Avenue, Long Beach CA, 90806, USA
Notes	Unclear if the intervention was continued following discharge from the ICU, although PU incidence was collected. Also unclear, but unlikely that nurses diagnosing PUs in the post-ICU wards underwent inter-rater reliability testing. We attempted to contact the author to seek additional information. The author responded and provided answers to several questions.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation; quote: "using a computerized research randomiser"
Allocation concealment (selection bias)	Unclear risk	Quote: "Randomization of participants was undertaken by the principal investigator or study nurse" Comment: unclear if allocation was concealed
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not stated, but difference in the appearance of dressing makes blinding impossible
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "Dressing pulled back daily for routine skin assessment"
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants accounted for
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Low risk	None detected

Karimi 2020

Study characteristics

Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: yes **Follow-up period**: 7 days **Sample size estimate**: yes; number needed: 25 for each group. **ITT analysis**: yes; **number randomised**: 50; **number analysed**: 50 **Funding**: "The present study is part of a larger study approved at Yasuj University of Medical Sciences."
Participants	**Inclusion criteria** • Moderate to high risk of pressure injury development, based on Braden Scale score

Karimi 2020 *(Continued)*

- Aged at least 18 years old
- No sign of pressure injuries in the heel at the time of hospitalisation in the ICU

Exclusion criteria: allergic to oils, according to the patient's family and physician's reports

Pretreatment

- Age (years, SD): olive oil group: 41.1 ± 12.3; fish oil group: 45.2 ± 13.8
- Sex: Male - olive oil (N): 11; fish oil (N): 13. Female - olive oil (N): 9; fish oil (N): 7

Interventions	**Intervention group 1** • Standard care, plus gauze soaked in olive oil applied to both heels daily • This procedure was continued for up to 7 days for each participant. **Intervention group 2** • Standard care, plus gauze soaked in fish oil applied to both heels daily • This procedure was continued for up to 7 days for each participant.
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Adverse events • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** not stated **Country**: Iran **Setting**: hospital setting, ICU **Comments**: no comments **Author's name**: Mohammad Behnammoghadam **Institution**: Medicine Plants Research Center, Yasuj University of Medical Sciences, **Email**: mbehnam1363@gmail.com **Address**: Next to Imam Sajad Hospital, Bagher Street, Yasuj, Iran
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomly allocated to one of the two groups using a random number table

Karimi 2020 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Allocation concealment not clearly described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Dressing was performed by one of the researchers with the help of nurses.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The statistician did not have any information about participants' groups in the SPSS file.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up
Selective reporting (reporting bias)	Unclear risk	States that the study protocol was recorded in the Iranian Registry of Clinical Trials, but we could not locate it. Thus, unclear if all planned outcomes were measured.
Other bias	Low risk	None detected

Lee 2019

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: yes **Follow-up period**: unclear **Sample size estimate**: yes, a sample size of 36 participants for each group was required **ITT analysis**: yes; **number randomised**: 66; **number analysed**: 61 **Funding**: Smith & Nephew
Participants	**Inclusion criteria** • People who did not have incontinence-associated dermatitis or PIs before study participation • Those with intact skin • Braden Scale score < 18 • Quadriplegia or spinal cord injury • Age older than 65 years **Exclusion criteria** • People with a contraindication to changing positions • Those with an existing PI on admission • Those younger than 18 years **Pretreatment** • Participants' mean age was 61.03 (17.44) years • Mean Braden Scale score was 14.29, SD 2.53

Lee 2019 *(Continued)*

	• Male n = 34; female n = 32
Interventions	**Intervention group:** silicone adhesive dressing to the sacrum and buttocks every 3 days, in addition to standard pressure ulcer prevention **Control group:** standard pressure ulcer prevention
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Unit of measure**: numbers • **Reporting**: fully reported • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** Smith & Nephew **Country**: Korea **Setting**: hospital setting, ICU **Comments**: no comments **Author's name**: Jung Y. Kim **Institution**: Department of Nursing, Seoul National University Bundang Hospital **Email**: 10602@snubh.org **Address**: eongnamsi 463-707 Republic of Korea
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Sequence generation not stated
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not stated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	High risk	5 participants lost to follow-up
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Low risk	None identified

Lovegrove 2022

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: yes **Follow-up period**: 28 days **Sample size estimate**: yes, a sample size of 120 **ITT analysis**: yes; **number randomised**: 120; **number analysed**: 120 **Funding**: partially funded by a small industry grant from Smith & Nephew
Participants	**Inclusion criteria** • People 65 years and older • At risk of a pressure ulcer **Exclusion criteria** • Pre-existing sacral PI • Sacral region skin disease; trauma or other injury • Incontinence-associated dermatitis • Allergy to adhesive • Previous recruitment to and participation in pilot study **Pretreatment** • Age in years: Mean (SD) Median (IQR): 84.9 (7.4) 86 (81 to 90) • Gender, male/female, n (%): 45/85 (34.6/65.4)
Interventions	**Intervention group:** a shaped, silicone, gel adhesive multilayer hydrocellular foam dressing plus standard care **Control group:** standard care
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Unit of measure**: numbers • **Reporting**: fully reported • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** Smith & Nephew **Country**: Australia **Setting**: subacute hospitalised older adults **Comments**: no comments **Author's name**: Josephine Lovegrove **Institution**: Nursing Research and Practice Development Centre **Email**: Josephine.Lovegrove@health.qld.gov.au

Lovegrove 2022 *(Continued)*

	Address: Level 5 Clinical Sciences Bldg, The Prince Charles Hospital, Rode Rd, Chermside, QLD 4032, Australia
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A random number generator was used to allocate participants 1:1 to the intervention (sacral dressing plus standard care) or control group (standard care).
Allocation concealment (selection bias)	Low risk	"Documentation specifying the study group was packed into consecutively numbered opaque envelopes based on randomization and sealed. Envelopes were allocated to each participant, relative to their consecutive recruitment number. To conceal allocation until point of assignment, envelopes were only opened once consent had been obtained."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Open-label
Blinding of outcome assessment (detection bias) All outcomes	High risk	Open-label
Incomplete outcome data (attrition bias) All outcomes	Low risk	All randomised participants analysed per ITT
Selective reporting (reporting bias)	Unclear risk	Unable to locate trial registration on the ANZ Clinical Trial Registry; therefore, unclear if all planned outcomes were measured.
Other bias	Low risk	None detected

Lupianez-Perez 2015

Study characteristics

Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: yes **Follow-up period**: 16 weeks **Sample size estimate**: yes, a sample size of 765 participants was required **ITT analysis**: yes; **number randomised**: 831; **number analysed**: 831 **Funding**: this research was undertaken pursuant to the independent clinical calls and proposals managed by the Spanish Ministry of Health, Social Policy and Equality (EC11-526).
Participants	**Inclusion criteria** • People receiving home nursing service who were aged > 18 years

Lupianez-Perez 2015 *(Continued)*

- Aided by a family member or paid caregiver for treatment application
- Risk of impaired skin integrity according to the Braden scale, identified by a nurse
- Nutritional status of 10 according to the Mini Nutritional Assessment (MNA)

Exclusion criteria

- Refused to take part in the trial
- Permanent address was outside the catchment area of the corresponding health centre
- Planned to be elsewhere during the follow-up period
- Required hospitalisation during the sampling period
- Terminally ill
- Already had PU

Pretreatment

- Mean age of the participants was 80.56 years (SD 13.36)
- Mean level of PU risk, measured on the Braden scale, was 12.91 (SD 2.33)
- Risk of malnutrition, assessed by MNA, was 6.98 (SD 2.08)
- Over half of the participants, in both groups (299; 68.4% and 284; 72.1% in the control and target groups, respectively), suffered some degree of cognitive impairment.
- No differences in baseline characteristics between the groups

Interventions	**Intervention group 1:** target group received two applications daily of the olive oil-based formula, to the skin areas of the sacrum, hips and heels, as well as pressure ulcer preventive measures. **Intervention group 2:** control group received two applications per day of the HOFA-based product, in the sacral area and on the hips and heels, as well as pressure ulcer preventive measures.
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Unit of measure**: numbers • **Reporting**: fully reported • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source**: "this research was undertaken pursuant to the Independent Clinical Calls and Proposals managed by the Spanish Ministry of Health, SocialPolicy and Equality (EC11-526). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript." **Country**: Spain **Setting**: people included in the immobilised patients programme receiving home nursing service provided by health centres **Comments**: no comments **Author's name**: Inmaculada Lupianez-Perez **Institution**: Malaga-Guadalhorce Primary Healthcare District, Andalusian Health Service, Malaga, Spain **Email**: ilupianezperez@gmail.com **Address**: Andalusian Health ServiceC/La Unión, 29651 Mijas Costa, Malaga
Notes	**Pre-treatment**: there were no differences between the groups
Risk of bias	

Lupianez-Perez 2015 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomly allocated to a 1:1 control/target group scheme by a computer system.
Allocation concealment (selection bias)	Low risk	When an individual met the inclusion criteria, his/her nurse was informed of the group to which they had been allocated by a telephone call from a centralised randomisation unit.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Triple-blind. Both topical applications were delivered using a spray.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Triple-blind
Incomplete outcome data (attrition bias) All outcomes	Low risk	Both per-protocol and ITT analysis were reported. However, the ITT analysis included imputed data.
Selective reporting (reporting bias)	Unclear risk	The protocol stated that the primary outcome was stage 2 PUs and the secondary outcome, cost. Only PU data were reported. Additionally, data were reported by area affected rather than by total number of PUs (ClinicalTrials.gov NCT01595347).
Other bias	Unclear risk	Unequal number of participants allocated to each group (may indicate selection bias). 28% loss to follow-up in olive oil group compared with 34% in the HOFA group

Madadi 2015

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: yes **Follow-up period**: not stated **Sample size estimate**: yes, a total of 70 participants would be needed **ITT analysis**: no; **number randomised:** 70 **number analysed**: 60 **Funding**: no funding sources
Participants	**Inclusion criteria** • Lack of skin disorders and bedsores • No history of diabetes • Lack of apparent peripheral vascular disease • No history of sensitivity to olive and its by-products • No history of previous bedsore • No history of paraplegia or quadriplegia • Having a Foley catheter

Madadi 2015 *(Continued)*

- Being transferred to ICU in the first day of hospitalisation

Exclusion criteria

- Any sensitivity or skin problems (rash, hives, redness, swelling, ulcers)
- Having continuous fever
- Lack of consent of patient or his/her guardians to take part in the study
- Transfer to another medical centre outside of Qazvin city
- Death

Pretreatment

- Gender: intervention group: 19 male (63.3%), 11 female (36.7%); control group: 20 male (66.7%), 10 female (33.3%)
- Age: intervention group: average age of 60.46 ± 18.06; control group: average age of 50.96 ± 21.38
- Average BMI: intervention group: 24.96 ± 4.02; control group: 24.81 ± 3.69

Interventions	**Intervention group 1:** • Received routine care (changing position every 2 hours as well as a vibrating wavy mattress) AND they 15 cc premium and standard formula olive oil. This oil was applied gently once a day on the following areas of patient's bodies without any massaging: Earlobes (0.5 cc each), shoulders (1.5 cc each), spine (1.5 cc), waist (1.5 cc), buttocks (1.5 cc each), iliac (1 cc), sacrum (1cc), elbows (0.5 cc each), heels (0.5 cc each) and ankles (0.5 cc each) **Control group:** • Received routine skin care including changing their position every 2 hours and a vibrating wavy mattress
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Unit of measure**: numbers • **Reporting**: fully reported • **Direction**: lower is better • **Data value**: endpoint Anatomical location of PU development • **Outcome type**: dichotomous outcome • **Unit of measure**: numbers • **Reporting**: fully reported • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source**: none **Country**: Iran **Setting**: intensive care unit patients **Comments**: no comments **Author's name**: Mr. Zahra Abbas Ali Madadi **Institution**: Nursing & Midwifery Faculty, Qazvin University of medical sciences **Email**: madadi_z20@yahoo.com **Address**: Qazvin, Iran

Madadi 2015 *(Continued)*

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Selected by simple random sampling method
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	High risk	"All processes of intervention, observation and recording have been done by just one person"
Blinding of outcome assessment (detection bias) All outcomes	High risk	"All processes of intervention, observation and recording have been done by just one person"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.
Selective reporting (reporting bias)	Low risk	Planned outcomes were measured (trial registered in Iranian Registry of Clinical Trials, NO. IRCT 2013111014634N2)
Other bias	Low risk	None noted

Nakagami 2007

Study characteristics

Methods	**Trial design**: RCT **Trial grouping**: within-participant (participant acting as their own control) **Ethics and informed consent**: yes **Follow-up period**: 3 weeks **Sample size estimate**: yes, the estimated sample size was 33, and therefore 37 participants were enroled, assuming a loss to follow-up of 10% **ITT analysis**: yes; **number randomised**: 37; **number analysed**: 37 **Funding**: this study was supported by a Grant-in-Aid for scientific research from the Ministry of Education, Culture, Sports, Science and Technology, Japan [(B) (2) 16390637]
Participants	**Inclusion criteria** • Aged ≥ 65 • Braden score of < 15 **Exclusion criteria** • Impaired judgement

Nakagami 2007 *(Continued)*

- Lack of consciousness
- Presence of a PU or skin disorder in the study area
- Poor general medical condition
- Inability to position the body in either a right or left lateral position

Pretreatment

- Age, years, mean (SD): 86.4 ± 8.2
- Women: 28 (75.7%)
- Braden score, mean (SD): 10.4 ± 1.2
- Bedridden: 37 (100%)
- Body weight: mean (SD): 36.6 ± 2.8
- 11 (29.7%) did not have support surfaces in use
- Diagnosis: cerebrovascular disease: 30 (81.1%); heart disease: 10 (27.0%); diabetes mellitus: 4 (10.8%)

Interventions	**Intervention group** • pressure ulcer preventive dressing (PPD): dressing with skin adhesive layer (hydrocolloid), a support layer (urethane film), and an outer layer of multi filament nylon fibres • Applied to either the right or the left trochanter • PPD replaced every week **Control group:** participants acted as their own control, i.e. no dressing was applied to the opposite trochanter
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Incidence of persistent erythema • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source**: not stated **Country**: Japan **Setting**: 500-bed geriatric hospital **Comments**: no comments **Author's name**: G Nakagami **Institution**: Division of Health Sciences and Nursing, Graduate School of Medicine **Email**: not provided **Address**: University of Tokyo, Tokyo, Japan
Notes	PU classification system not clearly described

Nakagami 2007 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not stated
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded; quote: “impossible due to the type of intervention”
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not blinded; quote: "test area outlined so that the dressing applied back to the same area"
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT conducted
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	High risk	Investigators were part of the group that developed the PPD.

Oe 2020

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel groups **Ethics and informed consent**: yes **Follow-up period**: 14 days **Sample size estimate**: yes; would need a sample size of 600 participants (n = 300 per group) **ITT analysis**: yes **number randomised**: 600; **number analysed**: 600 **Funding**: funded by research grants from the Japanese Society of Wound, Ostomy, and Continence Management
Participants	**Inclusion criteria:** hospital inpatients with persistent severe diarrhoea and/or fragile skin **Exclusion criteria** • Those with existing pressure ulcers • Aged < 20 years **Pretreatment** • Age in years (SD): Intervention: 75.6 (15.3); control group: 74.2 (16.2)

Oe 2020 *(Continued)*

	• Sex: males: intervention group: 161 (53.7%), control group: 150 (50.0%) Females: intervention group: 139 (46.3%), control group: 150 (50.0%)
Interventions	**Intervention group** • Standard care and a multilayer silicone foam dressing applied to the sacrum and coccyx of the intervention group and monitored daily by partially peeling the dressings to assess the skin and pressure ulcer development • Soiled or dislodged dressings were changed **Control group:** standard care
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint PU location • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint PU stage • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** not stated **Country**: Japan **Setting**: inpatients in 3 hospitals **Comments**: no comments **Author's name**: Makoto Oe **Institution**: Department of Gerontological Nursing and Wound Care Management, Division of Health Science and Nursing, Graduate School of Medicine, The University of Tokyo, Tokyo **Email**: hsanada-tky@umin.ac.jp **Address**: Tokyo, Japan
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement

Oe 2020 *(Continued)*

Random sequence generation (selection bias)	Low risk	Randomised using Excel to intervention or control group in a 1:1 ratio. An investigator who was blinded to the identity of the participants used computer software (Excel) to generate a series of random numbers.
Allocation concealment (selection bias)	Low risk	An investigator who was blinded to the identity of the participants used computer software (Excel) to generate a series of random numbers. Participants were allocated to either the intervention or the control group at each participating institution based on these series of random numbers.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and care providers were not blinded to the interventions after assignment.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome adjudicators were not blinded to the interventions after assignment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All those randomised were analysed.
Selective reporting (reporting bias)	Low risk	Planned outcomes were measured (Trial registered UMIN000024609)
Other bias	Low risk	None noted

Otero 2017

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel groups **Ethics and informed consent**: yes **Follow-up period**: followed participants for 5 to 10 hours following treatment (average treatment 14.5 hours) **Sample size estimate**: a total of 152 participants needed to be recruited **ITT analysis**: no; **number randomised**: 171; **number analysed**: 152 **Funding**: not stated
Participants	**Inclusion criteria** • Adults (≥ 18 years) with acute respiratory failure, requiring non-invasive ventilation • Absence of facial soft tissue injury • Absence of facial anatomy structural deformity **Exclusion criteria** • People not agreeing to participate and not signing the informed consent form • People with facial soft tissue lesions • People with any deformity of the facial anatomy

Otero 2017 *(Continued)*

	Pretreatment • 56.6% men; 43.4% women • The average Norton score (a scale widely used to assess risk of developing PU) of the total population was 10.69 (SD = 2.85)
Interventions	**Intervention group 1: adhesive thin dressing (ATD)**: the oro-nasal mask was applied over skin protected with adhesive thin polyurethane foam dressings **Intervention group 2: adhesive foam dressing**: the oro-nasal mask was applied over skin protected with adhesive foam dressings **Intervention group 3: HOFA**: the oro-nasal mask was applied over skin protected with a solution of HOFA, gently applied without rubbing on the chin, cheekbones, nasal bridge and forehead **Control group:** the oro-nasal mask was applied directly over the participant's skin Study group 2 and control group included in comparison 1; study groups 1 and 2 included in comparison 4; study groups 2 and 3 included in comparison 5
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported for those analysed • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Adverse events • **Outcome type**: dichotomous outcome • **Reporting**: fully reported for those analysed • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source**: Istituto Ortopedico Rizzoli **Country**: Spain **Setting**: HDU section of an emergency and critical care department in the University General Hospital in Madrid, Spain **Comments**: no comments **Author's name**: DP Otero **Institution**: University General Hospital Gregorio Marañón; Gregorio Marañón Healthcare Research Institute-Nursing Department (IiSGM); Centre for Health Sciences San Rafael-Antonio Nebrija University, **Email**: david.penha.otero@hotmail.com **Address**: Madrid, Spain
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement

Otero 2017 *(Continued)*

Random sequence generation (selection bias)	Low risk	Quote: "we randomised subjects into four different groups, using specifically designed tables of random numbers"
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "As the researchers were also part of the care team at the HDU, it was impossible to implement a blinded study"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "We employed independent double evaluations"
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "A total of 19 patients were lost to follow-up; 4 died before the end of the trial, and data recording was incomplete for 4 patients"
Selective reporting (reporting bias)	Low risk	Planned outcomes were measured. The study was registered at the European Medicines Agency clinical trials database (EudraCT number 2015-004185-28) and the ClinicalTrials.gov database, under the number NCT02526862.
Other bias	Low risk	None noted

Ozbudak 2020

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel groups **Ethics and informed consent**: yes **Follow-up period**: not stated **Sample size estimate**: yes, 40 participants (intervention and control group) **ITT analysis**: no; **number randomised**: 60; **number analysed**: 46 **Funding**: none
Participants	**Inclusion criteria** • Over the age of 18 • Diagnosed with respiratory failure • Undergoing non-invasive ventilation (NIV) for the first time • Receiving NIV with an oronasal mask • Continued ventilation • No skin breakdown or pressure ulcer on face • Able to tolerate the NIV mask • Conscious and able to communicate • Did not have claustrophobia **Exclusion criteria**

Ozbudak 2020 *(Continued)*

- Redness or pressure ulcers were in stage I or higher
- History of glaucoma or eye surgery within the previous 6 weeks
- Use of home non-invasive ventilation in the hospital
- Women who were pregnant

Pretreatment

- Age (years): intervention: 68.9 ± 2.22; control: 69.7±2.78
- Sex: male: intervention: n = 12, control: n= 12. Female: intervention: n = 13, control: n = 9

Interventions	**Intervention group:** transparent film was applied to the participants in the intervention group, before the oronasal mask was placed **Control group:** no dressing applied
Outcomes	Time to PU development • **Outcome type**: continuous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: higher is better • **Data value**: endpoint Cost benefit • **Outcome type**: continuous outcome • **Reporting**: partially reported • **Unit of measure**: Australian dollars • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** not stated **Country**: Turkey **Setting**: the chest diseases intensive care unit in the university hospital **Comments**: no comments **Author's name:** Dr. G Özbudak **Institution**:Department of Chest Diseases, Ege University Hospital **Email**: gizem-ozbudak@hotmail.com **Address**: Ege University Hospital, Bornova, Izmir 35100, Turkey
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Described as a randomised control trial. The data were first collected from the control group, then from the intervention group to avoid interaction in intervention and control group.
Allocation concealment (selection bias)	Unclear risk	Not stated

Ozbudak 2020 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	High risk	More participants lost to follow-up in the control group
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Low risk	None detected

Qiuli 2010

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel group **Ethics and informed consent**: not stated **Follow-up period**: 7 days **Sample size estimate**: not stated **ITT analysis**: yes; **number randomised**: 64; **number analysed**: 64 **Funding**: not stated
Participants	**Inclusion criteria** • Waterlow score 18 to 23 • Department of neurosurgery **Exclusion criteria** • Not reported **Pretreatment** • 30 men and 34 women • Aged 55 to 80 years • 26 suffered from hemiplegia, 4 with paraplegia, 24 with coma, and 6 with advanced tumours • Waterlow Pressure Sore Risk Assessment Scale scores: 18 to 23 • Haemoglobin: 90 g/L to 110 g/L • Fasting blood glucose: 4.2 to 6.5 mmol/L • 16 participants suffered from incontinence
Interventions	**Intervention group** • Silicone dressing applied to weight-bearing bony areas

Qiuli 2010 *(Continued)*

	• Turned 2-3 hourly and nursed on air cushion beds **Control group** • Massage of bony areas • Turned 2-3 hourly and nursed on air cushion beds
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source**: not stated **Country**: China **Setting**: long-term care **Comments**: no comments **Author's name**: Bao Qiuli **Institution**: Department of Neurosurgery **Email**: not provided **Address**: Second Affiliated Hospital of Harbin Medical University
Notes	PU classification system not described. We attempted to contact the authors to seek additional information, but received no response.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not stated
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not stated, but difference in the appearance of dressing makes blinding impossible
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants included in the final analysis
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.

