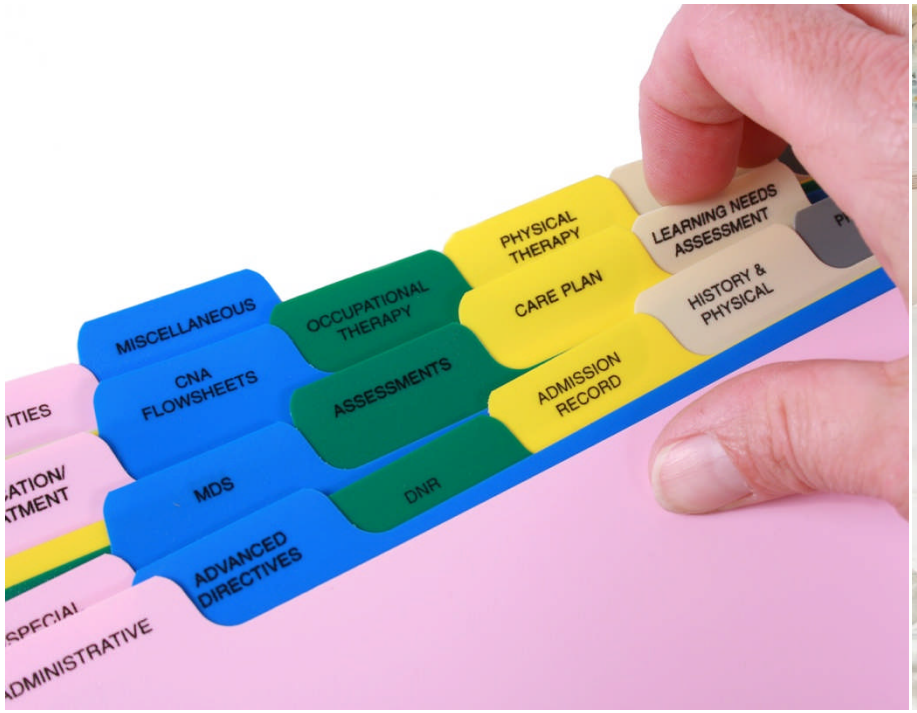
KCE REPORT 193S

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Center

A NATIONAL GUIDELINE FOR THE PREVENTION OF PRESSURE ULCERS

APPENDIX



KCE REPORT 193S
GOOD CLINICAL PRACTICE

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A NATIONAL GUIDELINE FOR THE PREVENTION OF PRESSURE ULCERS

APPENDIX

DIMITRI BEECKMAN, CATHY MATHEÏ, AURÉLIE VAN LANCKER, SABINE VAN HOUDT, GEERT VANWALLEGHEM, LUC GRYSON, HILDE HEYMAN, CHRISTIAN THYSE, ADINDA TOPPETS, SABINE STORDEUR, KOEN VAN DEN HEEDE

COLOPHON

Title:	A National Guideline for the prevention of pressure ulcers- Supplement
Authors:	Dimitri Beeckman (UGent), Cathy Matheï (KULeuven), Aurélie Van Lancker (UGent), Sabine Van Houdt (KULeuven), Geert Vanwalleghem (CNC vzw/ WCS/ H.-Hartziekenhuis Roeselare-Menen vzw), Luc Gryson (CNC vzw), Hilde Heyman (WCS), Christian Thyse (AFISCeP.be), Adinda Toppets (UZLeuven), Sabine Stordeur (KCE), Koen Van den Heede (KCE)
Reviewers:	Marijke Eyssen (KCE); Dominique Paulus (KCE)
External experts:	Diégo Backaert (Thuiszorg Groep Backaert); Hilde Beele (UZ Gent); Lieven Decaevele (OLV-Ziekenhuis, Aalst); Daniëlle Declercq (Institut Jules Bordet); Véronique del Marmolle (Hopital Erasme, ULB); Aurélia Bustillo (Hopital Erasme, ULB); Anne Hermand (Clinique Universitaire Saint-Luc, Bruxelles); Miguel Lardennois (SPF Santé Publique - FOD Volksgezondheid); Louis Paquay (Wit-Gele Kruis); Dominique Putzeys (CIPIQ-s); Lisette Schoonhoven (Radboud Universiteit NijmegenEvelien Touriany (Militair Hospitaal Koningin Astrid); Dirk Van De Looverbosch (Zelfstandig Huisarts); Katrien Vanderwee (O.L.V. van Lourdes ziekenhuis Waregem); Pascal Van Waeyenberghe (Home Health Care wound care BVBA); Christiane Vranken (CHU Liège)
Acknowledgements:	We thank Liz Avital (NCGC, UK), Katie Jones (NCGC, UK) and Julie Neilson (NCGC, UK) for the collaboration in the preparation of the evidence reports
External validators:	Nicky Cullum (University of Manchester); Siegfried Geens (CEBAM); Philippe Hanson (CHU UCL Mont-Godinne)
Conflict of interest:	Dominique Putzeys declared to have received funding for research related to the prevention of pressure ulcers. Diégo Backaert, Hilde Beele, Anne Hermand, Adinda Toppets, Geert Vanwalleghem, Pascal Van Waeyenberghe declared to have received a fee to lecture or reimbursement for training, travelling or participation to conferences related to the prevention of pressure ulcers.
Layout:	Ine Verhulst