Qiuli 2010 *(Continued)*

Other bias	Unclear risk	Baseline characteristics not reported

Saab 2015

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel groups **Ethics and informed consent**: not stated **Follow-up period**: not stated **Sample size estimate**: not stated **ITT analysis**: yes; **number randomised**: 80; **number analysed**: 80 **Funding**: not stated
Participants	**Inclusion criteria:** people admitted to surgical ICU from July to November 2014 **Exclusion criteria:** not reported **Pretreatment** • 44% women • Mean age was 62 (17.2) years • Mean Braden score was 15.1
Interventions	**Intervention group** • Application of a multilayered dressing incorporating hydrocellular foam, hyper-absorber, lock-away core with a silicone wound contact layer • The buttocks and the sacrum were examined daily. • The dressing was replaced as needed. **Control group:** no dressing
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source**: not reported **Country**: USA **Setting**: surgical ICU **Comments**: no comment **Author's name**: I Saab **Institution**: Henry Ford Hospital **Email**: not provided

Saab 2015 *(Continued)*

	Address: 2799 West Grand Boulevard, Detroit, MA 48202
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Sequence generation not stated
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	High risk	Open-label
Blinding of outcome assessment (detection bias) All outcomes	High risk	Open-label
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcomes reported for those randomised to each group
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Unclear risk	As the data have been extracted from an abstract, it is unclear if there are any other sources of bias.

Santamaria 2015

Study characteristics

Methods	**Trial design**: RCT **Trial grouping**: parallel groups **Ethics and informed consent**: yes **Follow-up period**: not stated **Sample size estimate**: yes, required a total of 220 people per group **ITT analysis**: yes; **number randomised**: 440; **number analysed**: 440 **Funding**: funded by Molnlycke Health Care, the manufacturer of the intervention product
Participants	**Inclusion criteria** • ED and ICU admission for critical illness and/or major trauma • > 18 years of age **Exclusion criteria**

Santamaria 2015 *(Continued)*

- Suspected or actual spinal injury precluding the patient being turned
- Pre-existing sacral or heel PU
- Trauma to sacrum and/or heels

Pretreatment

- Age, mean years (SD years): intervention: 54 (20.8); control: 56 (20.5)
- Gender, M/F: intervention: 126/89; control: 132/82
- Braden, mean (SD): intervention: 12 (4.2); control: 12 (3.9)
- APACHE (Acute Physiology and Chronic Health Evaluation) II, mean: intervention: 19; control: 19.5

Interventions	**Intervention group** • Soft silicone multilayered foam dressing • The dressing was applied bilaterally to the trochanteric and sacral regions. • The dressings were changed only if there was loss of adhesiveness, shear, excessive moisture, friction, presence of wrinkles, or the combination of these factors. **Control group:** no dressing applied
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Cost benefit • **Outcome type**: continuous outcome • **Reporting**: partially reported • **Unit of measure**: Australian dollars • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source**: funded by Molnlycke Health Care, the manufacturer of the intervention product **Country**: Australia **Setting**: ICU **Comments**: no comments Author's name: N Santamaria **Institution**: Royal Melbourne Hospital **Email**: nick.santamaria@mh.org.au **Address**: Level 6 Office for Research, Royal Melbourne Hospital, Grattan Street, Parkville VIC 3050, Australia
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement

Santamaria 2015 *(Continued)*

Random sequence generation (selection bias)	Low risk	Participants were randomised in the ED to either the intervention group or to the control group by retrieving the next envelope in a pre-prepared series of envelopes that had been randomised using a computer-generated set of random numbers to determine group allocation.
Allocation concealment (selection bias)	Unclear risk	Whether the envelopes were opaque and sealed was not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Cannot blind as one group has a dressing and the other doesn't
Blinding of outcome assessment (detection bias) All outcomes	High risk	The outcome assessor was not independent of the study team
Incomplete outcome data (attrition bias) All outcomes	Low risk	The analysis was based on ITT where all participants randomised to the intervention were analysed regardless of protocol violations.
Selective reporting (reporting bias)	Low risk	Planned outcomes were measured: registered as a clinical trial with the Australian Therapeutic Goods Administration CTN Scheme and with Clinical Trials.gov (NCT01356459)
Other bias	Unclear risk	The sample size calculation was based on a control event rate of 4.0% (presumably this was known from existing hospital data). In the study, the control event rate was 13.1%, raising questions about the accuracy of PU diagnosis in the control group during the study. The study was registered on ClinicalTrials.gov but only after data collection had begun.

Santamaria 2018

Study characteristics	
Methods	**Trial design**: cluster-RCT **Trial grouping**: parallel groups **Ethics and informed consent**: yes **Follow-up period**: 4 weeks **Sample size estimate**: yes; a total of 260 residents (130 residents per group) were required **ITT analysis**: yes; **number randomised**: 305; **number analysed**: 288 **Funding**: Molnlycke Health Care and Australian Commonwealth Government Wound Management Innovation Cooperative Research Centre
Participants	**Inclusion criteria** • Recently admitted to the facility • Were bed-bound • Had a Braden Scale score of ≤ 12 • Had an expected length of stay in the facility of more than 4 weeks **Exclusion criteria**

Santamaria 2018 *(Continued)*

- Pre-existing sacral and/or heel PIs
- Life expectancy of less than 4 weeks
- Classed as palliative care or end of life

Pretreatment

- Age (years) Mean (SD): Intervention: 84 (9); Control: 82 (12)
- Sex: Male 48, female 90 (intervention); Male 38, female 112 (control)

Interventions	**Intervention group** • Standard care • Silicone adhesive multilayer foam dressing applied to the sacrum • Silicone adhesive multilayer foam dressing, retained with Tubifast, applied to each heel • The interval between dressing changes was 3 days or as required, if the dressing became soiled or dislodged • The sacrum and heels were observed every day by partially peeling off the dressings so that the skin could be visualised and assessed for the development of pressure ulcers **Control group:** standard care
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint PU location • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint PU severity • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** Molnlycke Health Care and Australian Commonwealth Government Wound Management Innovation Cooperative Research Centre **Country**: Australia **Setting**: Aged care **Comments**: no comment **Author's name**: Nick Santamaria **Institution**: Department of Nursing, University of Melbourne, Australia. **Email**: n.santamaria@unimelb.edu.au

Santamaria 2018 *(Continued)*

	Address: Australia Alan Gilbert Building, Level 7, 161 Barry Street, Melbourne, Victoria 3010,
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Facilities were randomised by a member of the research team, who was blinded to the identity of the facilities using a computer programme to generate a series of random numbers. These random numbers were then used to allocate each facility to either the intervention or control group
Allocation concealment (selection bias)	Low risk	Following the randomisation, centre managers of the facilities were informed by the chief investigator whether their facility was an intervention or control group facility.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "The study is limited by our inability to blind the subject to the presence or absence of the intervention."
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "The study is limited by our inability to blind the assessor to the presence or absence of the intervention."
Incomplete outcome data (attrition bias) All outcomes	Low risk	All those that received the intervention were analysed
Selective reporting (reporting bias)	Unclear risk	States that registered as a clinical trial with the Australian Therapeutic Goods Administration Clinical Trial Notification Scheme. No number was provided, and we could not locate the trial registration.
Other bias	Low risk	There is no indication that the cluster design was accounted for in the analysis.

Smith 1985

Study characteristics

Methods	**Trial design**: RCT **Trial grouping**: parallel groups **Ethics and informed consent**: yes **Follow-up period**: 24 weeks **Sample size estimate**: not stated **ITT analysis**: yes; **number randomised**: 258; **number analysed**: 258 **Funding**: grant from WB Pharmaceuticals
Participants	**Inclusion criteria:** people with intact skin **Exclusion criteria:** not stated

Smith 1985 *(Continued)*

	Pretreatment • Age, mean: intervention: 82 years; control: 83 years • Gender, F/M: intervention: 104/25; control: 106/23 • Incontinent urine: intervention: 19%; control: 29% • Incontinent faeces: intervention: 29%; control: 42%
Interventions	**Intervention group:** Conotrane (silicone cream; 20% dimethicone 350; and a broad spectrum antiseptic (0.05% hydrargaphen)), skin washed, dried and ointment applied **Control group:** Unguentum cream, skin washed, dried and ointment applied
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source**: WB Pharmaceuticals **Country**: UK **Setting**: long stay **Comments**: no comment **Author's name**: RG Smith **Institution**: Department of Geriatric Medicine **Email**: not stated **Address**: City Hospital, Greenbank Drive, Edingburgh, UK
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not stated
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "The placebo ointment had been suitably scented so that it was indistinguishable from the active preparation"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	No mention within the article. Quote: "The placebo ointment had been suitably scented so that it was indistinguishable from the active preparation"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Results table 1: 258 participants. Data presented related to those who entered the study

Smith 1985 *(Continued)*

Selective reporting (reporting bias)	Unclear risk	No trial registration identified; therefore, unclear if all planned outcomes were measured
Other bias	Unclear risk	One-third more participants in the placebo group were incontinent of urine and one-quarter more were incontinent of faeces when compared with the treatment group.

Sonmez 2020

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel groups **Ethics and informed consent**: yes **Follow-up period**: not stated **Sample size estimate**: yes, 128 participants needed in total **ITT analysis**: yes; **number randomised**: 129; **number analysed**: 129 **Funding**: none
Participants	**Inclusion criteria** • People aged 18 years and older, with a Braden scale score of 12 or lower • No PI at admission to the ICU • Not diagnosed with brain death • A hospitalisation of at least five days • Without positioning contraindications or medical disability **Exclusion criteria** • Receiving vasoconstrictive drug therapy • Those who were in the terminal period • Those with casts or bandages on lower extremities **Pretreatment** • Age in years: mean (SD): Intervention: 61.48 (17.49); Control: 58.56 (19.22) • Sex: Intervention: male 37 (56.9%), female: 28 (43.1%). Control: male: 35 (54.7%), female: 29 (45.3%)
Interventions	**Intervention group** • In addition to routine care, extra virgin olive oil (EVOO) was applied to the sacrum, trochanteric regions, and heels • One researcher applied the EVOO twice a day (9:00–10:00 am; 9:00–10:00 pm) **Control group:** routine nursing care for PI prevention
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better

Sonmez 2020 *(Continued)*

- **Data value**: endpoint

Identification	**Sponsorship source:** not stated **Country**: Turkey **Setting**: ICU in one hospital **Comments**: no comment **Author's name**: Munevver Sonmez **Institution**: Zonguldak Bülent Ecevit University **Email**: m.sonmez@beun.edu.tr **Address**: Zonguldak Bülent Ecevit University, Faculty of Health Science, Fundamentals of Nursing Department, 67000, Zonguldak, Turkey
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomly assigned with a 1:1 allocation using a computer-generated randomisation schedule.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not clearly described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	All randomised participants were analysed
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Low risk	None detected

Stankiewicz 2019

Study characteristics

Methods	**Trial design:** cluster-controlled clinical trial **Trial grouping:** clusters of three monthly allocations of each product, alternating between dressing 1 and dressing 2; that is, three cycles each. **Ethics and informed consent**: yes

Stankiewicz 2019 *(Continued)*

Follow-up period: 3 months

Sample size estimate: yes, 200 participants in each group

ITT analysis: yes; **number randomised**: 302; **number analysed**: 302

Funding: none

Participants	**Inclusion criteria** • Adults (> 18 years) were enroled into the study within 48 hours of their admission to ICU **Exclusion criteria** • PI present on admission to the ICU • Had dislodged or soiled a sacral dressing more than three times in a 24-hour period or were unable to have a dressing applied for more than 24 hours **Pretreatment** • Age, years (SD): Dressing 1: 56 ± 19; Dressing 2: 58 ± 17 0.52 • Gender, male (%): Dressing 1: 73 (56.6); Dressing 2: 103 (59.5)
Interventions	**Intervention group 1:** silicone adhesive multilayer foam dressing 1 applied to the sacrum **Intervention group 2:** silicone adhesive multilayer foam dressing 2 applied to the sacrum
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Cost • **Outcome type**: continuous outcome • **Reporting**: fully reported • **Unit of measure**: Australian dollars • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** not stated **Country**: Australia **Setting**: ICU in hospital setting **Author's name**: Jodie Gordon **Institution**: Redcliffe Hospital, Metro North Hospital and Health Service, QLD, Australia **Email**: Jodie.Gordon@health.qld.gov.au **Address**: Not stated
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement

Stankiewicz 2019 *(Continued)*

Random sequence generation (selection bias)	High risk	Participants were allocated to one dressing type based on clusters of three monthly allocations of each product
Allocation concealment (selection bias)	High risk	Participants were allocated to one dressing type based on clusters of three monthly allocations of each product
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	High risk	There was no blinding of outcome assessment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All randomised participants included in analysis
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	High risk	There is no indication that the cluster design was accounted for in the analysis.

Torra i Bou 2005

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel groups **Ethics and informed consent**: yes **Follow-up period**: 30 days **Sample size estimate**: yes, 188 people per group required **ITT analysis**: no; **number randomised**: 380; **number analysed**: 359 **Funding**: Laboratorios Bama-Geve SA, Barcelona, Spain
Participants	**Inclusion criteria** • Participants had to be at medium, high, or very high risk of developing PUs • Participants had to be able to participate for an evaluation period of 30 days • Participants or their carers needed to provide written consent to take part **Exclusion criteria** • Were terminally ill or receiving chemotherapy • Had > 3 PUs • Were allergic to HOFA or topical fatty products • Had peripheral vascular disease **Pretreatment** • Age, mean (SD): intervention: 84.8 (6.7); control: 84.8 (5.9)

Torra i Bou 2005 *(Continued)*

- Gender: F/M: intervention: 48/17; control: 46/19

Interventions	**Intervention group** • Mepentol, a HOFA compound (consisting of: oleic acid, palmitic acid, stearic acid, palmitoleic acid, linoleic acid, gamma-linoleic acid, arachidonic acid, and eicosenoic acid) • Applied twice daily to ≥ 3 areas of the body: sacrum, trochanter, heels **Control group** • A placebo compound consisting of triisostearin (99.4%) and perfume (0.6%) • Applied twice daily to ≥ 3 areas of the body: sacrum, trochanter, heels
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint Cost benefit • **Outcome type**: continuous outcome • **Reporting**: partially reported • **Unit of measure**: Euro • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source**: Laboratorios Bama-Geve SA, Barcelona, Spain **Country**: Spain **Setting**: internal medicine or surgical patients at high risk of pressure injury **Comments**: no comment **Author's name**: JE Torra i Bou **Institution**: Clinical and Education Manager, Advanced Wound Care Division, Smith & Nephew, Spain **Email**: jetorrabou@hotmail.com **Address**: not stated
Notes	We attempted to contact the authors to seek additional information, but received no response.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Did not state how the randomisation sequence was generated
Allocation concealment (selection bias)	Unclear risk	Coded randomisation in closed envelopes; did not state that the envelopes were opaque
Blinding of participants and personnel (performance bias)	Low risk	Blinded. Quote: "only the coordinator had access to the packaging codes so neither the investigator nor patient knew which group a patient had been allocated to"

Torra i Bou 2005 *(Continued)*

All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinded. Quote: "only the coordinator had access to the packaging codes so neither the investigator nor patient knew which group a patient had been allocated to"
Incomplete outcome data (attrition bias) All outcomes	High risk	ITT not conducted. Results presented for 167 and 164 participants and not for the original 380 enrolled
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Low risk	None detected

Van Der Cammen 1987

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel groups **Ethics and informed consent**: not stated **Follow-up period**: 3 weeks **Sample size estimate**: not stated **ITT analysis**: no; **number randomised**: 120; **number analysed**: 104 **Funding**: not stated
Participants	**Inclusion criteria** • Norton score between 5 and 14, indicating risk of PUs • Chair-bound individuals **Exclusion criteria** • Had existing PUs • Severe or terminal disease • Likely period of stay in the ward of < 3 weeks **Pretreatment** • Age, mean (range): intervention: 82.2 (53 to 98); control: 82.9 (64 to 97) • Gender: F/M: intervention: 40/14; control: 37/13
Interventions	**Intervention group:** participants' buttocks and sacral areas washed and dried, and Prevasore (Hexyl nicotinate, zinc stearate, isopropyl myristate, dimethicone 350, cetrimide and glycol) applied at least twice daily, and after changing, if wet or soiled **Control group:** participants' buttocks and sacral areas washed and dried, and Dermalex (hexachlorophane, squalene and allantoin) applied at least twice daily, and after changing, if wet or soiled
Outcomes	PU incidence • **Outcome type**: dichotomous outcome

Van Der Cammen 1987 *(Continued)*

- **Reporting**: fully reported
- **Unit of measure**: numbers
- **Direction**: lower is better
- **Data value**: endpoint

Identification	**Sponsorship source**: none stated **Country**: UK **Setting**: geriatric medicine **Comments**: no comment **Author's name**: TJM Van Der Cammen **Institution**: Lewisham and Hither Green Hospitals **Email**: none provided **Address**: Lewisham and Hither Green Hospitals, London, UK
Notes	Data presented for 104 participants. We attempted to contact the authors to seek additional information but received no response.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not stated
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "... this formulation was compared, in a double blind clinical trial..."
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not mentioned and although unclear, it is probable that outcome assessment was blinded, given that the trial was "double-blinded"
Incomplete outcome data (attrition bias) All outcomes	High risk	ITT not conducted. Data presented relate to the number who completed the study, and exclude those withdrawn
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	High risk	Corresponding author was member of staff of the manufacturer of the product under investigation.

Verdu 2012

Study characteristics

Verdu 2012 *(Continued)*

Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: yes **Follow-up period**: 2 weeks **Sample size estimate**: yes; 434 participants would be required (217 each group) **ITT analysis**: yes; **number randomised**: 194; **number analysed**: 194 **Funding**: a research contract between Fundacíon Sergio Juan Jordán para la Investigacíon y Estudio de las Heridas Crónicas (Sergio Juan Jordan Foundation for the Study and Research of Chronic Wounds) and Laboratorios Inibsa S.A. (INIBSA Laboratories).
Participants	**Inclusion criteria** • Male and female individuals over 18 years of age presenting with medium, high, or very high risk of PU development according to the Braden scale (scoring 15 points or lower) • Without PU at the moment of inclusion and receiving treatment at hospitals or socio-sanitary centres **Exclusion criteria** • Terminally ill • Active PUs or peripheral vasculopathy • History of allergies to some components of the products under study • Receiving ongoing treatment with vasopressor or chemotherapy agents • Participating in a clinical study or who had participated in one within the previous month **Pretreatment** • Intervention participants were 78.16 ± 13.85 years old (median = 81, range = 39 to 101). Control participants were 78.51 ± 13.25 years old (median = 82, range = 29 to 98) • Gender: 61.2% were women in the intervention group, compared to 62.1% in the control group
Interventions	**Intervention group:** routine pressure ulcer prevention and a topical agent (IPARZINE-4A-SKR) applied to the sacrum, trochanters and heels, every 12 hours **Control group:** routine pressure ulcer prevention and a placebo topical agent applied to the sacrum, trochanters and heels, every 12 hours
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** not stated **Country**: Spain **Setting**: Hospital and socio-sanitary centre patients in 8 centres **Comments:** no comments **Author's name**: José Verdu **Institution**: Universidad de Alicante **Email**: pepe.verdu@ua.es

Verdu 2012 *(Continued)*

	Address: Department of Public Health and History of Science, Universidad de Alicante, Campus de San Vicente del Raspeig s/n. Ap. 99. E-03080 Alicante, Spain
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was carried out using a randomisation code generated with random numbers by the SPSS 18.0 software package, thus producing block randomisation.
Allocation concealment (selection bias)	Low risk	The participants were randomly allocated in a 1:1 ratio to be treated either in the control group or in the experimental group, according to a randomisation code contained in a sealed envelope.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Double-blind
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Double-blind
Incomplete outcome data (attrition bias) All outcomes	Low risk	All randomised participants were analysed.
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Low risk	None detected

Walker 2015

Study characteristics

Methods	**Trial design**: RCT **Trial grouping**: parallel groups **Ethics and informed consent**: yes **Follow-up period**: 5 days **Sample size estimate**: yes: a sample size of 1500 (750 in each group) would be required to test the effectiveness of the intervention **ITT analysis**: yes; **number randomised**: 77; **number analysed**: 77 **Funding**: this study was funded by the National Health and Medical Research Council's Centre of Research Excellence in Nursing, and an Early Career Researcher Mentored Grant from the Centre for Health Practice Innovation, Griffith University
Participants	**Inclusion criteria**

Walker 2015 *(Continued)*

- ≥ 18 years of age
- Able to provide written informed consent either in person or via their family member or legal guardian
- Assessed as being at high risk or greater of PI (as per a risk assessment score of 15+ using the Waterlow Scale) on hospital admission to the medical or surgical study wards
- Expected hospital length of stay ≥ 72 hours following recruitment

Exclusion criteria

- Suspected or actual spinal injury that prevented the patient being repositioned
- Lower back surgery (lumbar spine) that prevented the application of a sacral dressing
- Existing sacral PI, injury, or allergy in the sacral area at the time of hospital admission
- Faecal incontinence at the time of hospital admission
- Unable to speak or understand English with no interpreter present

Pretreatment

- Age, median: intervention: 77 years; control: 72 years
- Women: intervention: 59%; control: 82%
- Waterlow median: intervention 17; control 17

Interventions	**Intervention group** • Silicone foam border dressing • Dressing changed every 3 days • Skin assessed daily • Usual care **Control group** • No dressing • Usual care only
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source**: this study was funded by the National Health and Medical Research Council's Centre of Research Excellence in Nursing, and an Early Career Researcher Mentored Grant from the Centre for Health Practice Innovation, Griffith University **Country**: Australia **Setting**: Surgical Care Unit; the ED; or participating medical and orthopaedic surgical wards **Comments**: no comment **Author's name**: Rachel Walker **Institution**: Princess Alexandra Hospital **Email**: r.walker@griffith.edu.au **Address**: Nursing Practice Development Unit, Princess Alexandra Hospital, Building 15, Level 2, Ipswich Road, Woolloongabba QLD 4102
Notes	

Walker 2015 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random allocation of participants to either the routine-care group or the dressing group was achieved using an online clinical trial co-ordinating web site
Allocation concealment (selection bias)	Low risk	Using an online clinical trial co-ordinating web site accessed by the research nurse using a smart phone or tablet
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unable to blind as one group had a dressing and the other didn't
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Sacral assessment was undertaken by a suitably qualified blind-to-intervention ("blinded") nurse assessor
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants were accounted for
Selective reporting (reporting bias)	Low risk	Planned outcomes were measured. This study is registered with the Australian and New Zealand Clinical Trials: ACTRN12613001328763 http:// www.ANZCTR.org.au/ACTRN12613001328763.aspx
Other bias	Low risk	This was a small feasibility study and was not powered to find differences between groups.

Wang 2016

Study characteristics

Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: not stated **Follow-up period**: not stated **Sample size estimate**: not stated **ITT analysis**: yes; **number randomised:** 126; **number analysed**: 126 **Funding**: not stated
Participants	**Inclusion criteria:** people using nasal mask, or nose and mouth mask for non-invasive ventilator **Exclusion criteria:** not stated **Pretreatment:** not stated
Interventions	**Intervention group:** adhesive foam dressing **Control group:** usual care (no dressing)

Wang 2016 *(Continued)*

Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: not reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source**: not stated **Country**: China **Setting**: not stated **Comments:** abstract only **Author's name**: Lin Wang **Institution**: First Hospital of Jilin University, Changchun, China **Email**: not stated **Address**: 3808 Jiefang Rd, 红旗街 Chaoyang District, Changchun, Changchun, Jilin, China, 130021
Notes	Abstract only. We attempted to contact the authors to seek additional information but received no response.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "were randomly divided"
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Low risk	All randomised participants were analysed
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Unclear risk	As the data have been extracted from an abstract, it is unclear if there are any other sources of bias.

Yang 2020

Study characteristics	
Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: yes **Follow-up period**: 72 hours **Sample size estimate**: yes; a sample size of 438 (219 per arm) was required **ITT analysis**: no; **number randomised**: 470; **number analysed**: 450 **Funding**: no
Participants	**Inclusion criteria** • Had undergone any of 3 surgical procedures: Le Fort I maxillary osteotomy, bilateral mandibular sagittal split osteotomy, and/or genioplasty osteotomy • Older than 17 years • Male or female **Exclusion criteria** • People with nasal ala lesions • People with severe skin allergies • People with poor nutritional status such as diagnosis of anaemia or hypoalbuminemia **Pretreatment** • The average age of the sample was 24.36 ± 5.37 years in the control group and 24.15 ± 5.20 years in the experimental group. • Females comprised 65.3% (n = 147) of the control group and 68.0% (n = 153) of the experimental group.
Interventions	**Intervention group:** hydroactive dressing. Before application, the nasal ala was cleaned with a 70% isopropyl alcohol pad; the dressing was applied with 20 seconds of gentle pressure to assure it was properly bonded and to make sure it covered at least 10 mm of nasal mucosa and skin of the nasal ala. **Control group:** a type of medical adhesive tape was applied to the nasal ala to which the nasotracheal tube was affixed
Outcomes	**Primary outcome: PU incidence** • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** not stated **Country**: China **Setting**: hospital setting, patients undergoing orthognathic surgery **Comments**: no comments **Author's name**: Guoyong Yang **Institution**: Department of Oral and Maxillofacial Surgery, Peking University School and Hospital of Stomatology.

Yang 2020 *(Continued)*

Email: gyyang@bjmu.edu.cn

Address: Peking University School and Hospital of Stomatology, 22, Zhongguancun South Ave, Haidian, Beijing 100081, China

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomly assigned to the experimental or control group using a 1:1 allocation sequence generated by the principal investigator via the RAND function in Microsoft Excel software
Allocation concealment (selection bias)	Low risk	The random number was sealed in an envelope not opened until before the surgery procedure started.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The main observers (nurses) and participants were both “double” blinded from knowing to which group they were allocated.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The main observers (nurses) and participants were both “double” blinded from knowing to which group they were allocated.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Low risk	None detected

Yanping 2018

Study characteristics

Methods	**Trial design**: RCT **Trial grouping**: parallel **Ethics and informed consent**: not stated **Follow-up period**: not stated **Sample size estimate**: not stated **ITT analysis**: yes; **number randomised**: 115; **number analysed**: 115 **Funding**: not stated
Participants	**Inclusion criteria:** not stated **Exclusion criteria:** not stated **Pretreatment:** not stated

Yanping 2018 *(Continued)*

Interventions	**Intervention group:** foam dressing **Control group:** transparent film
Outcomes	PU incidence • **Outcome type**: dichotomous outcome • **Reporting**: fully reported • **Unit of measure**: numbers • **Direction**: lower is better • **Data value**: endpoint
Identification	**Sponsorship source:** not stated **Country**: China **Setting**: hospitalised **Comments:** no comments **Author's name**: Wu Yanping **Institution**: Zhongren Geriatric Nursing Hospital **Email**: not stated **Address**: Department of Geriatrics, Zhongren Geriatric Nursing Hospital, Jinshan District, Shanghai, Shanghai, 201501
Notes	We attempted to contact the authors to seek additional information. We were unable to locate them.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Just states "random"
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Low risk	All randomised participants were analysed
Selective reporting (reporting bias)	Unclear risk	Trial not registered. Therefore, it is unclear if all planned outcomes were measured.
Other bias	Unclear risk	Limited important information provided in the paper

BMI: body mass index; **CCU:** coronary care unit; **ED:** emergency department; **h:** hour(s); **HD:** hydrocolloid dressing; **HDU:** high-dependency unit; **HOFA:** hyperoxygenated fatty acids; **ICU:** intensive care unit; **IQR:** interquartile range; **ITT:** intention-to-treat analysis; **NPUAP:** National Pressure Ulcer Advisory Panel; **PF:** polyurethane film; **PI:** pressure injury; **PICU:** paediatric intensive care unit; **PPD:** pressure ulcer preventative dressing; **PU:** pressure ulcer; **RCT:** randomised controlled trial; **SD:** standard deviation

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

Study	Reason for exclusion
Alvarez Vázquez 2014	Ineligible study design
Callaghan 1998	Not an RCT
Declaire 1997	Not an RCT
Duimel-Peeters 2007	Cross-over trial
Garcia Fernandez 2005	Review of a previous study by Torra i Bou
Genc 2022	Intervention not a dressing or topical agent
Guo 2015	Not an RCT
Hsu 2011	Quasi-experimental
Huang 2009	Not an RCT
Kalowes 2013	In previous version of the review
Kim 2016	Not an RCT
Kuisma 1987	Treatment intervention not prevention
Lockwood 2022	Study protocol for a planned study
Miraj 2020	Treatment intervention not prevention
Park 2014a	Ineligible study design
Park 2014b	Duplicate
Poursadra 2019	Treatment intervention not prevention
Santamaria 2013	Duplicate
Smith 2010	Not an RCT
Stoker 1990	Treatment intervention not prevention
Torra i Bou 2009	Cost analysis from an unpublished study, presented at a Pressure Ulcer Advisory Panel meeting in 2002. No abstract available
Wen-Yi 2013	Ineligible study design
Yang TY 2020	This study did not randomise individuals; instead, it randomised site (left/right chest)

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

ACTRN12619000763145

Study name	Do foam dressings prevent pressure sores?
Methods	Multisite RCT
Participants	A consecutive sample of all eligible adults admitted to the participating medical-surgical wards who are assessed as at risk of developing a sacral hospital-acquired pressure injury (HAPI), will be invited to participate in the trial.
Interventions	Participants allocated to the intervention group will receive a prophylactic silicone foam dressing (Mepliex Border Sacrum®) in addition to routine care according to the hospital procedures informed by state governance and international standards.
Outcomes	Number of sacral HAPI
Starting date	10 July 2020
Contact information	b.gillespie@griffith.edu.au
Notes	

ACTRN12620000875909

Study name	Testing sacral dressings to prevent pressure injuries in adult intensive care unit patients
Methods	Multisite randomised controlled trial
Participants	• Aged 18 years and older • Assessed by intensive care unit staff as being at high-risk for pressure injury (research nurse to confirm eligibility using Waterlow score equal to or greater than 15 AND Braden scale score equal to or less than 13) • Anticipated ICU length of stay of 48 hours and longer
Interventions	Arm 1: Mepilex Border Sacrum (Molnlycke) (dressing 1), sacral sub-epidermal moisture (SEM) scanner and usual pressure injury prevention (PIP) care (Intervention 1) "Dressing 1: involves the Research Nurse applying the Mepilex® Border dressing to the patient's sacrum on study recruitment and changed as per the manufacturer's recommendations. The Research Nurse will check the dressing each day. The manufacturer recommends the dressing is changed when the edge begins to roll and lose adhesion or it becomes soiled. Dressings will also be changed if saturation of the dressing occurs, staff accidentally remove the dressing or if the dressing becomes dislodged. The dressing will be removed when the patient reaches any of the trial end points." Arm 2: Allevyn Life Sacrum (Smith+Nephew) (dressing 2), sacral SEM scanner and usual PIP care (Intervention 2) "Dressing 2: involves the Research Nurse applying the Allevyn Life Sacrum (Smith + Nephew) dressing to the patient's sacrum on study recruitment and changed as per the manufacturer's recommendations. The Research Nurse will check the dressing each day. An inbuilt 'dressing change indicator' signals when the dressing should be replaced. Dressings will also be changed [when] saturation and soiling of the dressing occurs, if the adhesive edges 'roll', staff accidentally remove the dressing or if the dressing becomes dislodged. The dressing will be removed when the patient reaches any of the trial end points."

ACTRN12620000875909 *(Continued)*

Outcomes	Development of sacral hospital-acquired pressure injury (HAPI) (any stage)
Starting date	12 May 2021
Contact information	s.latimer@griffith.edu.au
Notes	

ACTRN12621001072808

Study name	Hyperoxygenated Fatty Acids (HOFAs): the impact of implementation and dissemination on facial pressure injuries from medical devices (HOFA-ID)
Methods	RCT
Participants	"All adult patients in Intensive Care with facial medical devices (CPAP, BiPAP, ETT, NGT, Nasal prongs, High-flow nasal prongs) as part of their current treatment are eligible to participate in the trial."
Interventions	• HOFA • Usual care
Outcomes	Development of pressure ulcers
Starting date	22 November 2021
Contact information	l.hunt@westernsydney.edu.au
Notes	Sponsor: Leanne Hunt

ACTRN12622000728730

Study name	Multilayer Silicone Dressings as Compared with Standard Care for Prevention of Sacral Pressure Injuries in Community Cancer Patients: A Cluster Randomised Control Trial
Methods	Cluster RCT
Participants	People with a primary diagnosis of a cancer; over 18 years of age living in the community care setting
Interventions	Participants will receive one of 2 five-layer silicone dressings
Outcomes	Primary outcomes: cost of using prophylactic multilayer silicone dressings as part of a prevention plan; incidence of PU in the study groups
Starting date	01 June 2023
Contact information	Mrs Gordana Petkovska; Silver Chain Group 6 Sundercombe Street, Osborne Park, WA, 6017 Australia; Gordana.Petkovska@silverchain.org.au
Notes	

ACTRN12622000793718

Study name	Testing the efficacy of two sacral dressings in preventing pressure injuries(z) in adult intensive care population: TOWARDS ZERO pilot study
Methods	Randomised controlled trial
Participants	Adult at-risk ICU patients
Interventions	Allevyn Life Sacrum (Smith+Nephew) and usual pressure injury prevention (PIP) care
Outcomes	• Hospital-acquired sacral PI • Evaluate the feasibility of conducting a larger multisite RCT
Starting date	03 October 2022
Contact information	Dr Sharon L Latimer; Griffith University, School of Nursing and Midwifery, L05 3.44 Logan campus, Meadowbrook, Qld, 4131 Australia; s.latimer@griffith.edu.au
Notes	

ACTRN12622001360707

Study name	A single blinded, multi-centre randomised controlled trial (RCT) will be conducted to investigate the effectiveness of a twice-daily application of a barrier wipe (contiplan) on the incidence of pressure injuries (PI) in residential aged care facilities (RACF)
Methods	RCT
Participants	Older adults living in residential care facilities
Interventions	Application of a twice daily barrier wipe to the heels, sacrum, and buttocks of participants AND usual care
Outcomes	The incidence of pressure injuries (PIs) to sacrum, buttocks, and heels per participant
Starting date	22 November 2022
Contact information	Mrs Hayley Ryan; Hayley Ryan Newcastle University PO Box 3143, Glendale, 2285 NSW Australia; hayley.ryan10@uon.edu.au
Notes	

ChiCTR2100050305

Study name	Intervention of skin microclimate on intraoperative pressure injury
Methods	Parallel-group design
Participants	People with spinal dysfunction undergoing surgery
Interventions	• Intervention group A: foam dressings • Intervention group B: ventilated head frame

ChiCTR2100050305 *(Continued)*

	• Control group: no intervention
Outcomes	Intraoperative pressure injury
Starting date	26 August 2021
Contact information	Li Xiaodan; 1095 Jiefang Avenue, Qiaokou District, Wuhan, Hubei 133000; 978452215@qq.com
Notes	

CTRI/2021/11/038231

Study name	Does intermittent nasal massage with coconut oil reduce nasal injury in neonates on nasal CPAP compared with nasal barrier dressing: a randomised control trial
Methods	RCT
Participants	Neonates on nasal CPAP (continuous positive airway pressure)
Interventions	CPAP nasal mask with intermittent coconut oil massage versus CPAP nasal mask with barrier dressing
Outcomes	Incidence of nasal injury
Starting date	27 November 2021
Contact information	S Thanigainathan; Department of Neonatology, AIIMS, Basni industrial area, phase-2, Jodhpur, Rajasthan 342005, India; thanigaipaeds@yahoo.com
Notes	

IRCT20150519022320N20

Study name	"Comparative investigating of the Effect of Aloe Vera gel and Olive Oil on Incidence of pressure ulcer in patients Hospitalized"
Methods	RCT
Participants	• Age over 18 years • Braden score less than 14 • Lack of diabetes • Lack of skin diseases (such as psoriasis, fungal disease) • Lack of pressure ulcer beforehand • Having a systolic blood pressure of 10 mmHg and above • Not having fever (body temperature higher than 38/8) • Haemoglobin higher than 12 mg/dL • No history of allergy to olive oil and aloe vera gel and their products
Interventions	"Intervention 1: Intervention group A: Each person in this group receives an Aloe vera gel on one side of his sacrum and iliac, and on the other side he receives a placebo (a lubricant gel) at 5 cc twice a day for seven days.in addition to he receives Routine care, involves changing the patient's position every 2 hours and using wavy mattresses."

IRCT20150519022320N20 *(Continued)*

	"Intervention 2: Intervention group: intervention group B: Each person in this group receives olive oil on one side of his sacrum and his iliac, and on the other side he receives a placebo (glycerin oil) at 5 cc twice a day for seven days.in addition to he receives Routine care, involves changing the patient's position every 2 hours and using wavy mattresses." "Intervention 3: Intervention group C: Each person in this group receives olive oil on one side of his sacrum and his iliac, and on the other side he receives Aloe Vera gel at 5 cc twice a day for seven days.in addition to he receives Routine care, involves changing the patient's position every 2 hours and using wavy mattresses." "Intervention 4: Control group: Group D: No intervention other than routine care."
Outcomes	Incidence or absence of pressure ulcers
Starting date	20 March 2019
Contact information	t.mirzaei@rums.ac.ir
Notes	Sponsor: Rafsanjan University of Medical Sciences

IRCT20160110025929N23

Study name	Effect of fish oil in preventing pressure ulcer
Methods	RCT
Participants	• Stable haemodynamic status • Healthy skin • No sensitivity to seafood
Interventions	"Intervention 1: Intervention group: In the intervention group In addition to regular care, 2 cc of fish oil will be gently rubbed by the researcher daily in the sacrum area. Intervention 2: Placebo group: In the placebo group,soybean oil(without having any therapeutic effect) will be used at the skin of target area. Intervention 3: Control group: In the control group other than routine care, no special action will be taken."
Outcomes	Incidence of pressure ulcers
Starting date	21 April 2019
Contact information	borzou@umsha.ac.ir
Notes	Sponsor: Hamedan University of Medical Sciences

IRCT20210317050732N1

Study name	The effect of topical application of black seed oil on the prevention of bedsores in patients admitted to the intensive care unit
Methods	RCT
Participants	Inclusion criteria include: • between 18 and 75 years old

IRCT20210317050732N1 *(Continued)*

	• not participating in similar research projects in the previous six months • stable haemodynamic status. Exclusion criteria include having bedsores, diabetes, and a history of allergy to black seed oil.
Interventions	"Intervention group: In this group, in addition to the wavy mattress and change Positions every two hours, 1-3 cc of the black seed oil is rubbed on the Susceptible areas of bed sores for 7 days. Control group: In this group, only the wavy mattress and change Positions every two hours will be used."
Outcomes	Incidence of pressure ulcers
Starting date	15 May 2021
Contact information	maboodiazam@gmail.com
Notes	Sponsor: Islamic Azad University

IRCT20220110053683N1

Study name	Comparison of the effect of olive oil and sesame oil on the prevention of pressure ulcers in ICU patients
Methods	RCT
Participants	ICU patients
Interventions	Olive oil versus sesame oil
Outcomes	Incidence of PU
Starting date	09 April 2022
Contact information	Parsa Ahmadi; No. 54, Dokhaniat town, Daneshgah town, Saqqez 6681473677 Arak Iran (Islamic Republic of); parsawe@gmail.com
Notes	

JPRN-UMIN000024609

Study name	Prevention effect of wound dressings for pressure sores in high-risk patients
Methods	RCT
Participants	"People with high risks of pressure sores who have chronic severe diarrhoea and/or extremely weak skins among the people who will be admitted in the participating medical institutions"
Interventions	Wound dressing applied to the areas of the sacrum bone and the coccyx versus no wound dressing over the areas of the sacrum bone and the coccyx
Outcomes	Incidence of pressure sores
Starting date	22 April 2016

JPRN-UMIN000024609 *(Continued)*

Contact information	hsanada-tky@umin.ac.jp
Notes	Sponsor: Japanese Society of Wound Ostomy Continence Management

KCT0006781

Study name	A randomised controlled trial of the effectiveness of multi-layer silicone foam dressings for the prevention of pressure injuries in postoperative patients
Methods	RCT
Participants	• Adults over 18 years of age • Patients in the risk group for pressure injuries with a Braden scale score of 18 or less, recovering in a ward after general surgery requiring general anaesthesia for more than 3 hours • Patients returning to a general ward after surgery
Interventions	"Medical Device: The experimental group and control group were randomly assigned on the day before the operation by the researcher, a Wound, Ostomy, and Continence Nurse (WOCN), using a computer randomization program (www.randomization.com). To the experimental group, Mepilex border sacrum (22x25cm, molnlycke, Sweden) was applied to the sacrum from the day of surgery after registration of the study subjects. Mepilex border sacrum is a 5-layer soft silicone foam dressing that relieves pressure, friction, and shear forces when applied to the sacrum. During the hospitalization period, the dressing area was opened once per shift to assess the skin condition, and when pressure injuries occurred, they were assessed and recorded according to the NPIAP and EPUAP guidelines. Prior to the start of the study, a WOCN provided training on how to assess pressure injuries and how to apply dressings to nurses in the ward. For the control group, standard pressure injuries prevention activities were performed except for preventive dressings such as posture change and skin assessment."
Outcomes	Incidence of pressure ulcer
Starting date	07 June 2021
Contact information	wocnhj@amc.seoul.kr
Notes	Sponsor: Chung-Ang University

NCT02565745

Study name	Impact of the use of dressings versus lubrication of the skin with cream to prevent pressure ulcers: clinical trial (PENFUP)
Methods	RCT
Participants	People with a high or very high risk of PU development assessed using the Braden Scale
Interventions	Hydrocolloid dressing vs conventional lubricated skin
Outcomes	PU incidence; length of stay; total days; time to event; PU stage; time to first walk in hospital; cost of hospitalisation
Starting date	October 2015

NCT02565745 *(Continued)*

Contact information	olgacortesf@gmail.com
Notes	Sponsor: Fundacion Cardioinfantil Instituto de Cardiologia

NCT04682925

Study name	Effect of Evidence-Based Skin Care and Hydrocolloid Dressing in the Prevention of Nasogastric-Related Pressure Injury
Methods	RCT
Participants	• 18 years of age or older, • Having written permission from relatives and/or participant • A nasogastric tube is inserted after admission to the ICU • "In accordance with the literature reporting that nasogastric tube-induced pressure injuries occur on the second day after nasogastric tube, patients with a planned nasogastric tube stay of at least 48 hours will be included."
Interventions	Quote: 1. The nasal mucosa and nasal skin under the nasogastric tube will be cleaned and dried twice a day with a pH-compatible cleanser. 2. A water-based moisturizing cream will be applied to the nasal skin under the nasogastric tube twice a day, after care with a pH-compatible cleanser. 3. Spray skin barrier will be applied twice a day after applying water-based moisturizing cream to the nasal skin under the nasogastric tube. 4. The nasal mucosa and nasal skin under the nasogastric tube will be evaluated twice daily for signs of pressure-related injury. All these care interventions applied to the skin care arm will be applied together with the doctor and nurse responsible for the treatment and care of the patient.
Outcomes	Rate of pressure ulcer from nasogastric tube
Starting date	15 January 2021
Contact information	md91yesilyurt@gmail.com
Notes	

NCT05198167

Study name	Efficacy of Hyperoxygenated Fatty Acids Versus Hydrocolloid Dressings in the Prevention of Pressure Ulcers in Critically Ill Prone Patients
Methods	RCT
Participants	Critically ill, prone patients
Interventions	Hydrocolloid dressings versus hyperoxygenated fatty acids
Outcomes	Pressure ulcer incidence
Starting date	12 June 2021