Publication date:	11 January 2013
Domain:	Good Clinical Practice (GCP)
MeSH:	Pressure ulcer ; Practice Guidelines; Prevention and control
NLM Classification:	WR 598
Language:	English
Format:	Adobe® PDF™ (A4)
Legal depot:	D/2013/10.273/98

How to refer to this document?

Beeckman D, Matheï C, Van Lancker A, Van Houdt S, Vanwalleghem G, Gryson L, Heyman H, Thyse C, Toppets A, Stordeur S, Van den Heede K. A National Guideline for the prevention of pressure ulcers - Supplement. Good Clinical Practice (GCP). Brussels: Belgian Health Care Knowledge Centre (KCE). 2012. KCE Reports 193S. D/2013/10.273/98.

This document is available on the website of the Belgian Health Care Knowledge Centre.

APPENDIX REPORT

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LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
A&E	Accident and Emergency
AHCPR	Agency of Health Care Policy and Research
AP mattresses	Alternating pressure mattresses
BMI	Body Mass Index
CI	Confidence Interval
CPG	Clinical Practice Guideline
DOR	Diagnostic Odds Ratio
EPUAP	European Pressure Ulcer Advisory Panel
GDG	Guideline Development Group
HRQoL	Health-Related Quality of Life
HUI	The Health Utilities Index
IAD	Incontinence Associated Dermatitis
ILD	Indentation load deflection
IQR	Inter-quartile range
ITT	Intention-to-treat
KCE	Belgian Healthcare Knowledge Centre
LTCF	Long-term care facilities
LR	Likelihood ratio
MID	Minimal important difference
NBE	Non-blanchable erythema
NCGC	National Clinical Guideline Centre
NICE	National Institute for Health and Clinical Excellence
NPUAP	National Pressure Ulcer Advisory Panel
NPV	Negative Predictive Value
PICO	Population, Intervention, Comparison, Outcome
PPV	Positive Predictive Value
PSPS	Pressure Sore Prediction Score

PU	Pressure Ulcer
RAPS	Risk Assessment Pressure Sore scale
RCT	Randomized Controlled Trial
SF-36	Short form 36 health survey
SS	Suriadi and Sanada scale
SD	Standard Deviation
TNH-PUPP	The Northern Hospital Pressure Ulcer Prevention Plan
WHOQOL-BREF	An abbreviated 26 item version of the World Health Organization – Quality of Life (WHOQOL-100) instrument
EQ-5D	A standardised measure of health status developed by the EuroQol Group

1. RISK ASSESSMENT – CLINICAL EFFECTIVENESS

1.1. Review protocol

Table 1 – Protocol review question

Protocol	Risk assessment
Protocol	**Risk assessment**
Review question	What is the clinical effectiveness of risk assessment tools in the prevention of pressure ulcers?
Population	Individuals of all ages in all settings
Intervention	• Clinical judgement based on risk factors • Risk assessment tool (any reported cut-off score) o Braden, o Norton, o Waterlow, o Cubbin-Jackson, o Braden-Q, o Other scales (e.g. Gosnell scale, Knoll scale, Andersen, Pressure Sore Prediction Score, Risk Assessment Pressure Sore, Douglas, Emina, Glamorgan)
Comparison	• Each other • No risk assessment
Outcomes	**Critical outcome for decision-making** • Proportion of participants developing new pressure ulcers (dichotomous outcome)(describe different categories of ulcer) **Important outcomes** • Patient acceptability; • Rate of development of pressure ulcers; • Time to develop new pressure ulcer (time to event data); • Time in hospital or other health care setting (continuous data); • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in

Protocol	Risk assessment
	pressure ulcer patients, therefore may have to be narratively summarised) o Short-form health survey (SF36) o Manchester Short Assessment of Quality of Life o EQ-5D o WHOQOL-BREF o Cardiff HRQoL tool o HUI o Pressure ulcer quality of life (Gorecki)
Study design	• High quality systematic reviews of RCTs or RCTs only; • Cochrane reviews will be included if they match the inclusion criteria and have appropriate assumptions for missing data such as available case analysis or intention-to-treat – ITT (with the appropriate assumptions); • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies with another population, intervention, comparison or outcome; • Non-English, non-French, non-Dutch language papers.
Search strategy	**The electronic databases to be searched are:** • Medline (OVID interface), Cinahl (EBSCO-interface), Embase, Library of the Cochrane Collaboration; • All years.
Review strategy	**How will individual PICO characteristics be combined across studies):** • Population – any population will be combined except those specified in the strata; • Intervention – combine same tools only; • Comparison – any comparison will be combined; • Outcomes – same outcomes will be combined; • Blinding – Blinded and unblinded studies will be meta-analysed together; • Minimum follow up = no minimum; • Minimum total size = no minimum; • Use available case analysis for dealing with missing data if there is a 10% differential or higher between the groups or if the missing data is higher than the event rate, if cannot work out the available case analysis will take the author's data.
Analysis	**Strata:**