NCT05198167 *(Continued)*

Contact information	Montserrat Solis Muñoz; montserrat.solis@salud.madrid.org
Notes	

NCT05578638

Study name	"A Randomized Prospective Clinical Study on the Effect of Aloe Vera Gel and Rosmery Oil for Skin Ulcer Protection in Orthopedic Wards"
Methods	RCT
Participants	At-risk orthopaedic patients
Interventions	Aloe vera gel versus rosemary oil
Outcomes	Incidence of stage 1 pressure ulcers
Starting date	October 2022
Contact information	Mansoura University
Notes	

RBR-4s8qjx

Study name	Randomized clinical trial about multilayered soft silicone foam dressing to transparent polyurethane film: effectiveness in pressure ulcer prevention
Methods	RCT
Participants	• > 18 years old • High risk and very high risk for developing PU according to Braden scale • Evaluated by researcher within 24 hours of hospitalisation • Heels are healthy
Interventions	Multilayered soft silicone foam dressing versus transparent film
Outcomes	PU incidence; skin temperature
Starting date	22 July 2017
Contact information	rheasilviasoares@yahoo.com.br
Notes	Sponsor: Universidade Federal de Santa Maria - UFSM - Santa Maria, RS, Brazil

ICU: intensive care unit; **PI:** pressure injury; **PU**: pressure ulcer; **RCT**: randomised controlled trial

DATA AND ANALYSES

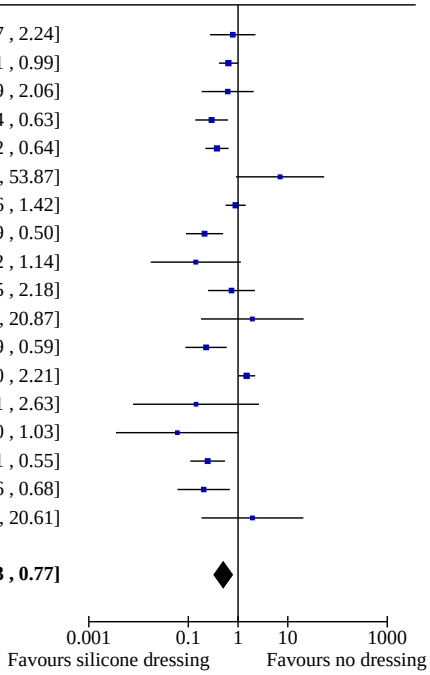
Comparison 1. Silicone dressing versus no dressing

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Pressure ulcer	18	5903	Risk Ratio (M-H, Random, 95% CI)	0.50 [0.33, 0.77]
1.2 Pressure ulcer stage	11		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.2.1 Stage 1	8	1823	Risk Ratio (M-H, Random, 95% CI)	0.32 [0.13, 0.79]
1.2.2 Stage 2	10	2873	Risk Ratio (M-H, Random, 95% CI)	0.47 [0.30, 0.73]
1.2.3 Stage 3	3	718	Risk Ratio (M-H, Random, 95% CI)	0.45 [0.06, 3.21]
1.2.4 Stage 4	2	610	Risk Ratio (M-H, Random, 95% CI)	0.21 [0.02, 1.77]
1.2.5 Unstageable	1	366	Risk Ratio (M-H, Random, 95% CI)	0.20 [0.01, 4.09]
1.2.6 Deep tissue injury	3	840	Risk Ratio (M-H, Random, 95% CI)	0.32 [0.09, 1.08]
1.3 Time to pressure ulcer development	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.4 Anatomical location of pressure ulcer development	5		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.4.1 Sacral pressure ulcer	5	2868	Risk Ratio (M-H, Random, 95% CI)	0.39 [0.24, 0.65]
1.4.2 Heel pressure ulcer	4	2624	Risk Ratio (M-H, Random, 95% CI)	0.44 [0.21, 0.95]

Analysis 1.1. Comparison 1: Silicone dressing versus no dressing, Outcome 1: Pressure ulcer

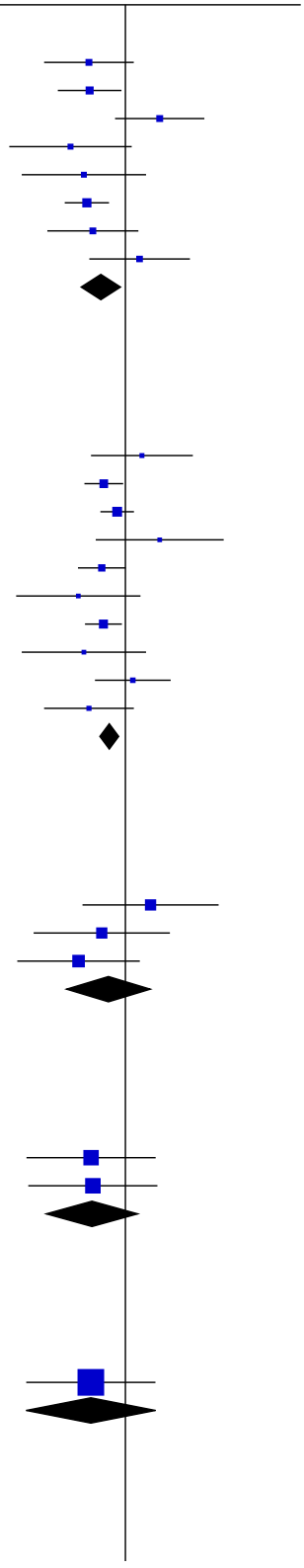
Study or Subgroup	Silicone dressing Events	Total	No dressing Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Aloweni 2017	5	129	10	202	6.1%	0.78 [0.27 , 2.24]
Beeckman 2021	43	1066	34	539	8.8%	0.64 [0.41 , 0.99]
De Wert 2019	4	117	7	127	5.4%	0.62 [0.19 , 2.06]
Forni 2018	8	177	28	182	7.4%	0.29 [0.14 , 0.63]
Forni 2022	17	351	46	358	8.4%	0.38 [0.22 , 0.64]
Gazineo 2020	7	34	1	34	3.0%	7.00 [0.91 , 53.87]
Guerra 2017	17	38	21	42	8.7%	0.89 [0.56 , 1.42]
Hahnel 2020	6	212	28	210	6.9%	0.21 [0.09 , 0.50]
Kalowes 2016	1	184	7	182	2.9%	0.14 [0.02 , 1.14]
Lee 2019	5	35	6	31	5.9%	0.74 [0.25 , 2.18]
Lovegrove 2022	2	66	1	64	2.4%	1.94 [0.18 , 20.87]
Oe 2020	5	300	22	300	6.5%	0.23 [0.09 , 0.59]
Otero 2017	48	74	17	39	9.0%	1.49 [1.00 , 2.21]
Qiuli 2010	0	26	3	26	1.7%	0.14 [0.01 , 2.63]
Saab 2015	0	45	6	35	1.8%	0.06 [0.00 , 1.03]
Santamaria 2015	7	161	27	152	7.2%	0.24 [0.11 , 0.55]
Santamaria 2018	3	138	16	150	5.4%	0.20 [0.06 , 0.68]
Walker 2015	2	39	1	38	2.4%	1.95 [0.18 , 20.61]
Total		**3192**		**2711**	**100.0%**	**0.50 [0.33 , 0.77]**
Total events:	180		281			

Test for overall effect: Z = 3.20 (P = 0.001)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² = 0.47; Chi² = 63.76, df = 17 (P < 0.00001); I² = 73%



Analysis 1.2. Comparison 1: Silicone dressing versus no dressing, Outcome 2: Pressure ulcer stage

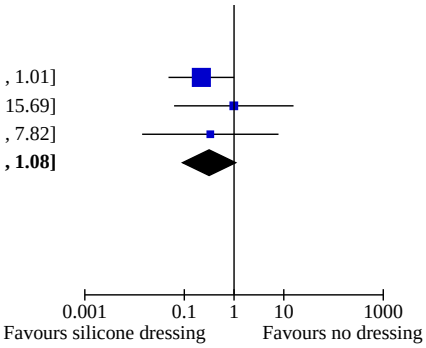
Study or Subgroup	Silicone dressing Events	Total	No dressing Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
1.2.1 Stage 1						
De Wert 2019	1	117	6	127	11.8%	0.18 [0.02 , 1.48]
Forni 2018	2	177	11	182	17.0%	0.19 [0.04 , 0.83]
Gazineo 2020	5	34	1	34	11.9%	5.00 [0.62 , 40.58]
Hahnel 2020	0	212	6	210	7.7%	0.08 [0.00 , 1.34]
Oe 2020	0	26	3	26	7.5%	0.14 [0.01 , 2.63]
Santamaria 2015	4	161	23	152	22.1%	0.16 [0.06 , 0.46]
Santamaria 2018	1	138	5	150	11.6%	0.22 [0.03 , 1.84]
Walker 2015	2	39	1	38	10.2%	1.95 [0.18 , 20.61]
Subtotal		**904**		**919**	**100.0%**	**0.32 [0.13 , 0.79]**
Total events:	15		56			
Test for overall effect: Z = 2.45 (P = 0.01)						
Heterogeneity: Tau² = 0.72; Chi² = 12.39, df = 7 (P = 0.09); I² = 44%						
1.2.2 Stage 2						
De Wert 2019	2	117	1	127	3.3%	2.17 [0.20 , 23.63]
Forni 2018	6	177	17	182	19.8%	0.36 [0.15 , 0.90]
Forni 2022	10	351	15	358	25.0%	0.68 [0.31 , 1.49]
Gazineo 2020	2	34	0	34	2.1%	5.00 [0.25 , 100.43]
Hahnel 2020	4	212	12	210	13.8%	0.33 [0.11 , 1.01]
Kalowes 2016	0	184	4	182	2.2%	0.11 [0.01 , 2.03]
Oe 2020	5	26	14	26	21.4%	0.36 [0.15 , 0.85]
Qiuli 2010	0	26	3	26	2.2%	0.14 [0.01 , 2.63]
Santamaria 2015	3	161	2	152	5.9%	1.42 [0.24 , 8.36]
Santamaria 2018	1	138	6	150	4.2%	0.18 [0.02 , 1.49]
Subtotal		**1426**		**1447**	**100.0%**	**0.47 [0.30 , 0.73]**
Total events:	33		74			
Test for overall effect: Z = 3.37 (P = 0.0008)						
Heterogeneity: Tau² = 0.04; Chi² = 9.77, df = 9 (P = 0.37); I² = 8%						
1.2.3 Stage 3						
De Wert 2019	1	117	0	127	31.4%	3.25 [0.13 , 79.11]
Hahnel 2020	0	212	1	210	31.3%	0.33 [0.01 , 8.06]
Oe 2020	0	26	4	26	37.3%	0.11 [0.01 , 1.96]
Subtotal		**355**		**363**	**100.0%**	**0.45 [0.06 , 3.21]**
Total events:	1		5			
Test for overall effect: Z = 0.79 (P = 0.43)						
Heterogeneity: Tau² = 0.54; Chi² = 2.44, df = 2 (P = 0.30); I² = 18%						
1.2.4 Stage 4						
Santamaria 2015	0	161	2	161	50.0%	0.20 [0.01 , 4.13]
Santamaria 2018	0	138	2	150	50.0%	0.22 [0.01 , 4.49]
Subtotal		**299**		**311**	**100.0%**	**0.21 [0.02 , 1.77]**
Total events:	0		4			
Test for overall effect: Z = 1.44 (P = 0.15)						
Heterogeneity: Tau² = 0.00; Chi² = 0.00, df = 1 (P = 0.97); I² = 0%						
1.2.5 Unstageable						
Kalowes 2016	0	184	2	182	100.0%	0.20 [0.01 , 4.09]
Subtotal		**184**		**182**	**100.0%**	**0.20 [0.01 , 4.09]**
Total events:	0		2			
Test for overall effect: Z = 1.05 (P = 0.29)						
Heterogeneity: Not applicable						
1.2.6 Deep tissue injury						



Analysis 1.2. (Continued)

1.2.6 Deep tissue injury						
Hahnel 2020	2	212	9	210	65.2%	0.22 [0.05 , 1.01]
Kalowes 2016	1	184	1	182	19.7%	0.99 [0.06 , 15.69]
Oe 2020	0	26	1	26	15.1%	0.33 [0.01 , 7.82]
Subtotal		**422**		**418**	**100.0%**	**0.32 [0.09 , 1.08]**
Total events:	3		11			

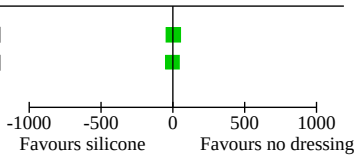
Test for overall effect: Z = 1.84 (P = 0.07)
Heterogeneity: Tau² = 0.00; Chi² = 0.88, df = 2 (P = 0.64); I² = 0%



Analysis 1.3. Comparison 1: Silicone dressing versus no dressing, Outcome 3: Time to pressure ulcer development

	Silicone dressing			No dressing			Mean Difference	Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**IV, Random, 95% CI**	**IV, Random, 95% CI**
Gazineo 2020	5.9	1.6	34	2.7	0.96	34	3.20 [2.57 , 3.83]	
Hahnel 2020	10.8	10.1	212	13.5	13.8	210	-2.70 [-5.01 , -0.39]	

Test for subgroup differences: Not applicable



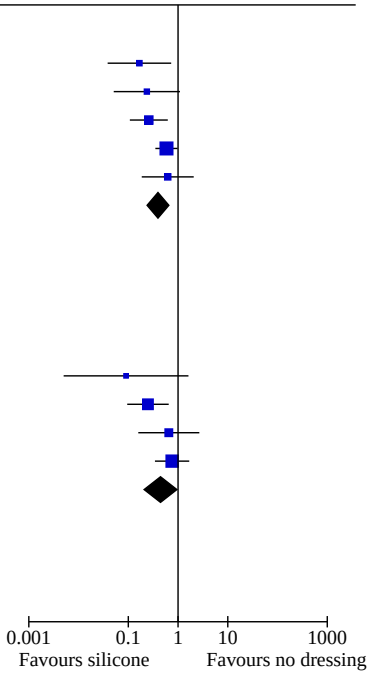
Analysis 1.4. Comparison 1: Silicone dressing versus no dressing, Outcome 4: Anatomical location of pressure ulcer development

	Silicone dressing		No dressing			Risk Ratio	Risk Ratio
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**M-H, Random, 95% CI**	**M-H, Random, 95% CI**
1.4.1 Sacral pressure ulcer							
Santamaria 2018	2	138	13	150	10.2%	0.17 [0.04 , 0.73]	
Santamaria 2015	2	161	8	152	9.5%	0.24 [0.05 , 1.09]	
Hahnel 2020	6	212	23	210	23.1%	0.26 [0.11 , 0.62]	
Beeckman 2021	30	1062	26	539	43.0%	0.59 [0.35 , 0.98]	
De Wert 2019	4	117	7	127	14.3%	0.62 [0.19 , 2.06]	
Subtotal		**1690**		**1178**	**100.0%**	**0.39 [0.24 , 0.65]**	
Total events:	44		77				

Test for overall effect: Z = 3.62 (P = 0.0003)
Heterogeneity: Tau² = 0.08; Chi² = 5.33, df = 4 (P = 0.25); I² = 25%

1.4.2 Heel pressure ulcer							
Hahnel 2020	0	212	5	210	6.3%	0.09 [0.01 , 1.62]	
Santamaria 2015	5	161	19	152	33.2%	0.25 [0.10 , 0.65]	
Santamaria 2018	3	138	5	150	20.5%	0.65 [0.16 , 2.68]	
Beeckman 2021	15	1063	10	538	40.0%	0.76 [0.34 , 1.68]	
Subtotal		**1574**		**1050**	**100.0%**	**0.44 [0.21 , 0.95]**	
Total events:	23		39				

Test for overall effect: Z = 2.10 (P = 0.04)
Heterogeneity: Tau² = 0.21; Chi² = 4.68, df = 3 (P = 0.20); I² = 36%

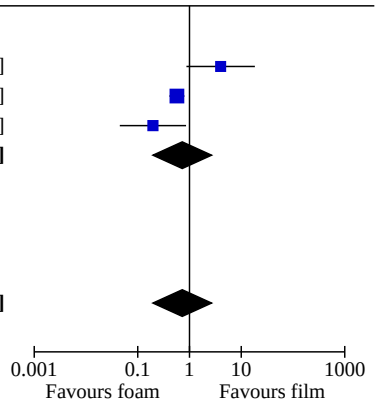


Comparison 2. Foam dressing versus film dressing

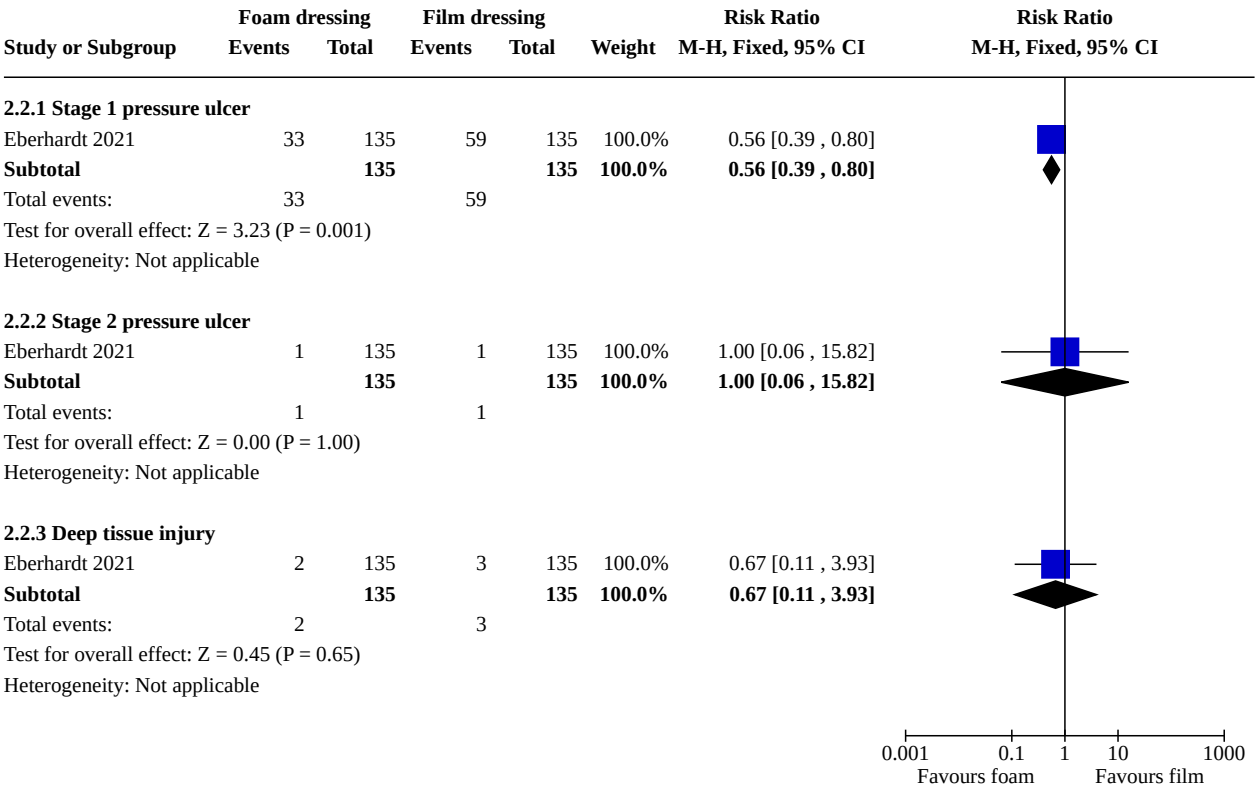
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Pressure ulcer	3	569	Risk Ratio (M-H, Random, 95% CI)	0.72 [0.20, 2.67]
2.1.1 Foam dressing versus film dressing	3	569	Risk Ratio (M-H, Random, 95% CI)	0.72 [0.20, 2.67]
2.2 Pressure ulcer stage	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.2.1 Stage 1 pressure ulcer	1	270	Risk Ratio (M-H, Fixed, 95% CI)	0.56 [0.39, 0.80]
2.2.2 Stage 2 pressure ulcer	1	270	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.06, 15.82]
2.2.3 Deep tissue injury	1	270	Risk Ratio (M-H, Fixed, 95% CI)	0.67 [0.11, 3.93]

Analysis 2.1. Comparison 2: Foam dressing versus film dressing, Outcome 1: Pressure ulcer

Study or Subgroup	Foam dressing Events	Foam dressing Total	Film dressing Events	Film dressing Total	Weight	Risk Ratio M-H, Random, 95% CI
2.1.1 Foam dressing versus film dressing						
Alves 2020	8	92	2	92	27.8%	4.00 [0.87 , 18.33]
Eberhardt 2021	36	135	63	135	43.6%	0.57 [0.41 , 0.80]
Yanping 2018	2	58	10	57	28.5%	0.20 [0.05 , 0.86]
Subtotal		**285**		**284**	**100.0%**	**0.72 [0.20 , 2.67]**
Total events:	46		75			
Test for overall effect: Z = 0.48 (P = 0.63)						
Heterogeneity: Tau² = 0.98; Chi² = 8.29, df = 2 (P = 0.02); I² = 76%						
Total		**285**		**284**	**100.0%**	**0.72 [0.20 , 2.67]**
Total events:	46		75			
Test for overall effect: Z = 0.48 (P = 0.63)						
Test for subgroup differences: Not applicable						
Heterogeneity: Tau² = 0.98; Chi² = 8.29, df = 2 (P = 0.02); I² = 76%						



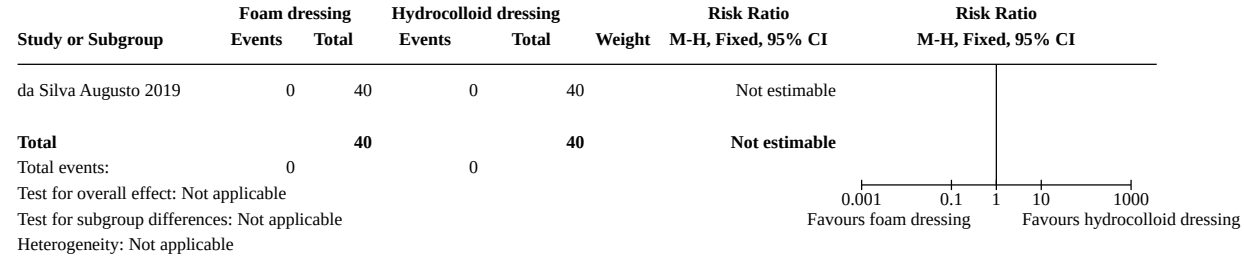
Analysis 2.2. Comparison 2: Foam dressing versus film dressing, Outcome 2: Pressure ulcer stage



Comparison 3. Hydrocellular foam dressing versus hydrocolloid dressing

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Pressure ulcer	1	80	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Analysis 3.1. Comparison 3: Hydrocellular foam dressing versus hydrocolloid dressing, Outcome 1: Pressure ulcer



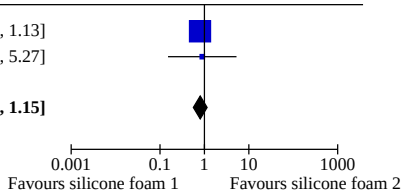
Comparison 4. Silicone foam dressing 1 versus silicone foam dressing 2

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.1 Pressure ulcer	2	376	Risk Ratio (M-H, Fixed, 95% CI)	0.80 [0.56, 1.15]

Analysis 4.1. Comparison 4: Silicone foam dressing 1 versus silicone foam dressing 2, Outcome 1: Pressure ulcer

Study or Subgroup	Silicone foam dressing 1 Events	Total	Silicone foam dressing 2 Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Otero 2017	20	35	28	39	91.2%	0.80 [0.56 , 1.13]
Stankiewicz 2019	2	129	3	173	8.8%	0.89 [0.15 , 5.27]
Total		**164**		**212**	**100.0%**	**0.80 [0.56 , 1.15]**
Total events:	22		31			

Test for overall effect: Z = 1.20 (P = 0.23)
Test for subgroup differences: Not applicable
Heterogeneity: Chi² = 0.02, df = 1 (P = 0.90); I² = 0%



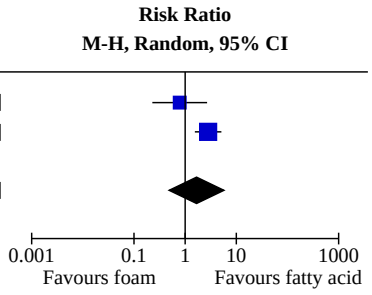
Comparison 5. Foam dressing versus fatty acid

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1 Pressure ulcer	2	300	Risk Ratio (M-H, Random, 95% CI)	1.67 [0.49, 5.72]

Analysis 5.1. Comparison 5: Foam dressing versus fatty acid, Outcome 1: Pressure ulcer

Study or Subgroup	Foam dressing Events	Total	Fatty acid Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Chang 2017	4	86	6	101	40.8%	0.78 [0.23 , 2.68]
Otero 2017	48	74	9	39	59.2%	2.81 [1.55 , 5.11]
Total		**160**		**140**	**100.0%**	**1.67 [0.49 , 5.72]**
Total events:	52		15			

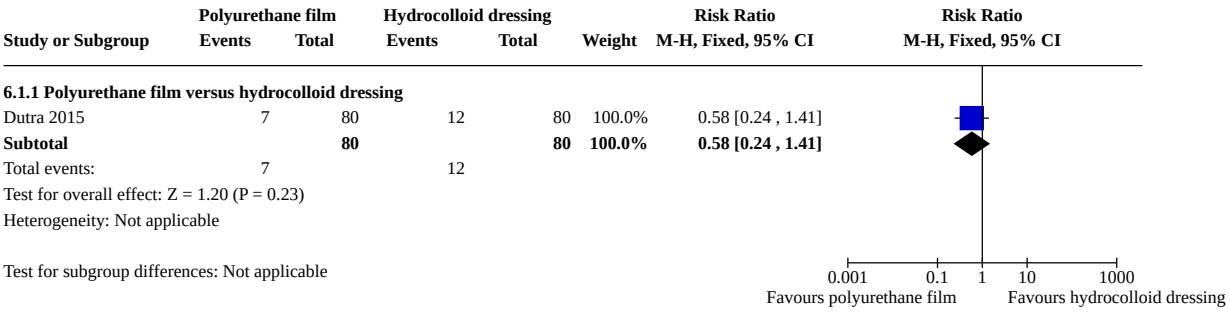
Test for overall effect: Z = 0.82 (P = 0.41)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² = 0.57; Chi² = 3.35, df = 1 (P = 0.07); I² = 70%



Comparison 6. Polyurethane film versus hydrocolloid dressing

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.1 Pressure ulcer	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
6.1.1 Polyurethane film versus hydrocolloid dressing	1	160	Risk Ratio (M-H, Fixed, 95% CI)	0.58 [0.24, 1.41]

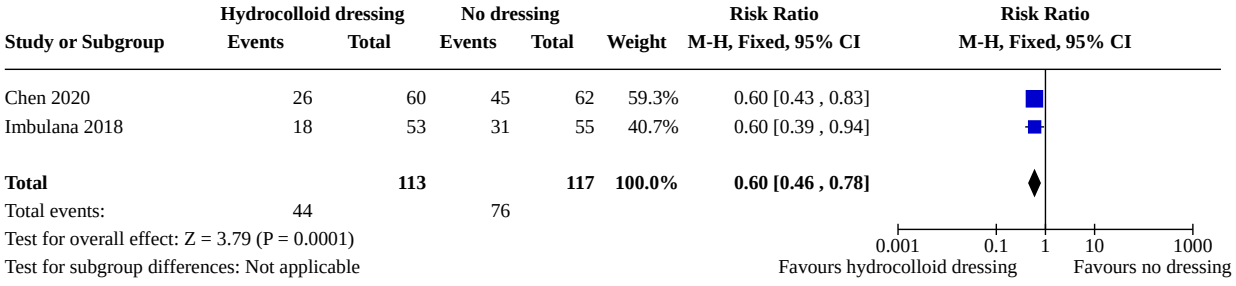
Analysis 6.1. Comparison 6: Polyurethane film versus hydrocolloid dressing, Outcome 1: Pressure ulcer



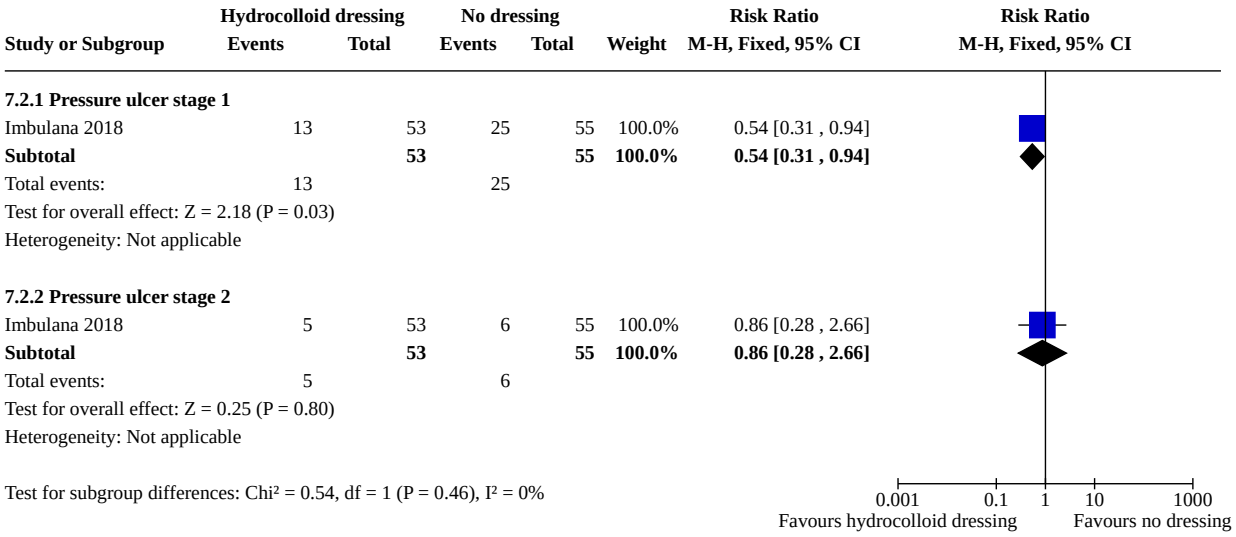
Comparison 7. Hydrocolloid dressing versus no dressing

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.1 Pressure ulcer	2	230	Risk Ratio (M-H, Fixed, 95% CI)	0.60 [0.46, 0.78]
7.2 Pressure ulcer stage	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
7.2.1 Pressure ulcer stage 1	1	108	Risk Ratio (M-H, Fixed, 95% CI)	0.54 [0.31, 0.94]
7.2.2 Pressure ulcer stage 2	1	108	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.28, 2.66]

Analysis 7.1. Comparison 7: Hydrocolloid dressing versus no dressing, Outcome 1: Pressure ulcer



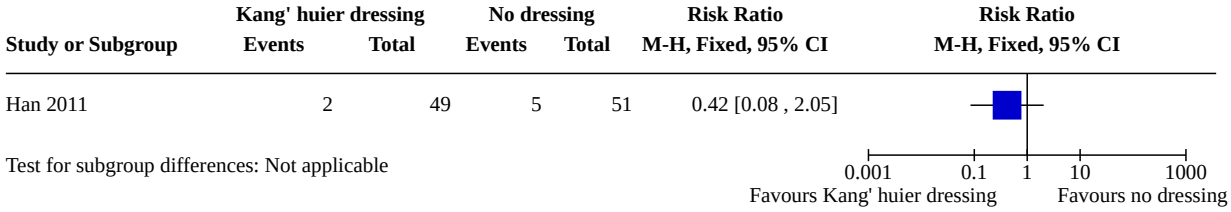
Analysis 7.2. Comparison 7: Hydrocolloid dressing versus no dressing, Outcome 2: Pressure ulcer stage



Comparison 8. Kang' huier dressing versus no dressing

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8.1 Pressure ulcer	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

Analysis 8.1. Comparison 8: Kang' huier dressing versus no dressing, Outcome 1: Pressure ulcer



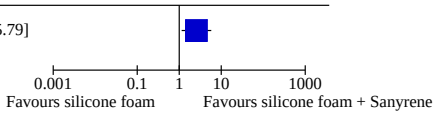
Comparison 9. Silicone foam dressing versus silicone foam dressing with Sanyrene

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
9.1 Pressure ulcer	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
9.2 Pressure ulcer stage	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
9.2.1 Pressure ulcer stage 1	1	150	Risk Ratio (M-H, Fixed, 95% CI)	2.50 [1.03, 6.09]
9.2.2 Pressure ulcer stage 2	1	150	Risk Ratio (M-H, Fixed, 95% CI)	3.00 [0.32, 28.19]

Analysis 9.1. Comparison 9: Silicone foam dressing versus silicone foam dressing with Sanyrene, Outcome 1: Pressure ulcer

Study or Subgroup	Silicone foam dressing Events	Total	Silicone foam dressing + Sanyrene Events	Total	Risk Ratio M-H, Fixed, 95% CI
Huang 2021	18	75	7	75	2.57 [1.14 , 5.79]

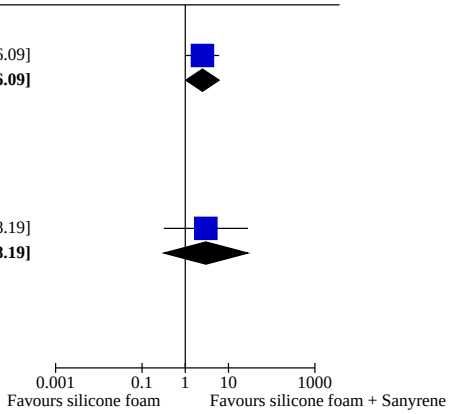
Test for subgroup differences: Not applicable



Analysis 9.2. Comparison 9: Silicone foam dressing versus silicone foam dressing with Sanyrene, Outcome 2: Pressure ulcer stage

Study or Subgroup	Silicone foam Events	Total	Silicone foam and sanyrene Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
9.2.1 Pressure ulcer stage 1						
Huang 2021	15	75	6	75	100.0%	2.50 [1.03 , 6.09]
Subtotal		**75**		**75**	**100.0%**	**2.50 [1.03 , 6.09]**
Total events:	15		6			
Test for overall effect: Z = 2.02 (P = 0.04)						
Heterogeneity: Not applicable						
9.2.2 Pressure ulcer stage 2						
Huang 2021	3	75	1	75	100.0%	3.00 [0.32 , 28.19]
Subtotal		**75**		**75**	**100.0%**	**3.00 [0.32 , 28.19]**
Total events:	3		1			
Test for overall effect: Z = 0.96 (P = 0.34)						
Heterogeneity: Not applicable						

Test for subgroup differences: $Chi^2 = 0.02$, df = 1 (P = 0.88), $I^2 = 0\%$



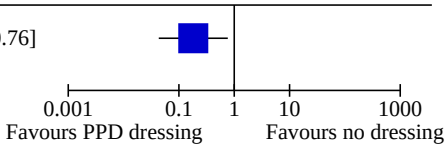
Comparison 10. Pressure ulcer preventative dressing versus no dressing

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
10.1 Pressure ulcer	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

Analysis 10.1. Comparison 10: Pressure ulcer preventative dressing versus no dressing, Outcome 1: Pressure ulcer

Study or Subgroup	PPD dressing Events	Total	No dressing Events	Total	Risk Ratio M-H, Fixed, 95% CI
Nakagami 2007	2	37	11	37	0.18 [0.04 , 0.76]

Test for subgroup differences: Not applicable



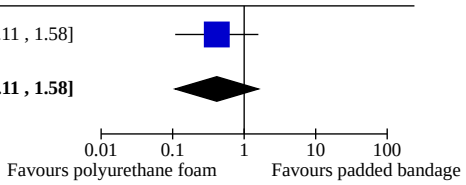
Comparison 11. Polyurethane foam dressing versus padded bandage

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
11.1 Pressure ulcer	1	409	Risk Ratio (M-H, Fixed, 95% CI)	0.41 [0.11, 1.58]

Analysis 11.1. Comparison 11: Polyurethane foam dressing versus padded bandage, Outcome 1: Pressure ulcer

Study or Subgroup	Polyurethane foam Events	Total	Padded bandage Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Ferrer Sola 2013	3	208	7	201	100.0%	0.41 [0.11 , 1.58]
Total		**208**		**201**	**100.0%**	**0.41 [0.11 , 1.58]**
Total events:	3		7			

Test for overall effect: Z = 1.29 (P = 0.20)
Test for subgroup differences: Not applicable
Heterogeneity: Not applicable



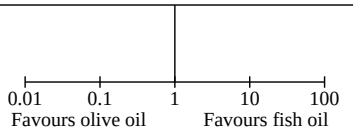
Comparison 12. Gauze soaked in olive oil versus gauze soaked in fish oil

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
12.1 Pressure ulcer	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

Analysis 12.1. Comparison 12: Gauze soaked in olive oil versus gauze soaked in fish oil, Outcome 1: Pressure ulcer

Study or Subgroup	Gauze soaked in olive oil Events	Total	Gauze soaked in fish oil Events	Total	Risk Ratio M-H, Fixed, 95% CI
Karimi 2020	0	50	0	50	Not estimable

Test for subgroup differences: Not applicable



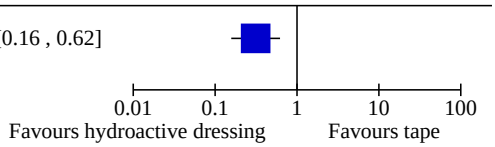
Comparison 13. Hydroactive dressing versus tape

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
13.1 Pressure ulcer	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

Analysis 13.1. Comparison 13: Hydroactive dressing versus tape, Outcome 1: Pressure ulcer

Study or Subgroup	Hydroactive dressing Events	Total	Tape Events	Total	Risk Ratio M-H, Fixed, 95% CI
Yang 2020	10	225	32	225	0.31 [0.16 , 0.62]

Test for subgroup differences: Not applicable

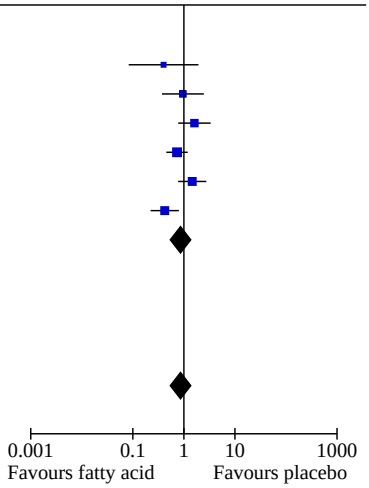


Comparison 14. Fatty acid versus placebo

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
14.1 Pressure ulcer	6	2201	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.54, 1.36]
14.1.1 Fatty acid versus placebo	6	2201	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.54, 1.36]
14.2 Anatomical location of pressure ulcer development	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
14.2.1 Sacral pressure ulcer	2	643	Risk Ratio (M-H, Fixed, 95% CI)	1.56 [0.63, 3.86]
14.2.2 Heel pressure ulcer	2	643	Risk Ratio (M-H, Fixed, 95% CI)	1.20 [0.39, 3.69]
14.2.3 Shoulder pressure ulcer	1	72	Risk Ratio (M-H, Fixed, 95% CI)	0.67 [0.12, 3.75]
14.3 Adverse event	3	967	Risk Ratio (M-H, Fixed, 95% CI)	4.38 [0.50, 38.30]

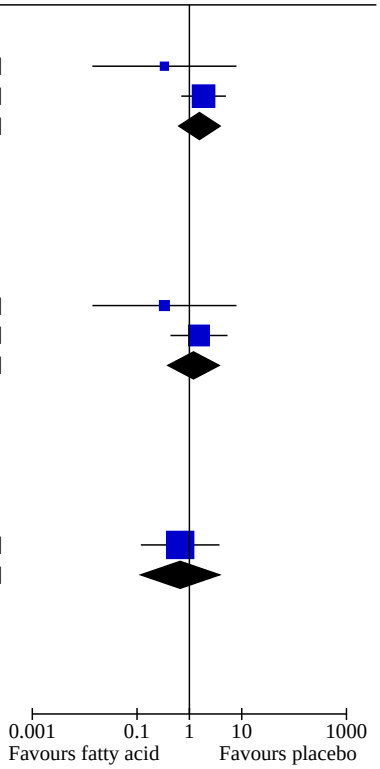
Analysis 14.1. Comparison 14: Fatty acid versus placebo, Outcome 1: Pressure ulcer

Study or Subgroup	Fatty acid Events	Total	Placebo Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
14.1.1 Fatty acid versus placebo						
Borzou 2020	2	36	5	36	6.7%	0.40 [0.08 , 1.93]
Díaz-Valenzuela 2014	8	117	8	112	13.5%	0.96 [0.37 , 2.46]
Díaz-Valenzuela 2019	18	288	11	283	17.5%	1.61 [0.77 , 3.34]
Green 1974	19	76	31	91	23.3%	0.73 [0.45 , 1.19]
Lupianez-Perez 2015	21	394	16	437	19.6%	1.46 [0.77 , 2.75]
Torra i Bou 2005	12	164	29	167	19.5%	0.42 [0.22 , 0.80]
Subtotal		**1075**		**1126**	**100.0%**	**0.86 [0.54 , 1.36]**
Total events:	80		100			
Test for overall effect: Z = 0.65 (P = 0.52)						
Heterogeneity: Tau² = 0.18; Chi² = 11.62, df = 5 (P = 0.04); I² = 57%						
Total		**1075**		**1126**	**100.0%**	**0.86 [0.54 , 1.36]**
Total events:	80		100			
Test for overall effect: Z = 0.65 (P = 0.52)						
Test for subgroup differences: Not applicable						
Heterogeneity: Tau² = 0.18; Chi² = 11.62, df = 5 (P = 0.04); I² = 57%						



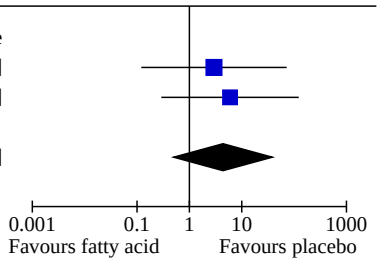
Analysis 14.2. Comparison 14: Fatty acid versus placebo, Outcome 2: Anatomical location of pressure ulcer development

Study or Subgroup	Fatty acid Events	Fatty acid Total	Placebo Events	Placebo Total	Weight	Risk Ratio M-H, Fixed, 95% CI
14.2.1 Sacral pressure ulcer						
Borzou 2020	0	36	1	36	20.1%	0.33 [0.01 , 7.92]
Díaz-Valenzuela 2019	11	283	6	288	79.9%	1.87 [0.70 , 4.98]
Subtotal		**319**		**324**	**100.0%**	**1.56 [0.63 , 3.86]**
Total events:	11		7			
Test for overall effect: Z = 0.96 (P = 0.34)						
Heterogeneity: Chi² = 1.04, df = 1 (P = 0.31); I² = 4%						
14.2.2 Heel pressure ulcer						
Borzou 2020	0	36	1	36	27.4%	0.33 [0.01 , 7.92]
Díaz-Valenzuela 2019	6	283	4	288	72.6%	1.53 [0.44 , 5.35]
Subtotal		**319**		**324**	**100.0%**	**1.20 [0.39 , 3.69]**
Total events:	6		5			
Test for overall effect: Z = 0.32 (P = 0.75)						
Heterogeneity: Chi² = 0.77, df = 1 (P = 0.38); I² = 0%						
14.2.3 Shoulder pressure ulcer						
Borzou 2020	2	36	3	36	100.0%	0.67 [0.12 , 3.75]
Subtotal		**36**		**36**	**100.0%**	**0.67 [0.12 , 3.75]**
Total events:	2		3			
Test for overall effect: Z = 0.46 (P = 0.65)						
Heterogeneity: Not applicable						



Analysis 14.3. Comparison 14: Fatty acid versus placebo, Outcome 3: Adverse event