Protocol	Risk assessment
	The following groups will be considered separately if data are present: • Children (neonates, infants and children) • ICU patients; • Patients with a spinal cord injury; • Palliative patients. **Subgroups:** The following groups will be considered separately as subgroups if data are present and there is inconsistency: • Different categories of pressure ulcer (from category 2 upwards where outcomes are reported separately) • Different ulcer locations: sacral, heel and others

1.2. Search strategy

1.2.1. Search filters

Table 2 – Search filters Medline (OVID)

Date	11/9/12	
Database	**Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R)** 1946 to Present	
Search Strategy	1. Pressure Ulcer/	9139
	2. decubit*.ti,ab.	3957
	3. (pressure adj (sore* or ulcer* or damage)).ti,ab.	6283
	4. (bedsore* or bed-sore*).ti,ab.	506
	5. ((friction or shear) adj2 (sore* or ulcer* or damage or wound* or injur* or lesion*)).ti,ab.	253
	6. OR/1 – 5	
	7. Risk assessment/	13521
	8. Nursing assessment/	152369
	9. nursing assess$.tw	26960
	10. risk assess$.tw	1108
	11. risk-benefit assess$.tw	28820
	12. structured assess$.tw	439
	13. unstructured assess$.tw	580
	14. instrument$.tw	9

Date	11/9/12	
	15. tool$.tw	165360
	16. scale$.tw	330115
	17. screening.tw	380195
	18. Risk factor/	289136
	19. risk factor$.tw	498760
	20. risk score$.tw	297520
	21. assess$ score?.tw	5804
	22. Judgment/	1858
	23. clinical judg?ment.tw	11574
	24. Observation/	4103
	25. observation?.tw	4267
	26. OR/7 – 25	479442
	27. randomized controlled trial.pt.	2222493
	28. controlled clinical trial.pt.	336587
	29. randomi#ed.ab.	85134
	30. placebo.ab.	301653
	31. randomly.ab.	139359
	32. Clinical Trials as topic/	184340
	33. trial.ti	162333
	34. OR/27 – 33	108321
	35. AND/6, 26, 34	824270
	36. Limit year: ‘2010 – September 2012’ and limit language: ‘English, Dutch, French’	311
		47

Table 3 – Search filters Embase

Date	**11/9/12**	
Database	Embase	
Search Strategy **(attention, for PubMed, check « Details »)**	1. 'decubitus'/exp 2. decubit*:ti,ab 3. (pressure NEAR/1 (score* OR ulcer* OR damage)):ab,ti 4. (bed NEAR/2 sore*):ab,ti OR bedsore*:ti,ab 5. ((friction or shear) near/2 (sore* or ulcer* or damage or wound* or injur* or lesion*)):ti,ab 6. OR/1 – 5 7. 'risk assessment'/exp 8. 'risk assessment$':ti,ab 9. 'assessment$ risk':ti,ab 10. 'risk-benefit assessment$':ti,ab 11. 'structured assessment$':ti,ab 12. 'assessment$ structured':ti,ab 13. 'unstructured assessment$':ti,ab 14. 'instrument'/exp 15. 'instrument$':ti,ab 16. 'tool$':ti,ab 17. 'scale$':ti,ab 18. 'screening':ti,ab 19. 'risk factor'/exp 20. 'risk factor$':ti,ab 21. 'factor risk$':ti,ab 22. 'risk score$':ti,ab 23. 'score$ risk':ti,ab 24. 'assessment$ score$':ti,ab 25. 'decision making'/exp 26. 'clinical judg?ment':ti,ab 27. 'clinical observation'/exp 28. 'nursing assessment'/exp 29. 'nursing assessment':ti,ab 30. 'observation$':ti,ab 31. OR/7 – 30 32. 'clinical trial'/exp	6949 3631 2357 390 240 9754 246481 26996 193 458 519 15 6 6212 60953 220029 323627 285932 383549 113655 104 6423 253 1121 64313 1312 13399 250 213 190956 1632721