Study or Subgroup	Fatty acid Events	Fatty acid Total	Placebo Events	Placebo Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Díaz-Valenzuela 2014	0	117	0	112		Not estimable
Díaz-Valenzuela 2019	1	288	0	283	52.5%	2.95 [0.12 , 72.07]
Green 1974	2	76	0	91	47.5%	5.97 [0.29 , 122.57]
Total		**481**		**486**	**100.0%**	**4.38 [0.50 , 38.30]**
Total events:	3		0			
Test for overall effect: Z = 1.34 (P = 0.18)						
Test for subgroup differences: Not applicable						
Heterogeneity: Chi² = 0.10, df = 1 (P = 0.75); I² = 0%						



Comparison 15. Fatty acid versus usual care

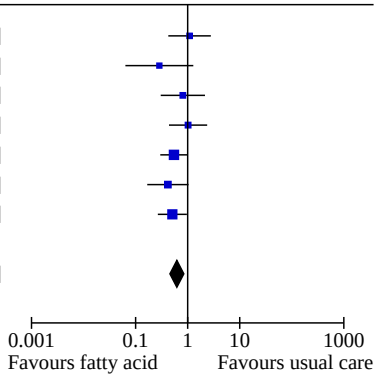
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
15.1 Pressure ulcer	7	1058	Risk Ratio (M-H, Fixed, 95% CI)	0.62 [0.46, 0.84]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
15.2 Pressure ulcer stage	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
15.2.1 Pressure ulcer stage 1	2	180	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.49, 2.03]
15.2.2 Pressure ulcer stage 2	2	180	Risk Ratio (M-H, Fixed, 95% CI)	0.19 [0.07, 0.53]
15.3 Time to pressure ulcer development	1	129	Mean Difference (IV, Fixed, 95% CI)	2.95 [1.11, 4.79]
15.4 Anatomical location of pressure ulcer	3		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
15.4.1 Sacral pressure ulcer	3	252	Risk Ratio (M-H, Fixed, 95% CI)	0.32 [0.15, 0.69]
15.4.2 Buttock pressure ulcer	2	180	Risk Ratio (M-H, Fixed, 95% CI)	0.60 [0.23, 1.58]
15.4.3 Iliac pressure ulcer	2	180	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.18, 5.66]
15.4.4 Shoulder pressure ulcer	2	132	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.21, 4.77]
15.4.5 Earlobe pressure ulcer	1	60	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.01, 7.87]
15.4.6 Heel pressure ulcer	1	72	Risk Ratio (M-H, Fixed, 95% CI)	0.20 [0.01, 4.03]

Analysis 15.1. Comparison 15: Fatty acid versus usual care, Outcome 1: Pressure ulcer

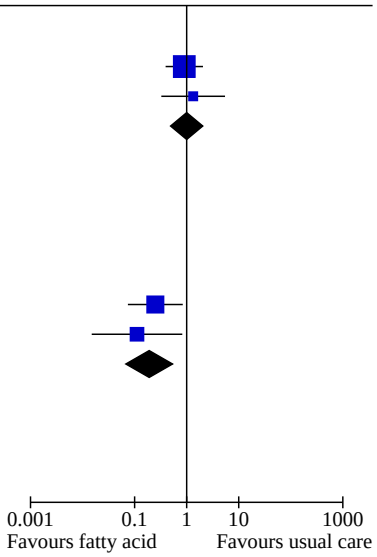
Study or Subgroup	Fatty acid Events	Fatty acid Total	Usual care Events	Usual care Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Aloweni 2017	7	130	10	202	8.9%	1.09 [0.42 , 2.79]
Borzou 2020	2	36	7	36	8.0%	0.29 [0.06 , 1.28]
Chang 2017	6	101	10	136	9.7%	0.81 [0.30 , 2.15]
Chiew 2010	9	54	9	55	10.2%	1.02 [0.44 , 2.37]
Fallahi 2022	12	60	22	60	25.1%	0.55 [0.30 , 1.00]
Madadi 2015	5	30	12	30	13.7%	0.42 [0.17 , 1.04]
Sonmez 2020	11	65	21	63	24.3%	0.51 [0.27 , 0.96]
Total		**476**		**582**	**100.0%**	**0.62 [0.46 , 0.84]**
Total events:	52		91			

Test for overall effect: Z = 3.06 (P = 0.002)
Test for subgroup differences: Not applicable
Heterogeneity: Chi² = 5.28, df = 6 (P = 0.51); I² = 0%



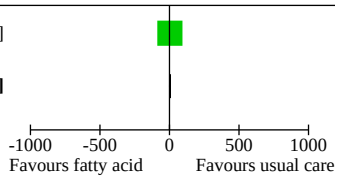
Analysis 15.2. Comparison 15: Fatty acid versus usual care, Outcome 2: Pressure ulcer stage

Study or Subgroup	Fatty acid Events	Fatty acid Total	Usual care Events	Usual care Total	Weight	Risk Ratio M-H, Fixed, 95% CI
15.2.1 Pressure ulcer stage 1						
Fallahi 2022	9	60	10	60	76.9%	0.90 [0.39 , 2.06]
Madadi 2015	4	30	3	30	23.1%	1.33 [0.33 , 5.45]
Subtotal		**90**		**90**	**100.0%**	**1.00 [0.49 , 2.03]**
Total events:	13		13			
Test for overall effect: Z = 0.00 (P = 1.00)						
Heterogeneity: Chi² = 0.22, df = 1 (P = 0.64); I² = 0%						
15.2.2 Pressure ulcer stage 2						
Fallahi 2022	3	60	12	60	57.1%	0.25 [0.07 , 0.84]
Madadi 2015	1	30	9	30	42.9%	0.11 [0.01 , 0.82]
Subtotal		**90**		**90**	**100.0%**	**0.19 [0.07 , 0.53]**
Total events:	4		21			
Test for overall effect: Z = 3.16 (P = 0.002)						
Heterogeneity: Chi² = 0.47, df = 1 (P = 0.49); I² = 0%						

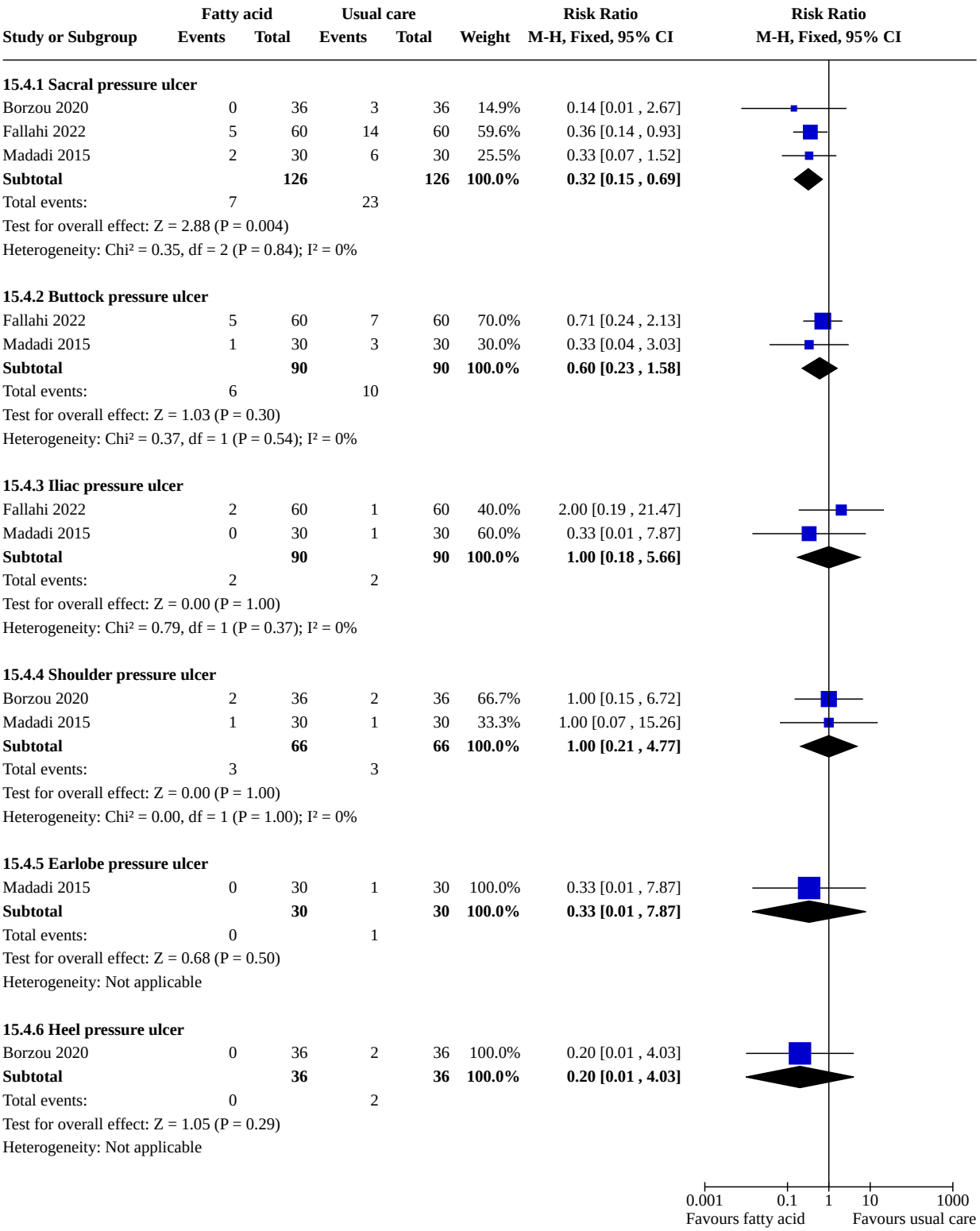


Analysis 15.3. Comparison 15: Fatty acid versus usual care, Outcome 3: Time to pressure ulcer development

Study or Subgroup	Fatty acid Mean	Fatty acid SD	Fatty acid Total	Usual care Mean	Usual care SD	Usual care Total	Weight	Mean Difference IV, Fixed, 95% CI
Sonmez 2020	10.45	5.2	65	7.5	5.43	64	100.0%	2.95 [1.11 , 4.79]
Total			**65**			**64**	**100.0%**	**2.95 [1.11 , 4.79]**
Test for overall effect: Z = 3.15 (P = 0.002)								
Test for subgroup differences: Not applicable								
Heterogeneity: Not applicable								



Analysis 15.4. Comparison 15: Fatty acid versus usual care, Outcome 4: Anatomical location of pressure ulcer

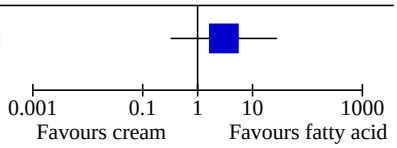


Comparison 16. Cream versus fatty acid

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
16.1 Pressure ulcer	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

Analysis 16.1. Comparison 16: Cream versus fatty acid, Outcome 1: Pressure ulcer

Study or Subgroup	Cream Events	Cream Total	Fatty acid Events	Fatty acid Total	Risk Ratio M-H, Fixed, 95% CI
Van Der Cammen 1987	3	60	1	60	3.00 [0.32 , 28.03]
Test for subgroup differences: Not applicable					

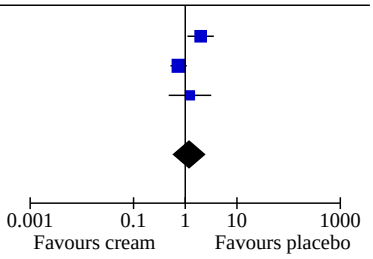


Comparison 17. Cream versus placebo

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
17.1 Pressure ulcer	3	513	Risk Ratio (M-H, Random, 95% CI)	1.18 [0.59, 2.36]
17.2 Pressure ulcer stage	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
17.2.1 Pressure ulcer stage 3	1	258	Risk Ratio (M-H, Fixed, 95% CI)	1.25 [0.34, 4.55]
17.2.2 Pressure ulcer stage 4	1	258	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.01, 8.11]

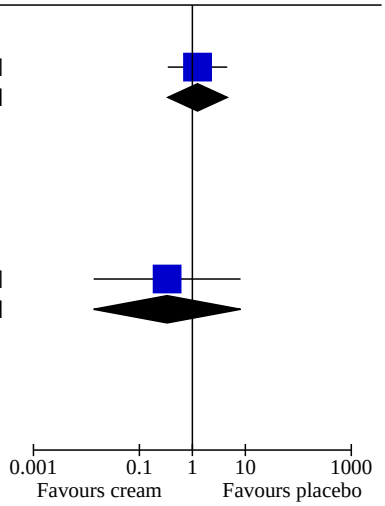
Analysis 17.1. Comparison 17: Cream versus placebo, Outcome 1: Pressure ulcer

Study or Subgroup	Cream Events	Cream Total	Placebo Events	Placebo Total	Weight	Risk Ratio M-H, Random, 95% CI
Houwing 2008	18	29	10	32	34.5%	1.99 [1.10 , 3.57]
Smith 1985	35	129	47	129	40.9%	0.74 [0.52 , 1.07]
Verdu 2012	9	99	7	95	24.6%	1.23 [0.48 , 3.18]
Total		**257**		**256**	**100.0%**	**1.18 [0.59 , 2.36]**
Total events:	62		64			
Test for overall effect: Z = 0.48 (P = 0.63)						
Test for subgroup differences: Not applicable						
Heterogeneity: Tau² = 0.27; Chi² = 7.97, df = 2 (P = 0.02); I² = 75%						



Analysis 17.2. Comparison 17: Cream versus placebo, Outcome 2: Pressure ulcer stage

Study or Subgroup	Cream Events	Cream Total	Placebo Events	Placebo Total	Weight	Risk Ratio M-H, Fixed, 95% CI
17.2.1 Pressure ulcer stage 3						
Smith 1985	5	129	4	129	100.0%	1.25 [0.34 , 4.55]
Subtotal		**129**		**129**	**100.0%**	**1.25 [0.34 , 4.55]**
Total events:	5		4			
Test for overall effect: Z = 0.34 (P = 0.73)						
Heterogeneity: Not applicable						
17.2.2 Pressure ulcer stage 4						
Smith 1985	0	129	1	129	100.0%	0.33 [0.01 , 8.11]
Subtotal		**129**		**129**	**100.0%**	**0.33 [0.01 , 8.11]**
Total events:	0		1			
Test for overall effect: Z = 0.67 (P = 0.50)						
Heterogeneity: Not applicable						

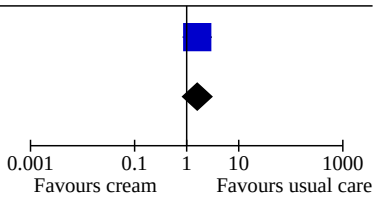


Comparison 18. Cream versus usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
18.1 Pressure ulcer	1	47	Risk Ratio (M-H, Fixed, 95% CI)	1.60 [0.84, 3.04]

Analysis 18.1. Comparison 18: Cream versus usual care, Outcome 1: Pressure ulcer

Study or Subgroup	Cream Events	Cream Total	Usual care Events	Usual care Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Houwing 2008	18	29	7	18	100.0%	1.60 [0.84 , 3.04]
Total		**29**		**18**	**100.0%**	**1.60 [0.84 , 3.04]**
Total events:	18		7			
Test for overall effect: Z = 1.42 (P = 0.16)						
Test for subgroup differences: Not applicable						
Heterogeneity: Not applicable						



Comparison 19. Aloe vera versus aloe vera and oil

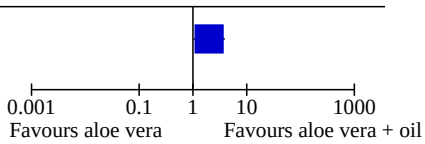
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
19.1 Pressure ulcer	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
19.2 Pressure ulcer stage	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
19.2.1 Pressure ulcer stage 1	1	120	Risk Ratio (M-H, Fixed, 95% CI)	1.62 [0.73, 3.63]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
19.2.2 Pressure ulcer stage 2	1	120	Risk Ratio (M-H, Fixed, 95% CI)	3.50 [0.76, 16.17]
19.3 Anatomical location of pressure ulcer	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
19.3.1 Sacral pressure ulcer	1	120	Risk Ratio (M-H, Fixed, 95% CI)	3.00 [0.85, 10.54]
19.3.2 Buttock pressure ulcer	1	120	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.34, 2.93]
19.3.3 Iliac pressure ulcer	1	120	Risk Ratio (M-H, Fixed, 95% CI)	5.00 [0.60, 41.53]

Analysis 19.1. Comparison 19: Aloe vera versus aloe vera and oil, Outcome 1: Pressure ulcer

Study or Subgroup	Aloe vera Events	Aloe vera Total	Aloe vera and oil Events	Aloe vera and oil Total	Risk Ratio M-H, Fixed, 95% CI
Fallahi 2022	20	60	10	60	2.00 [1.02 , 3.91]

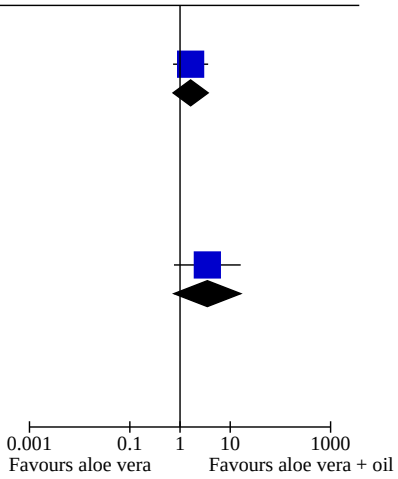
Test for subgroup differences: Not applicable



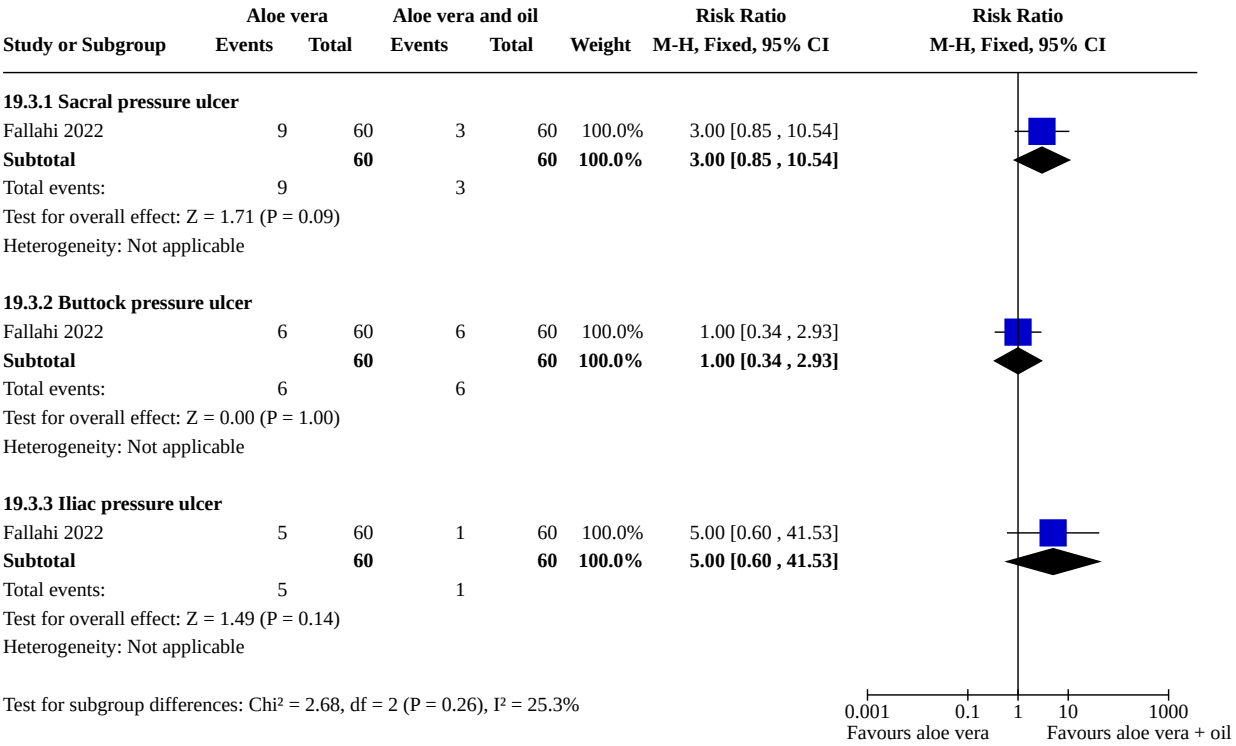
Analysis 19.2. Comparison 19: Aloe vera versus aloe vera and oil, Outcome 2: Pressure ulcer stage

Study or Subgroup	Aloe vera Events	Aloe vera Total	Aloe vera and oil Events	Aloe vera and oil Total	Weight	Risk Ratio M-H, Fixed, 95% CI
19.2.1 Pressure ulcer stage 1						
Fallahi 2022	13	60	8	60	100.0%	1.63 [0.73 , 3.63]
Subtotal		**60**		**60**	**100.0%**	**1.63 [0.73 , 3.63]**
Total events:	13		8			
Test for overall effect: Z = 1.18 (P = 0.24)						
Heterogeneity: Not applicable						
19.2.2 Pressure ulcer stage 2						
Fallahi 2022	7	60	2	60	100.0%	3.50 [0.76 , 16.17]
Subtotal		**60**		**60**	**100.0%**	**3.50 [0.76 , 16.17]**
Total events:	7		2			
Test for overall effect: Z = 1.60 (P = 0.11)						
Heterogeneity: Not applicable						

Test for subgroup differences: $Chi^2 = 0.76$, df = 1 (P = 0.38), $I^2 = 0\%$



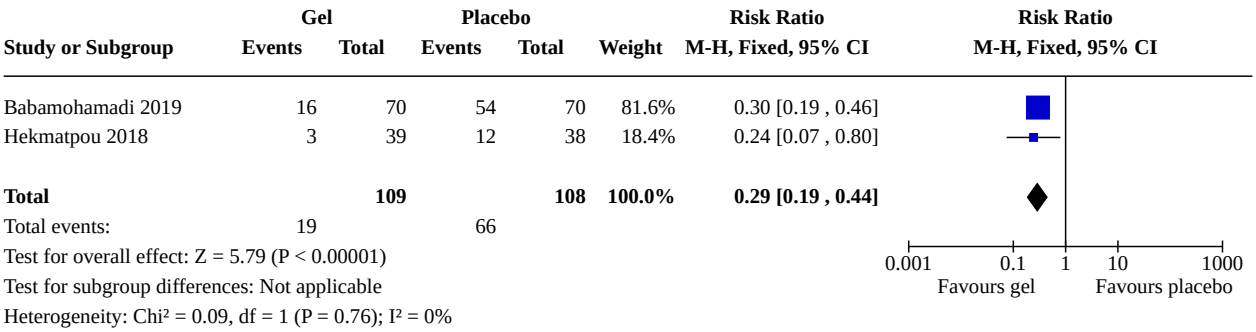
Analysis 19.3. Comparison 19: Aloe vera versus aloe vera and oil, Outcome 3: Anatomical location of pressure ulcer