Date	11/9/12	
	33. 'clinical trial (topic)'/exp	719572
	34. random*:ti,ab	37330
	35. factorial*:ti,ab	613232
	36. crossover*:ti,ab OR (cross NEXT/1 over*):ti,ab	13354
	37. ((doubl* or singl*) NEAR/2 blind*):ti,ab	54706
	38. (assign* or allocat* or volunteer* or placebo*):ti,ab	129598
	39. 'crossover procedure'/exp	474964
	40. 'single blind procedure'/exp	29089
	41. 'double blind procedure'/exp	12144
	42. OR/32 – 41	92686
	43. AND/6, 31, 42	1404456
	44. Limit year: '2010 – September 2012' and language: 'English, Dutch, French'	372
		108

Table 4 – Search filters Cochrane Library

Date	11/9/12	
Database	The Library of the Cochrane Collaboration	
Search Strategy (attention, for PubMed, check « Details »)	1. "Pressure ulcer" [MeSH]	489
	2. Decubit*:ti,ab,kw	349
	3. (pressure near/2 (sore* or ulcer* or damage*)):ti,ab,kw	834
	4. (bedsore* or bed-sore*):ti,ab,kw	33
	5. ((friction or shear) near/2 (sore* or ulcer* or damage or wound* or injur*or lesion*)):ti,ab,kw	3
	6. OR/1 – 5	
	7. "risk assessment"[MeSH]	1115
	8. (risk assess*):ti,ab,kw	5960
	9. (risk-benefit assess*):ti,ab,kw	23877
	10. (structured assessment):ti,ab,kw	132
	11. (unstructured assess*):ti,ab,kw	1872
	12. (instrument*):ti,ab,kw	44
	13. (tool*):ti,ab,kw	21013
	14. (scale*):ti,ab,kw	6381
	15. (screening*):ti,ab,kw	48545

Date	11/9/12	
	16. “risk factors”[MeSH]	12029
	17. (risk factor):ti,ab,kw	16190
	18. (risk score):ti,ab,kw	28808
	19. (assessment score):ti,ab,kw	6261
	20. “Judgment”[MeSH]	11419
	21. “nursing assessment”[MeSH]	430
	22. (nurs* assess*):ti,ab,kw	493
	23. (clinical judg?ment):ti,ab,kw	4271
	24. “Observation”[MeSH]	260
	25. (observation*):ti,ab,kw	139
	26. OR/7 – 25	22962
	27. (Clinical Trial):pt	145412
	28. (Randomized Controlled Trial):pt	294576
	29. “clinical trial as topic” [MeSH]	313652
	30. (trial*):ti,ab,kw	51548
	31. (randomized or randomised):ti,ab,kw	248378
	32. (randomly):ti,ab,kw	264947
	33. (group*):ti,ab,kw	85941
	34. OR/27 – 32	273734
	35. AND/6, 26, 33	533623
	36. Limit year: ‘2010 – September 2012’	323
		50

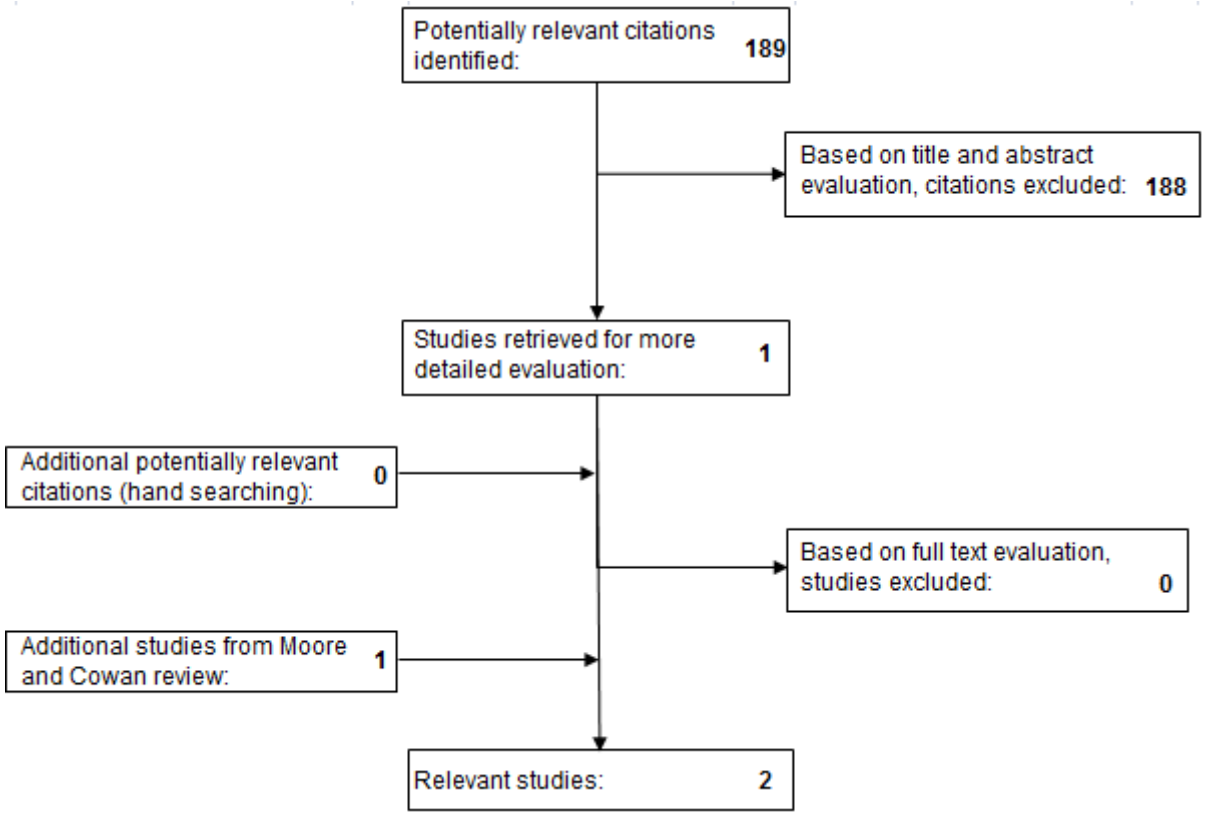
Table 5 – Search filters CINAHL

Date	12/9/12	
Database	CINAHL (EBSCO-interface)	
Search Strategy (attention, for PubMed, check « Details »)	1. MH “Pressure Ulcer”	7749
	2. bedsore* OR bed-sore*	157
	3. pressure n1 sore* OR pressure n1 ulcer* OR pressure n1 damage*	8547
	4. decubit*	
	5. ((friction or shear) and (sore* or ulcer* or damage or wound* or injur* or lesion*))	487
	6. OR/1 – 5	806

Date	12/9/12	
	7. MH “Risk assessment”	
	8. MH “Nursing assessment”	9407
	9. “risk assessment$” or “assessment$ risk”	28458
	10. “nurs$ assessment$ or “assessment$ nurs$”	13715
	11. “risk-benefit assessment$”	30248
	12. “structured assessment$” or “assessment$ structured”	336
	13. “unstructured assessment$”	345
	14. “instrument$”	139
	15. “tool$”	2
	16. “scale$”	31135
	17. “screening”	30351
	18. MH “risk factor”	6687
	19. “risk factor$” or “factor$ risk”	53154
	20. “risk score$” or “score$ risk”	53501
	21. “assessment score$”	13663
	22. MH "Decision Making, Clinical"	931
	23. MH "Judgment"	274
	24. “clinical judg?ment”	13120
	25. “observation” or “observations”	1889
	26. OR/7 – 25	277
	27. MH "Clinical Trials+"	26680
	28. “trial*”	282653
	29. “randomi#ed”	107538
	30. “randomly”	138201
	31. “randomized controlled trial”	66692
	32. PT “randomized controlled trial”	25374
	33. PT “clinical trial”	9144
	34. OR/27 – 33	10990
	35. AND/6, 26, 34	51404
	36. Limit year: ‘2010 – September 2012’ and language: ’English, Dutch, French’	169441
		222
		36

1.2.2. Selection of articles

Figure 1 – Flow chart search strategy



1.3. Clinical evidence

1.3.1. Summary table

Table 6 – Summary of included studies

Study	Intervention/comparator	Population	Outcome	Study length
Saleh 2009[1]	(1) Braden scale and training (2) Training only (3) Clinical judgement	Hospitalized patients with a pressure ulcer and/or Braden scale ≤ 18	Incidence of pressure ulcers	Eight weeks
Webster 2011[2]	(1) Waterlow scale (2) Ramstadius scale (3) Clinical judgement	Hospitalized patients older than 18 years with or without a pressure ulcer	Incidence of pressure ulcers	Maximum 98 days

1.3.2. Clinical evidence GRADE tables

Table 7 – Braden scale versus clinical judgement

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Braden scale**	**Clinical judgement**	**Relative (95% CI)**	**Absolute**		
Incidence of pressure ulcers – all grades												
Saleh 2009	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	16/74 (21.6%)	16/106 (15.1%)	RR 1.43 (0.77 to 2.68)	65 more per 1000 (from 35 fewer to 254 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								15.1%		65 more per 1000 (from 35 fewer to 254 more)		

1 Sequence allocation and blinding not reported; inadequate allocation concealment (ward allocation); difference at baseline not reported; no intention-to-treat analysis
2 Confidence interval crossed one MID

Table 8 – Braden scale versus training only

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Braden scale**	**Training only**	**Relative (95% CI)**	**Absolute**		
Incidence of pressure ulcers – all grades												
Saleh 2009	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	16/74 (21.6%)	17/76 (22.4%)	RR 0.97 (0.53 to 1.77)	7 fewer per 1000 (from 105 fewer to 172 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								22.4%		7 fewer per 1000 (from 105 fewer to 172 more)		

1 Sequence allocation and blinding not reported; inadequate allocation concealment (ward allocation); difference at baseline not reported; no intention-to-treat analysis
2 Confidence interval crossed both MIDs