Comparison 20. Gel versus placebo

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
20.1 Pressure ulcer	2	217	Risk Ratio (M-H, Fixed, 95% CI)	0.29 [0.19, 0.44]

Analysis 20.1. Comparison 20: Gel versus placebo, Outcome 1: Pressure ulcer



ADDITIONAL TABLES

Table 1. Intervention topical agents and dressings

Trial (author/year)	Topical agents	Dressings
Aloweni 2017	Fatty acid	Multilayered, silicone-adhesive polyurethane foam (Mölnlycke)
Alves 2020		1. Multilayered, soft silicone foam (name not stated) 2. Polyurethane film (name not stated)
Babamohamadi 2019	Gel (peppermint gel)	
Beeckman 2021		1. Silicone adhesive multilayer foam dressing (Smith & Nephew) 2. Silicone adhesive multilayer foam dressing (Mölnlycke)
Borzou 2020	Fatty acid (sweet almond oil)	
Chang 2017	Fatty acid	Multilayer silicone (name not stated)
Chen 2020		Hydrocolloid dressing (name not stated)
Chiew 2010	Fatty Acid (Sanyrene® solution, a hyperoxygenated oil of essential fatty acids)	
da Silva Augusto 2019		1. Hydrocellular foam (name not stated) 2. Hydrocolloid plate (name not stated)
De Wert 2019		Multilayer soft silicone self-adherent sacral dressing (Mölnlycke)
Díaz-Valenzuela 2014	Fatty acid (Mepentol, a hyperoxygenated fatty acid compound consisting of oleic acid, palmitic acid, stearic acid, palmitoleic acid, linoleic acid, gamma linoleic acid, arachidonic acid, and eicosenoic acid)	
Díaz-Valenzuela 2019	1. Hyperoxygenated fatty acid 2. Fatty acid (olive oil)	
Dutra 2015		1. Polyurethane film (OpSite, Smith and Nephew Ltd., Hull, UK) 2. Hydrocolloid dressing (Systagenix Wound Management Ltd., Vinhedo, Brazil)
Eberhardt 2021		1. Multilayered silicone foam (Mölnlycke) 2. Polyurethane film (Advanced, Cremer, brand used at the study site)
Fallahi 2022	Gel (aloe vera gel), fatty acid (olive oil), and gel (compound aloe vera gel-olive oil)	
Ferrer Sola 2013		1. Polyurethane heel (Allevyn Heel, Smith & Nephew) 2. Classic padded bandage

Table 1. Intervention topical agents and dressings *(Continued)*

Forni 2018		Polyurethane foam multilayer (Smith & Nephew)
Forni 2022		Multilayered, silicone-adhesive polyurethane foam (Smith & Nephew)
Gazineo 2020		Multilayered polyurethane foam dressing (Smith & Nephew)
Green 1974	Fatty acid (Dermalex: consisting of hexachlorophane 0.5%, squalene (Cosbiol 3%), and allantoin 0.2%, lanolin, fatty acids, fatty alcohols, and antioxidants)	
Guerra 2017		Polyurethane foam dressing (name not stated)
Hahnel 2020		Multilayered polyurethane foam dressing (Mölnlycke)
Han 2011		Kang' huier transparent strip and foam dressing
Hekmatpou 2018	Gel (aloe vera gel)	
Houwing 2008	Cream (DMSO-cream: consisting of 5% dimethyl sulfoxide in Vaseline-cetomacrogol cream)	
Huang 2021	Fatty acid (Sanyrene, hyperoxygenated oil of essential fatty acids), and foam dressing	1. Foam dressing (Mölnlycke) 2. Foam dressing (Mölnlycke) (and Sanyrene)
Imbulana 2018		Hydrocolloid dressing (Neo-Guard dressing)
Kalowes 2016		Soft silicone, self-adherent, bordered multilayer foam dressing (Mölnlycke)
Karimi 2020		Gauze soaked in olive oil Gauze soaked in fish oil
Lee 2019		Silicone adhesive dressing (Smith & Nephew)
Lovegrove 2022		Silicone adhesive dressing (Smith & Nephew)
Lupianez-Perez 2015	1. Fatty acid (hyperoxygenated fatty acids) 2. Fatty acid (an olive oil product)	
Madadi 2015	Fatty acid (premium and standard formula olive oil)	
Nakagami 2007		PPD (pressure ulcer preventive dressing) with skin adhesive layer (hydrocolloid), a support layer (urethane film), and an outer layer of multi-filament nylon fibres)
Oe 2020		Multilayered silicone foam dressing (Mölnlycke)
Otero 2017	Fatty acid (hyperoxygenated fatty acids, containing linoleic acid 60% to 70%)	Group B: adhesive thin polyurethane foam dressing (Allevyn thin; Smith & Nephew)

Table 1. Intervention topical agents and dressings *(Continued)*

		Group C: adhesive foam dressings (Askina Foam; B. Braun)
Ozbudak 2020		Transparent film (name not stated)
Qiuli 2010		Multilayered silicone foam dressing (Mölnlycke)
Saab 2015		Gel adhesive hydrocellular foam (name not stated)
Santamaria 2015		Soft silicone, self-adherent, bordered multilayer foam dressing (Mölnlycke)
Santamaria 2018		Soft silicone, self-adherent, bordered multilayer foam dressing (Mölnlycke)
Smith 1985	Cream (Conotrane: consisting of a silicone cream, 20% dimethicone 350, and a broad-spectrum antiseptic, 0.05% hydrargaphen)	
Sonmez 2020	Fatty acid (extra virgin olive oil)	
Stankiewicz 2019		1. Multilayer silicone foam dressing type (Mölnlycke) 2. Multilayer silicone foam dressing type (Smith & Nephew)
Torra i Bou 2005	Fatty acid (Mepentol: a hyperoxygenated fatty acid compound consisting of oleic acid, palmitic acid, stearic acid, palmitoleic acid, linoleic acid, gamma linoleic acid, arachidonic acid, and eicosenoic acid)	
Van Der Cammen 1987	Cream (Prevasore: consisting of hexyl nicotinate, zinc stearate, isopropyl myristate, dimethicone 350, cetrimide and glycol)	
Verdu 2012	Cream (IPARZINE-4A-SKR, containing: "Eau Purifiee; Miglyol, Ginkgo et Centella Asiatica Extraitglycerine, Huiles Vegetales a Forte Teneur en A.G.E. Sepigel, Lanette SX, Emulpharma 30, Glycerine pH Euro 99·5% PF, Cosmocil CQ, Iparzine-4A, Symdiol 68, Huile Silicone Baysilone M350, l-Serine, Coviox T50C, Perfume").	
Wang 2016		Adhesive foam dressing (Smith & Nephew)
Yang 2020		Hydroactive dressing Standard medical tape
Yanping 2018		Foam dressing (Coloplast) Transparent film dressing
Walker 2015		Soft silicone, self-adherent, bordered multilayer foam dressing (Molnlycke Health Care)

Table 2. Kang' huier dressing versus no dressing

Kang' huier dressing versus no dressing						
Patient or population: individuals at risk of pressure ulcer development **Settings:** spinal surgery **Intervention:** Kang' huier dressing **Comparison:** no dressing						
Outcomes	**Illustrative comparative risks* (95% CI)**		**Relative effect (95% CI)**	**№ of participants (studies)**	**Certainty of the evidence (GRADE)**	**Comments**
	Assumed risk with no dressing	**Corresponding risk with Kang' huier dressing**				
Pressure ulcer incidence Assessed with observation Follow-up: 3 days	**Study population**		**RR 0.42** (0.08 to 2.05)	100 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	Kang' huier dressing may have little to no effect on the incidence of pressure ulcers compared to no dressing, but the evidence is very uncertain (Kang' huier dressing group: 4%, 2/49; no dressing: 10%, 5/51).
	98 per 1000	**41 per 1000** (8 to 201)				
Pressure ulcer stage	Not reported					
Adverse events	Not reported					

*The basis for the **assumed risk** (e.g. the median control group risk across trials) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT:** randomised controlled trial; **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 once for high risk of performance and detection bias, and unclear risk of selection, reporting, and other bias; downgraded twice for very serious imprecision due to a small number of events and a very wide confidence interval, which includes 1.

Table 3. Silicone foam dressing versus silicone foam dressing and Sanyrene

Silicone foam dressing versus silicone foam dressing and Sanyrene for preventing pressure ulcers
Patient or population: individuals at risk of pressure ulcer development **Setting:** thoracolumbar surgery setting **Intervention:** silicone foam dressing **Comparison:** silicone foam dressing and Sanyrene

Table 3. Silicone foam dressing versus silicone foam dressing and Sanyrene *(Continued)*

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk with silicone foam dressing and Sanyrene	Corresponding risk with silicone foam dressing				
Pressure ulcer incidence Assessed with observation Follow-up: unclear	**Study population** 93 per 1000	**240 per 1000** (106 to 540)	**RR 2.57** (1.14 to 5.79	150 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	Silicone foam dressing with Sanyrene may reduce pressure ulcer incidence compared to silicone foam dressing, but the evidence is very uncertain (silicone foam dressing: 24%, 18/75; silicone foam dressing and Sanyrene: 9%, 7/75).
Pressure ulcer stage 1 Assessed with observation Follow-up: unclear	**Study population** 80 per 1000	**200 per 1000** (82 to 487)	**RR 2.50** (1.03 to 6.09)	150 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	Silicone foam dressing with Sanyrene may reduce stage 1 pressure ulcer incidence compared to silicone foam dressings, but the evidence is very uncertain (silicone foam dressing: 20%, 15/75; silicone foam dressing and Sanyrene: 8%, 6/75).
Pressure ulcer stage 2 Assessed with observation Follow-up: unclear	**Study population** 13 per 1000	**40 per 1000** (4 to 376)	**RR 3.00** (0.32 to 28.19)	150 (1 RCT)	⊕⊖⊖⊖ **Very low**[b]	Silicone foam dressing with Sanyrene may have little to no effect on the incidence of stage 2 pressure ulcer compared to silicone foam dressings, but the evidence is very uncertain (silicone foam dressing:4%, 3/75; silicone foam dressing and Sanyrene: 1.3%,1/75).
Adverse events	Not reported					

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT:** randomised controlled trial; **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 once for unclear risk of selection, performance, detection, and reporting bias; downgraded twice for imprecision due to the small number of events, small sample size, and very wide confidence interval.
[b]Downgraded once for unclear risk of selection, performance, detection, and reporting bias; downgraded twice for imprecision due to the small number of events, small sample size, and very wide confidence interval, which includes 1.

Table 4. Pressure ulcer preventative dressing versus no dressing

Pressure ulcer preventative dressing (PPD) versus no dressing						
Patient or population: individuals at risk of pressure ulcer development **Settings:** care of the older person **Intervention:** PPD dressing **Comparison:** no dressing						
Outcomes	**Illustrative comparative risks* (95% CI)**		**Relative effect (95% CI)**	**№ of participants (trials)**	**Certainty of the evidence (GRADE)**	**Comments**
	Assumed risk with no dressing	**Corresponding risk with PPD dressing**				
Pressure ulcer incidence Assessed with observation Follow-up: 3 weeks	**Study population**		**RR 0.18** (0.04 to 0.76)	74 (1 RCT)	⊕⊝⊝⊝ **Very low**[a]	PPD dressing may have little to no effect on the incidence of pressure ulcer compared to no dressing, but the evidence is very uncertain (PPD group: 5%,2/37; no-dressing group: 29%, 11/37).
	297 per 1000	**54 per 1000** (12 to 226)				
Pressure ulcer stage	Not reported					
Adverse events	Not reported					

*The basis for the **assumed risk** (e.g. the median control group risk across trials) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **PPD:** pressure ulcer preventive dressing; **RCT:** randomised controlled trial; **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 once for high risk of performance, detection, and other bias, and unclear risk of selection and reporting bias; downgraded twice for very serious imprecision due to a small number of events, a small sample size, and a wide confidence interval.

Table 5. Polyurethane foam dressing versus padded bandage

Polyurethane foam dressing versus padded bandage
Patient or population: individuals at risk of pressure ulcer development **Settings:** hospital setting **Intervention:** polyurethane foam dressing

Table 5. Polyurethane foam dressing versus padded bandage *(Continued)*
Comparison: padded bandage

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk with padded bandage	Corresponding risk with polyurethane foam				
Pressure ulcer incidence Assessed with observation Follow up: 15 days	**Study population**		RR 0.41 (0.11 to1.58)	409 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	Polyurethane foam dressings may have little to no effect on the incidence of pressure ulcers compared to padded bandages, but the evidence is very uncertain (polyurethane foam dressing group: 2.4%, 3/208; padded bandage group: 3.5%, 7/201).
	35 per 1000	**24 per 1000** (8 to 75)				
Stage of pressure ulcer	Not reported					
Adverse events	Not reported					

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT:** randomised controlled trial; **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 once for unclear risk of selection, performance, detection, and reporting bias; downgraded twice for very serious imprecision due to a small number of events and a very wide confidence interval, which includes 1.

Table 6. Gauze soaked in olive oil versus gauze soaked in fish oil

Gauze soaked in olive oil versus gauze soaked in fish oil

Patient or population: individuals at risk of pressure ulcer development
Settings: intensive care
Intervention: gauze soaked in olive oil
Comparison: gauze soaked in fish oil

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	№ of participants (trials)	Certainty of the evidence (GRADE)	Comments
	Assumed risk with fish oil	Corresponding				

Table 6. Gauze soaked in olive oil versus gauze soaked in fish oil *(Continued)*

		risk with olive oil				
Pressure ulcer incidence Assessed with observation Follow-up: 7days	**Study population**		Risk ratio not estimable	100 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	Gauze soaked in olive oil may have little to no effect on the incidence of pressure ulcers compared to gauze soaked in fish oil, but the evidence is very uncertain (olive oil group: 0%, 0/50; fish oil group: 0%, 0/50).
	0 per 1000	**0 per 1000** (0 to 0)				
Pressure ulcer stage	Not reported					
Adverse events Assessed with observation Follow-up: 7days	**Study population**		Risk ratio not estimable	100 (1 RCT)	⊕### **Very low**[a]	Gauze soaked in olive oil may have little to no effect on the incidence of adverse events compared to gauze soaked in fish oil, but the evidence is very uncertain (olive oil group: 0%, 0/50; fish oil group: 0%, 0/50).
	0 per 1000	**0 per 1000** (0 to 0)				

*The basis for the **assumed risk** (e.g. the median control group risk across trials) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT:** randomised controlled trial; **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 once for high risk of performance bias and unclear risk of selection and reporting bias; downgraded twice for serious imprecision due to no events and a small sample size.

Table 7. Hydroactive dressing versus tape

Hydroactive dressing versus tape						
Patient or population: at risk individuals **Setting:** hospital patients undergoing oral surgery **Intervention:** hydroactive dressing **Comparison:** tape						
Outcomes	**Anticipated absolute effects* (95% CI)**		**Relative effect (95% CI)**	**№ of participants (trials)**	**Certainty of the evidence (GRADE)**	**Comments**
	Assumed risk with tape	**Corresponding risk with hydroactive dressing**				
Pressure ulcer incidence	**Study population**		**RR 0.31**	450 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	Hydroactive dressings may reduce pressure ulcer incidence

Table 7. Hydroactive dressing versus tape *(Continued)*

Assessed with observation Follow-up: 72 hours	142 per 1000	**140 per 1000** (97 to 119)	(0.16 to 0.62)	compared to tape, but the evidence is very uncertain (hydroactive dressing group: 4.4% 10/225; tape group 14.2%; 32/225).
Pressure ulcer grade	Not reported			
Adverse events	Not reported			

***The risk in the intervention group** (and its 95% confidence interval) is based on the mean risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT:** randomised controlled trial; **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 once for unclear risk of selective reporting bias; downgraded twice for very serious imprecision due to a small number of events and a wide confidence interval.

Table 8. Aloe vera versus aloe vera and oil

Aloe vera versus aloe vera and oil

Patient or population: individuals at risk of pressure ulcer development
Setting: intensive care units
Intervention: aloe vera
Comparison: aloe vera and oil

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with aloe vera and oil	Risk with aloe vera				
Pressure ulcer incidence Assessed with observation Follow-up: 30 days	**Study population**		**RR 2.00** 1.02 to 3.91	120 (1 RCT)	⊕⊖⊖⊖ **Very low**[a]	Aloe vera may increase the incidence of pressure ulcers compared to aloe vera and oil, but the evidence is very uncertain (aloe vera group: 33%, 20/60; aloe vera and oil group: 16.7%, 10/60).
	167 per 1000	**333 per 1000** (170 to652)				
Pressure ulcer stage 1 Assessed with	**Study population**		**RR 1.63** 0.73 to 3.63	120 (1 RCT)	⊕⊖⊖⊖ **Very low**[b]	Aloe vera may have little to no effect on the incidence of stage 1 pressure ulcer compared to aloe vera and oil, but the evidence is very uncertain (aloe vera group: 21.7%, 13/60; aloe vera and oil group: 13.3%, 8/60).
	133 per 1000	**217 per 1000** (97 to 434)				

Table 8. Aloe vera versus aloe vera and oil *(Continued)*

observation Follow-up: 30 days						
Pressure ulcer stage 2 Assessed with observation Follow-up: 30 days	**Study population**		**RR 3.50** (0.76 to 16.17)	120 (1 RCT)	⊕⊖⊖⊖ **Very low**[b]	Aloe vera may have little to no effect on the incidence of stage 2 pressure ulcer compared to aloe vera and oil, but the evidence is very uncertain (aloe vera group: 11.7%, 7/60; aloe vera and oil group: 3.3%, 2/60).
	33 per 1000	**117 per 1000** (25 to 539)				
Adverse events	Not reported					

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the mean risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT:** randomised controlled trial; **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 three times for extremely serious imprecision due to a small sample size, a small number of events, and a wide confidence interval.
[b]Downgraded three times for extremely serious imprecision due to a small sample size, a small number of events, and a wide confidence interval, which crosses 1.

Table 9. Gel versus placebo

Gel versus placebo

Patient or population: individuals at risk of pressure ulcer development
Setting: intensive care unit
Intervention: gel
Comparison: placebo

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	№ of participants (trials)	Certainty of the evidence (GRADE)	Comments
	Assumed risk with placebo	Corresponding risk with gel				
Pressure ulcer incidence Assessed with observation Follow-up: 10 to 14 days	**Study population**		**RR 0.29** (0.19 to 0.44)	217 (2 RCTs)	⊕⊕⊕⊖ **Moderate**[a]	Gel probably results in a large reduction in pressure ulcer development (any stage) compared to placebo (gel group: 17.4%, 19/109; placebo group: 11%, 66/108).
	611 per 1000	**177 per 1000** (116 to 269)				

Table 9. Gel versus placebo *(Continued)*

Pressure ulcer grade	Not reported
Adverse events	Not reported

***The risk in the intervention group** (and its 95% confidence interval) is based on the mean risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT:** randomised controlled trial; **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 once for high or unclear risk of selection bias; downgraded once for imprecision due to few events and a small sample size. The risk ratio is large, based on two RCTs, and the range of the confidence interval is relatively narrow; thus, we upgraded the evidence by one level.

APPENDICES

Appendix 1. International NPUAP-EPUAP pressure ulcer classification system for ulcer grading

Category/Stage 1: non-blanchable redness of intact skin

Intact skin with non-blanchable erythema of a localised area usually over a bony prominence. Discolouration of the skin, warmth, oedema, hardness or pain may also be present. Darkly pigmented skin may not have visible blanching. **Further description**: the area may be painful, firm, soft, warmer or cooler than adjacent tissue. Category/stage 1 may be difficult to detect in individuals with dark skin tones. May indicate 'at risk' individuals.

Category/Stage 2: partial thickness skin loss or blister

Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled or sero-sanguinous-filled blister. **Further description**: presents as a shiny or dry shallow ulcer without slough or bruising. This category/stage should not be used to describe skin tears, tape burns, incontinence-associated dermatitis, maceration or excoriation.

Category/Stage 3: full thickness skin loss (fat visible)

Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Some slough may be present. May include undermining and tunnelling. **Further description**: the depth of a category/stage 3 pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have (adipose) subcutaneous tissue and category/stage 3 ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep category/stage 3 pressure ulcers. Bone/tendon is not visible or directly palpable.

Category/Stage 4: full thickness tissue loss (muscle/bone visible)

Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present. Often includes undermining and tunnelling. **Further description**: the depth of a category/stage 4 pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have (adipose) subcutaneous tissue and these ulcers can be shallow. Category/stage 4 ulcers can extend into muscle and/or supporting structures (e.g. fascia, tendon or joint capsule) making osteomyelitis or osteitis likely to occur. Exposed bone/muscle is visible or directly palpable.