Table 9 – Training only versus clinical judgement

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Training only	Clinical judgement	Relative (95% CI)	Absolute		
Incidence of pressure ulcers – all grades												
Saleh 2009	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	17/76 (22.4%)	16/106 (15.1%)	RR 1.48 (0.8 to 2.74)	72 more per 1000 (from 30 fewer to 263 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								15.1%		72 more per 1000 (from 30 fewer to 263 more)		

1 Sequence allocation and blinding not reported; inadequate allocation concealment (ward allocation); difference at baseline not reported; no intention-to-treat analysis
2 Confidence interval crossed one MID

Table 10 – Waterlow scale versus clinical judgement

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Waterlow scale	Clinical judgement	Relative (95% CI)	Absolute		
Incidence of pressure ulcers – all grades												
Webster 2011	randomised trials	No serious risk of bias	no serious inconsistency	no serious indirectness	very serious[1]	none	31/411 (7.5%)	28/410 (6.8%)	RR 1.1 (0.68 to 1.81)	7 more per 1000 (from 22 fewer to 55 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								6.8%		7 more per 1000 (from 22 fewer to 55 more)		
Incidence of pressure ulcers – grade 2												
Webster 2011	randomised trials	No serious risk of bias	no serious inconsistency	no serious indirectness	very serious[1]	none	10/411 (2.4%)	8/410 (2%)	RR 1.25 (0.5 to 3.13)	5 more per 1000 (from 10 fewer to 42 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								2%		5 more per 1000 (from 10 fewer to 43 more)		

1Confidence interval crossed both MIDs

Table 11 – Waterlow scale versus Ramstadius scale

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Waterlow scale	Ramstadius scale	Relative (95% CI)	Absolute		
Incidence of pressure ulcers – all grades												
Webster 2011	randomised trials	No serious risk of bias	no serious inconsistency	no serious indirectness	serious[1]	none	31/411 (7.5%)	22/410 (5.4%)	RR 1.41 (0.83 to 2.39)	22 more per 1000 (from 9 fewer to 75 more)	⊕⊕⊕O MODERATE	CRITICAL OUTCOME
								5.4%		22 more per 1000 (from 9 fewer to 75 more)		
Incidence of pressure ulcers – grade 2												
Webster 2011	randomised trials	No serious risk of bias	no serious inconsistency	no serious indirectness	serious[1]	none	10/411 (2.4%)	4/410 (1%)	RR 2.49 (0.79 to 7.89)	15 more per 1000 (from 2 fewer to 67 more)	⊕⊕⊕O MODERATE	CRITICAL OUTCOME
								1%		15 more per 1000 (from 2 fewer to 69 more)		

1 Confidence interval crossed one MID

Table 12 – Ramstadius scale versus clinical judgement

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Ramstadius scale	Clinical judgement	Relative (95% CI)	Absolute		
Incidence of pressure ulcers – all grades												
Webster 2011	randomised trials	No serious risk of bias	no serious inconsistency	no serious indirectness	very serious[1]	none	22/410 (5.4%)	28/410 (6.8%)	RR 0.79 (0.46 to 1.35)	14 fewer per 1000 (from 37 fewer to 24 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								6.8%		14 fewer per 1000 (from 37 fewer to 24 more)		
Incidence of pressure ulcers – grade 2												
Webster 2011	randomised trials	No serious risk of bias	no serious inconsistency	no serious indirectness	very serious[1]	none	4/410 (1%)	8/410 (2%)	RR 0.5 (0.15 to 1.65)	10 fewer per 1000 (from 17 fewer to 13 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								2%		10 fewer per 1000 (from 17 fewer to 13 more)		

1Confidence interval crossed both MIDs

1.3.3. Forest plots

Figure 2 – Braden scale versus clinical judgement – all stages

Study or Subgroup	Braden scale Events	Total	Clinical judgement Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Saleh 2009	16	74	16	106	100.0%	1.43 [0.77, 2.68]
Total (95% CI)		**74**		**106**	**100.0%**	**1.43 [0.77, 2.68]**
Total events	16		16			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.12 (P = 0.26)

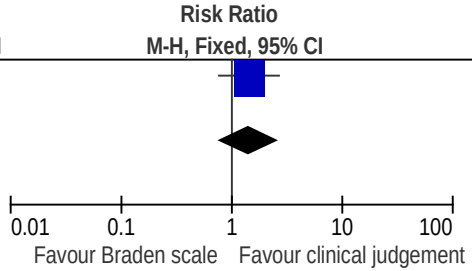


Figure 3 – Braden scale versus training only – all stages

Study or Subgroup	Braden scale Events	Total	Training only Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Saleh 2009	16	74	17	76	100.0%	0.97 [0.53, 1.77]
Total (95% CI)		**74**		**76**	**100.0%**	**0.97 [0.53, 1.77]**
Total events	16		17			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.11 (P = 0.91)