Abbreviations: **NPUAP:** National Pressure Injury Advisory Panel; **EPUAP:** European Pressure Ulcer Advisory Panel

Appendix 2. Search strategy

Cochrane Wounds Specialised Register

1 MESH DESCRIPTOR Biological Dressings EXPLODE ALL AND INREGISTER

2 MESH DESCRIPTOR occlusive dressings EXPLODE ALL AND INREGISTER

3 MESH DESCRIPTOR Bandages, Hydrocolloid EXPLODE ALL AND INREGISTER

4 MESH DESCRIPTOR Hydrogels EXPLODE ALL AND INREGISTER

5 MESH DESCRIPTOR Alginates EXPLODE ALL AND INREGISTER

6 dressing* AND INREGISTER

7 (hydrocolloid* or alginate* or hydrogel* or foam or bead or film or films or tulle or gauze or non-adherent or non adherent) AND INREGISTER

8 MESH DESCRIPTOR Anti-Bacterial Agents EXPLODE ALL AND INREGISTER

9 MESH DESCRIPTOR Administration, Topical EXPLODE ALL AND INREGISTER

10 #8 AND #9

11 (topical near2 antibiotic*) AND INREGISTER

12 MESH DESCRIPTOR Anti-Infective Agents EXPLODE ALL AND INREGISTER

13 MESH DESCRIPTOR Anti-Inflammatory Agents EXPLODE ALL AND INREGISTER

14 MESH DESCRIPTOR Glucocorticoids EXPLODE ALL AND INREGISTER

15 #13 OR #14

16 #9 AND #15

17 (topical near2 (steroid* or corticosteroid* or glucocorticoid*)) AND INREGISTER

18 MESH DESCRIPTOR Estrogens EXPLODE ALL AND INREGISTER

19 #18 AND #9

20 (topical near2 (oestrogen or estrogen)) AND INREGISTER

21 MESH DESCRIPTOR Enzymes EXPLODE ALL AND INREGISTER

22 #21 AND #9

23 (topical near2 enzym*) AND INREGISTER

24 MESH DESCRIPTOR Growth Substances EXPLODE ALL AND INREGISTER

25 #24 AND #9

26 (topical near2 growth factor*) AND INREGISTER

27 MESH DESCRIPTOR Collagen EXPLODE ALL AND INREGISTER

28 #27 AND #9

29 (topical near2 collagen) AND INREGISTER

30 (topical near2 silver) AND INREGISTER

31 MESH DESCRIPTOR Honey EXPLODE ALL AND INREGISTER

32 honey* AND INREGISTER

33 MESH DESCRIPTOR Ointments EXPLODE ALL AND INREGISTER

34 (ointment* or lotion* or cream* or gel* or oil*) AND INREGISTER

35 (topical next (agent* or preparation* or therap* or treatment*)) AND INREGISTER

36 #35 OR #34 OR #33 OR #32 OR #31 OR #30 OR #29 OR #28 OR #26 OR #25 OR #23 OR #22 OR #20 OR #19 OR #17 OR #16 OR #12 OR #11 OR #10 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1

37 MESH DESCRIPTOR Pressure Ulcer EXPLODE ALL AND INREGISTER

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

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

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

41 #37 OR #38 OR #39 OR #40

42 #36 AND #41

The Cochrane Central Register of Controlled Clinical Trials (CENTRAL)

#1 MeSH descriptor: [Biological Dressings] explode all trees

#2 MeSH descriptor: [Occlusive Dressings] explode all trees

#3 MeSH descriptor: [Bandages, Hydrocolloid] explode all trees

#4 MeSH descriptor: [Hydrogels] explode all trees

#5 MeSH descriptor: [Alginates] explode all trees

#6 dressing*:ti,ab,kw

#7 (hydrocolloid* or alginate* or hydrogel* or foam or bead or film or films or tulle or gauze or non-adherent or non adherent):ti,ab,kw

#8 MeSH descriptor: [Anti-Bacterial Agents] explode all trees

#9 MeSH descriptor: [Administration, Topical] explode all trees

#10 #8 and #9

#11 (topical near/2 antibiotic*):ti,ab

#12 MeSH descriptor: [Anti-Infective Agents, Local] explode all trees

#13 MeSH descriptor: [Anti-Inflammatory Agents] explode all trees

#14 MeSH descriptor: [Glucocorticoids] explode all trees

#15 #13 or #14

#16 #9 and #15

#17 (topical near/2 (steroid* or corticosteroid* or glucocorticoid*)):ti,ab,kw

#18 MeSH descriptor: [Estrogens] explode all trees

#19 #9 and #18

#20 (topical near/2 (oestrogen or estrogen)):ti,ab,kw

#21 MeSH descriptor: [Enzymes] explode all trees

#22 #9 and #21

#23 (topical near/2 enzym*):ti,ab,kw

#24 MeSH descriptor: [Growth Substances] explode all trees

#25 #9 and #24

#26 (topical near/2 growth factor*):ti,ab,kw

#27 MeSH descriptor: [Collagen] explode all trees

#28 #9 and #27

#29 (topical near/2 collagen):ti,ab,kw

#30 (topical near/2 silver):ti,ab

#31 MeSH descriptor: [Ointments] explode all trees

#32 (ointment* or lotion* or cream* or gel* or oil*):ti,ab,kw

#33 MeSH descriptor: [Honey] explode all trees

#34 honey.ti,ab,kw

#35 (topical next (agent* or preparation* or therap* or treatment*)):ti,ab,kw

#36 (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #10 or #11 or #12 or #16 or #17 or #19 or #20 or #22 or #23 or #25 or #26 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35)

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

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

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

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

#41 (#37 or #38 or #39 or #40)

#42 #36 and #41 in Trials

Ovid MEDLINE

1 exp Biological Dressings/

2 exp Occlusive Dressings/

3 exp Bandages, Hydrocolloid/

4 exp Hydrogels/

5 exp Alginates/

6 dressing$.ti,ab.

7 (hydrocolloid$ or alginate$ or hydrogel$ or foam or bead or film or films or tulle or gauze or non-adherent or non adherent).ti,ab.

8 exp Anti-Bacterial Agents/

9 exp Administration, Topical/

10 and/8-9

11 (topical adj2 antibiotic$).ti,ab.

12 exp Antiinfective Agents, Local/

13 exp Anti-Inflammatory Agents/

14 exp Glucocorticoids/

15 or/13-14

16 9 and 15

17 (topical adj2 (steroid$ or corticosteroid$ or glucocorticoid$)).ti,ab.

18 exp Estrogens/

19 9 and 18

20 (topical adj2 (oestrogen or estrogen)).ti,ab.

21 exp Enzymes/

22 9 and 21

23 (topical adj2 enzym$).ti,ab.

24 exp Growth Substances/

25 9 and 24

26 (topical adj2 growth factor$).ti,ab.

27 exp Collagen/

28 9 and 27

29 (topical adj2 collagen).ti,ab.

30 (topical adj2 silver).ti,ab.

31 exp Honey/

32 honey$.ti,ab.

33 exp Ointments/

34 (ointment$ or lotion$ or cream$ or gel$ or oil$).ti,ab.

35 (topical adj (agent$ or preparation$ or therap$ or treatment$)).ti,ab.

36 or/1-7,10-12,16-17,19-20,22-23,25-26,28-35

37 exp Pressure Ulcer/

38 (pressure adj (ulcer$ or sore$ or injur$)).ti,ab.

39 (decubitus adj (ulcer$ or sore$)).ti,ab.

40 (bedsore$ or (bed adj sore$)).ti,ab.

41 or/37-40

42 36 and 41

43 randomized controlled trial.pt.

44 controlled clinical trial.pt.

45 randomi?ed.ab.

46 placebo.ab.

47 clinical trials as topic.sh.

48 randomly.ab.

49 trial.ti.

50 or/43-49

51 exp animals/ not humans.sh.

52 50 not 51

53 42 and 52

Ovid Embase

1 exp foam dressing/

2 exp gauze dressing/

3 exp hydrocolloid dressing/

4 exp hydrogel dressing/

5 exp Wound Dressing/

6 exp Hydrogel/

7 exp Calcium Alginate/

8 dressing*.ti,ab.

9 (hydrocolloid* or alginate* or hydrogel* or foam or bead or film or films or tulle or gauze or non-adherent or non adherent).ti,ab.

10 exp Antibiotic Agent/

11 exp Topical Drug Administration/

12 and/10-11

13 (topical adj2 antibiotic*).ti,ab.

14 exp Antiinfective Agent/

15 11 and 14

16 exp Antiinflammatory Agent/

17 exp Corticosteroid/

18 exp Glucocorticoid/

19 or/16-18

20 11 and 19

21 (topical adj2 (steroid* or corticosteroid* or glucocorticoid*)).ti,ab.

22 exp Estrogen/

23 11 and 22

24 (topical adj2 (oestrogen or estrogen)).ti,ab.

25 exp Enzymes/

26 11 and 25

27 (topical adj2 enzym*).ti,ab.

28 exp Growth Factor/

29 11 and 28

30 (topical adj2 growth factor*).ti,ab.

31 exp Collagen/

32 11 and 31

33 (topical adj2 collagen).ti,ab.

34 (topical adj2 silver).ti,ab.

35 exp Honey/

36 honey*.ti,ab.

37 exp Ointments/

38 (ointment* or lotion* or cream* or gel* or oil*).ti,ab.

39 (topical adj (agent* or preparation* or therap* or treatment*)).ti,ab.

40 or/1-9,12-13,15,20-21,23-24,26-27,29-30,32-39

41 exp Decubitus/

42 (pressure adj (ulcer* or sore* or injur*)).ti,ab.

43 (decubitus adj (ulcer* or sore*)).ti,ab.

44 (bedsore* or (bed adj sore*)).ti,ab.

45 or/41-44

46 40 and 45

47 Randomized controlled trial/

48 Controlled clinical study/

49 Random$.ti,ab.

50 randomization/

51 intermethod comparison/

52 placebo.ti,ab.

53 (compare or compared or comparison).ti.

54 ((evaluated or evaluate or evaluating or assessed or assess) and (compare or compared or comparing or comparison)).ab.

55 (open adj label).ti,ab.

56 ((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab.

57 double blind procedure/

58 parallel group$1.ti,ab.

59 (crossover or cross over).ti,ab.

60 ((assign$ or match or matched or allocation) adj5 (alternate or group$1 orintervention$1 or patient$1 or subject$1 or participant $1)).ti,ab.

61 (assigned or allocated).ti,ab.

62 (controlled adj7 (study or design or trial)).ti,ab.

63 (volunteer or volunteers).ti,ab.

64 human experiment/

65 trial.ti.

66 or/47-65

67 (random$ adj sampl$ adj7 (cross section$ or questionnaire$1 or survey$ or database$1)).ti,ab. not (comparative study/ or controlled study/ or randomi?ed controlled.ti,ab. or randomly assigned.ti,ab.)

68 Cross-sectional study/ not (randomized controlled trial/ or controlled clinical study/ or controlled study/ or randomi?ed controlled.ti,ab. or control group$1.ti,ab.)

69 (((case adj control$) and random$) not randomi?ed controlled).ti,ab.

70 (Systematic review not (trial or study)).ti.

71 (nonrandom$ not random$).ti,ab.

72 Random field$.ti,ab.

73 (random cluster adj3 sampl$).ti,ab.

74 (review.ab. and review.pt.) not trial.ti.

75 we searched.ab. and (review.ti. or review.pt.)

76 update review.ab.

77 (databases adj4 searched).ab.

78 (rat or rats or mouse or mice or swine or porcine or murine or sheep or lambs or pigs or piglets or rabbit or rabbits or cat or cats or dog or dogs or cattle or bovine or monkey or monkeys or trout or marmoset$1).ti. and animal experiment/

79 Animal experiment/ not (human experiment/ or human/)

80 or/67-79

81 66 not 80

82 46 and 81

EBSCO CINAHL Plus

S63 S39 AND S62

S62 S61 NOT S60

S61 S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 OR S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53 OR S54

S60 S58 NOT S59

S59 MH (human)

S58 S55 OR S56 OR S57

S57 TI (animal model*)

S56 MH (animal studies)

S55 MH animals+

S54 AB (cluster W3 RCT)

S53 MH (crossover design) OR MH (comparative studies)

S52 AB (control W5 group)

S51 PT (randomized controlled trial)

S50 MH (placebos)

S49 MH (sample size) AND AB (assigned OR allocated OR control)

S48 TI (trial)

S47 AB (random*)

S46 TI (randomised OR randomized)

S45 MH cluster sampl

S44 MH pretest-posttest design

S43 MH random assignment

S42 MH single-blind studies

S41 MH double-blind studies

S40 MH randomized controlled trials

S39 S33 and S38

S38 S34 or S35 or S36 or S37

S37 TI decubitus or AB decubitus

S36 TI (bed sore* or bedsore*) or AB (bed sore* or bedsore*)

S35 TI (pressure ulcer* or pressure sore* or pressure injur*) or AB (pressure ulcer* or pressure sore* or pressure injur*)

S34 (MH "Pressure Ulcer")

S33 S1 or S2 or S3 or S6 or S7 or S8 or S9 or S10 or S12 or S13 or S15 or S16 or S18 or S19 or S21 or S22 or S26 or S27 or S28 or S29 or S30 or S31 or S32

S32 TI (topical agent* or topical preparation* or topical therap* or topical treatment*) or AB (topical agent* or topical preparation* or topical therap* or topical treatment*)

S31 TI (ointment* or lotion* or cream* or gel* or oil*) or AB (ointment* or lotion* or cream* or gel* or oil*)

S30 (MH "Ointments")

S29 TI honey* or AB honey*

S28 (MH "Honey")

S27 TI topical* N2 silver* or AB topical* N2 silver*

S26 S5 and S25

S25 S23 or S24

S24 (MH "Silver Sulfadiazine")

S23 (MH "Silver")

S22 TI collagen* or AB collagen*

S21 S5 and S20

S20 (MH "Collagen")

S19 TI topical* N2 growth factor* or AB topical* N2 growth factor*

S18 (S5 and S17)

S17 (MH "Growth Substances+")

S16 TI topical* N2 enzyme* or AB topical* N2 enzyme*

S15 S5 and S14

S14 (MH "Enzymes+")

S13 TI (topical* N2 oestrogen* or topical* N2 estrogen*) or AB (topical* N2 oestrogen* or topical* N2 estrogen*)

S12 S5 and S11

S11 (MH "Estrogens+")

S10 TI (topical* N2 steroid* or topical* N2 corticosteroid* or topical* N2 glucocorticoid*) or AB (topical* N2 steroid* or topical* N2 corticosteroid* or topical* N2 glucocorticoid*)

S9 (MH "Antiinflammatory Agents, Topical+")

S8 (MH "Antiinfective Agents, Local+")

S7 TI topical* N2 antibiotic* or AB topical* N2 antibiotic*

S6 S4 and S5

S5 MH "Administration, Topical+")

S4 (MH "Antibiotics+")

S3 TI (dressing* or pad or pads or gauze or tulle or film or bead or foam* or non-adherent or non adherent or hydrocolloid* or alginat* or hydrogel*) or AB (dressing* or pad or pads or gauze or tulle or film or bead or foam* or non-adherent or non adherent or hydrocolloid* or alginat* or hydrogel*)

S2 (MH "Alginates")

S1 (MH "Bandages and Dressings+")

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

dressing OR pad OR gauze OR tulle OR film OR bead OR foam OR hydrocolloid OR alginate OR hydrogel OR honey OR silicone OR gel OR topical OR anti bacterial OR oil OR ointment OR lotion OR cream | Pressure Ulcer

World Health Organization International Clinical Trials Registry Platform

pressure ulcer* [Title] AND dressing OR pad OR gauze OR tulle OR film OR bead OR foam OR hydrocolloid OR alginate OR hydrogel OR honey OR silicone OR gel OR topical OR anti bacterial OR oil OR ointment OR lotion OR cream

pressure ulcer* [condition] AND dressing OR pad OR gauze OR tulle OR film OR bead OR foam OR hydrocolloid OR alginate OR hydrogel OR honey OR silicone OR gel OR topical OR anti bacterial OR oil OR ointment OR lotion OR cream

pressure injur* [Title] AND dressing OR pad OR gauze OR tulle OR film OR bead OR foam OR hydrocolloid OR alginate OR hydrogel OR honey OR silicone OR gel OR topical OR anti bacterial OR oil OR ointment OR lotion OR cream

pressure injur* [Condition] AND dressing OR pad OR gauze OR tulle OR film OR bead OR foam OR hydrocolloid OR alginate OR hydrogel OR honey OR silicone OR gel OR topical OR anti bacterial OR oil OR ointment OR lotion OR cream

Appendix 3. 'Risk of bias' criteria

1. Was the allocation sequence randomly generated?

Low risk of bias

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

High risk of bias

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

Unclear

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

2. Was the treatment allocation adequately concealed?

Low risk of bias

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

High risk of bias

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

Unclear

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

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

Low risk of bias

Any one of the following.

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

High risk of bias

Any one of the following.

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

Unclear

Either of the following.

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

4. Were incomplete outcome data adequately addressed?

Low risk of bias

Any one of the following.

- No missing outcome data.
- Reasons for missing outcome data are unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias).
- Missing outcome data are 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 the observed event risk is not enough to have a clinically relevant impact on the intervention effect estimate.
- For continuous outcome data, a plausible effect size (difference in means or standardised difference in means) among missing outcomes is not enough to have a clinically relevant impact on the 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 are likely to be related to the true outcome, with either an imbalance in numbers or reasons for missing data across intervention groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with the observed event risk is enough to induce clinically relevant bias in the intervention effect estimate.
- For continuous outcome data, a plausible effect size (difference in means or standardised difference in means) among missing outcomes is enough to induce a clinically relevant bias in the observed effect size.
- 'As-treated' analysis done with a substantial departure of the intervention received from that assigned at randomisation.
- Potentially inappropriate application of simple imputation.

Unclear

Either of the following.

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

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

Low risk of bias

Either of the following.

- The study protocol is available and all of the study's 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 is/are reported using measurements, analysis methods, or subsets of the data (e.g. subscales) that were not prespecified.
- One or more reported primary outcomes was/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 is/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 provided to permit a judgement of low or high risk of bias. It is likely that the majority of trials will fall into this category.

6. Other sources of potential bias

Low risk of bias

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

High risk of bias

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

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

Unclear

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

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

WHAT'S NEW

Date	Event	Description
3 December 2024	New search has been performed	Search updated November 2022. 33 new trials, with 9674 participants added, bringing the total to 51 included studies and 13,303 participants.
3 December 2024	New citation required but conclusions have not changed	• New authors added: Patton D, Boland F, Chaboyer WP, Latimer SL, Walker RM, Avsar P. One author no longer on the authoring team: Joan Webster. • Conclusions not changed; it is still unclear whether any of the included dressings or topical agents make any difference and the certainty of the evidence is still low to very low.

HISTORY

Protocol first published: Issue 10, 2011
Review first published: Issue 8, 2013

Date	Event	Description
6 December 2018	New citation required and conclusions have changed	Second update. 28 new studies were eligible for inclusion in the review.
30 November 2018	New search has been performed	First update. New search with nine trials added. Content updated, conclusions changed. The search was updated in May 2018 and six trials were added to Studies awaiting classification (Aloweni 2017; Guo 2015; Imbulana 2018; Kim 2016; Tai 2016; Wang 2016).

CONTRIBUTIONS OF AUTHORS

Declan Patton: designed and coordinated the review update; checked the quality of data extraction; checked quality assessment; checked the quality of the statistical analysis; contributed to writing and editing the review update; approved the final review update prior to submission and is a guarantor of the review update.

Zena Moore: conceived the review; extracted data; checked the quality of data extraction; analysed or interpreted data; undertook and checked quality assessment; performed statistical analysis; checked the quality of the statistical analysis; produced the first draft of the review update; contributed to writing and editing the review update; approved the final review update prior to submission and is a guarantor of the review update.

Rachel Walker: contributed to writing and editing the review update; approved the final review update prior to submission.

Wendy Chaboyer: contributed to writing and editing the review update; approved the final review update prior to submission.

Sharon Latimer: contributed to writing and editing the review update; approved the final review update prior to submission.

Fiona Boland: analysed or interpreted data; undertook and checked quality assessment; performed statistical analysis; checked the quality of the statistical analysis; contributed to writing and editing the review update; approved the final review update prior to submission.

Pinar Avsar: extracted data; checked the quality of data extraction; analysed or interpreted data; undertook and checked quality assessment; performed statistical analysis; checked the quality of the statistical analysis; produced the first draft of the review update; contributed to writing and editing the review update; wrote to trial authors/experts/companies and approved the final review update prior to submission.

DECLARATIONS OF INTEREST

Declan Patton: no declarations of interest.

Zena Moore: has received an honorarium for speaking at a professional meeting for 3M, for Smith & Nephew Inc, and for HARTMANN USA, INC; advisor on a wound assessment tool for Smith & Nephew, Inc.

Rachel Walker: has declared a grant to her institution, Griffith University, from Becton, Dickinson and Co. Involvement in conducting a study eligible for inclusion in the review (Walker 2015). Therefore, did not make study eligibility decisions about, extract data from, carry out the risk of bias assessment for, or perform GRADE assessments of that study.

Wendy Chaboyer: no declarations of interest.

Sharon Latimer: Wounds Australia membership, editorial board member of *Wounds Practice and Research*.

Fiona Boland: no declarations of interest.

Pinar Avsar: no declarations of interest.

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External sources

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

- We added the words, "or any other intervention" under the heading 'Types of interventions.'
- We added the words, 'we completed a PRISMA flowchart to summarise this process' to the section 'Selection of studies.'
- We added a section, 'Summary of findings table and GRADE assessment of the certainty of the evidence' to the methods.
- We have changed the wording in the 'Unit of analysis issues' to: "Ideally a trial would be designed with participant-level randomisation and analysis, and only one pressure ulcer per participant (adjustment for clustering not necessary in this case). However, in the pressure ulcer literature, it is not unusual to find trials that report on multiple pressure ulcers per participant, randomised or analysed, or both, at wound level, and unadjusted for clustering. In such cases, we planned to contact the trial authors and attempt to obtain: patient-level data or results; data or results for one pressure ulcer per participant; or pressure ulcer-level data, and then perform multilevel regression to calculate the adjusted effect. We would then combine the adjusted results in the meta-analysis with those of participant-level trials (using the generic inverse method), and performed sensitivity analyses (Higgins 2011c). If we had been unsuccessful in obtaining the additional data required, then we would have excluded the trial from the meta-analysis."

Differences between this version of the review and the previous version

- We have analysed and presented data for the anatomical location of pressure ulcer development if these data were reported by the study authors.
- We removed the line 'If heterogeneity was very high (I^2 over 75%), we did not plan to pool trials.' While an I^2 value above75% is high, studies with higher values are regularly combined, caution is emphasised in relation to any conclusions, and the evidence is downgraded for inconsistency during the GRADE appraisal.

INDEX TERMS

Medical Subject Headings (MeSH)

Administration, Cutaneous; Allantoin [administration & dosage]; *Bandages; Dimethyl Sulfoxide [administration & dosage]; Drug Administration Schedule; Drug Combinations; Fatty Acids [administration & dosage]; Hexachlorophene [administration & dosage]; Incidence; Olive Oil [administration & dosage]; Pressure Ulcer [epidemiology] [*prevention & control]; Randomized Controlled Trials

as Topic; Silicones [administration & dosage]; Skin Care [*methods]; Skin Cream [*administration & dosage] [chemistry]; Squalene [administration & dosage]

MeSH check words

Aged; Humans; Middle Aged