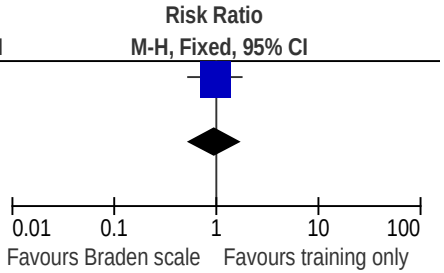


Figure 4 – Training only versus clinical judgement – all stages

Study or Subgroup	Training only Events	Total	Clinical judgement Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Saleh 2009	17	76	16	106	100.0%	1.48 [0.80, 2.74]
Total (95% CI)		**76**		**106**	**100.0%**	**1.48 [0.80, 2.74]**
Total events	17		16			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.25 (P = 0.21)

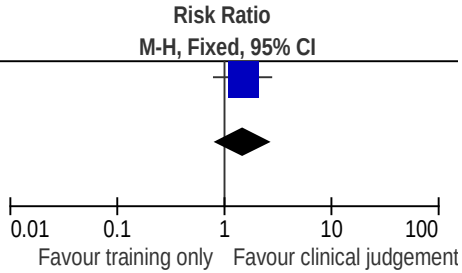


Figure 5 – Waterlow scale versus clinical judgement – all stages

Study or Subgroup	Waterlow scale Events	Total	Clinical judgement Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Webster 2011	31	411	28	410	100.0%	1.10 [0.68, 1.81]
Total (95% CI)		**411**		**410**	**100.0%**	**1.10 [0.68, 1.81]**
Total events	31		28			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.40 (P = 0.69)

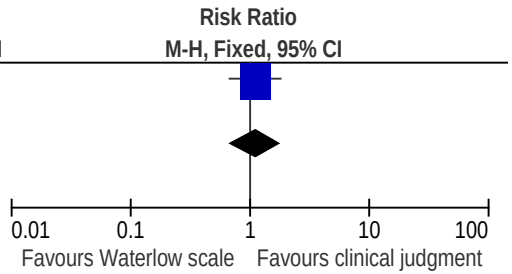


Figure 6 – Waterlow scale versus Ramstadius scale – all stages

Study or Subgroup	Waterlow scale Events	Total	Ramstadius scale Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Webster 2011	31	411	22	410	100.0%	1.41 [0.83, 2.39]
Total (95% CI)		**411**		**410**	**100.0%**	**1.41 [0.83, 2.39]**
Total events	31		22			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.26 (P = 0.21)

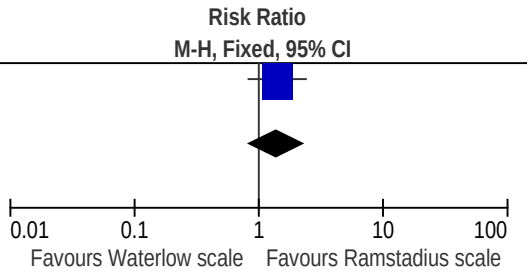


Figure 7 – Ramstadius scale versus clinical judgement – all stages

Study or Subgroup	Ramstadius scale Events	Total	Clinical judgement Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Webster 2011	22	410	28	410	100.0%	0.79 [0.46, 1.35]
Total (95% CI)		**410**		**410**	**100.0%**	**0.79 [0.46, 1.35]**
Total events	22		28			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.87 (P = 0.38)

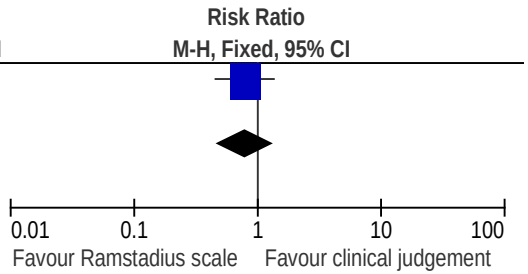


Figure 8 – Waterlow scale versus clinical judgement – stage 2

Study or Subgroup	Waterlow scale Events	Total	Clinical judgement Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Webster 2011	10	411	8	410	100.0%	1.25 [0.50, 3.13]
Total (95% CI)		**411**		**410**	**100.0%**	**1.25 [0.50, 3.13]**
Total events	10		8			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.47 (P = 0.64)

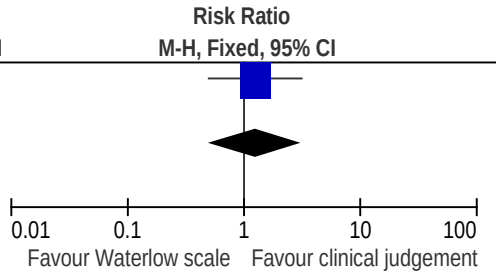


Figure 9 – Waterlow scale versus Ramstadius scale – stage 2

Study or Subgroup	Waterlow scale Events	Total	Ramstadius scale Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Webster 2011	10	411	4	410	100.0%	2.49 [0.79, 7.89]
Total (95% CI)		**411**		**410**	**100.0%**	**2.49 [0.79, 7.89]**
Total events	10		4			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.56 (P = 0.12)

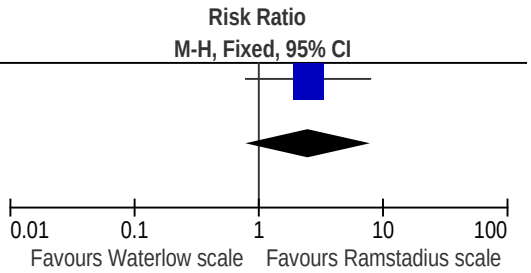
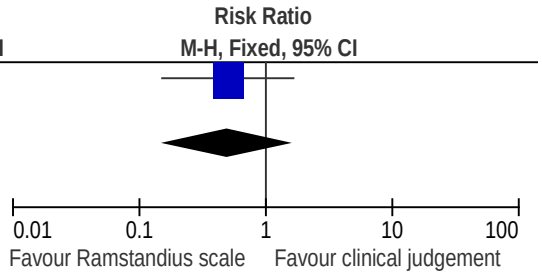


Figure 10 – Ramstadius scale versus clinical judgement – stage 2

Study or Subgroup	Ramstadius scale Events	Total	Clinical judgement Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Webster 2011	4	410	8	410	100.0%	0.50 [0.15, 1.65]
Total (95% CI)		**410**		**410**	**100.0%**	**0.50 [0.15, 1.65]**
Total events	4		8			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.14 (P = 0.25)



1.3.4. Evidence tables

Table 13 – Saleh 2009

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Saleh (2009)*** Title: **The impact of pressure ulcer risk assessment on patient outcomes among hospitalised patients** Journal: **Journal of Clinical Nursing, 18; 1923-29.** Study type: **cluster randomized controlled trial** Sequence generation: **not reported**	**Patient group:** hospitalized patients with or without a PU **All patients** **Randomised N:** not reported **Completed N:** 256 **Drop-outs:** not reported **Group 1** **Randomised N:** not reported **Completed N:** 74 **Dropouts:** not reported	**Group 1:** assessment of all patients with the Braden scale. All nurses received a mandatory training on wound care management, PU prevention and use of the Braden scale. **Group 2:** All nurses received a mandatory training on wound care management, PU prevention and use of the Braden scale. Use of the Braden scale was not required. **Group 3:** All nurses received a mandatory training on wound care management.	**Outcome 1:** Incidence of PU	**Group 1:** 16/74 **Group 2:** 17/76 **Group 3:** 16/106	**Funding:** / **Limitations:** sequence generation not reported; allocation concealment not reported; no blinding; no report on baseline difference regarding presence of PU on admission; no intention-to-treat analyses and high dropout

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Allocation concealment: **wards were unit of allocation** Blinding: **not reported** Addressing incomplete outcome data: **no intention-to-treat analysis. 198 patients were excluded because they were discharged before 8 weeks (total study period)** Statistical analysis: **Data were analysed by using descriptive and inferential statistical procedures (tests). The inferential statistics may be parametric or nonparametric. Chi-square test was used to test independence of nominal variables. Student t test for independent groups and one way ANOVA were not used to test differences between respectively two or**	**Age:** / **Gender (m/f):** / **Group 2** **Randomised N:** not reported **Completed N:** 76 **Dropouts:** not reported **Age:** / **Gender (m/f):** / **Group 3** **Randomised N:** not reported **Completed N:** 106 **Dropouts:** not reported **Age:** / **Gender (m/f):** / **Inclusion criteria:** Braden scale ≤ 18 and/or having a PU stage I-IV. **Exclusion criteria:** Patients with a PU stage I-IV and a Braden score > 18	Clinical judgement group. **All groups:** all patients were monitored for preventive measures and included following categories: Protective mattresses such as the standard hospital bed mattress (Stryker®, Inc., Hamilton, ON, Canada), alternating pressure relief system Therakair® (Kinetic Concepts, Inc., San Antonio, TX, USA), Gen Air 8000® (Genadyne Inc., Great Neck, NY, USA), Atmosair® (Kinetic Concepts, Inc., USA) and gel overlay or air fluidised bed (Clinitron®, Hill-Rom, Inc., Batesville, IN, USA); Creams and skin barriers; Vitamin supplements and special nutritional formulas; Patients' turning (positioning) schedules every two, three to four, or six hours.			(discharge before end of study period); patients with PU before intervention included. Very high risk of bias. **Additional outcomes:** association was measured with PU incidence. AUC for Braden scale and clinical judgement were reported. **Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
more than two groups because the data were not normally distributed. Mann-Whitney U (MW) test and Kruskal-Wallis (KW) test were used to test differences between respectively two or more than two groups with data that were at least ordinal, but not sufficiently normally distributed to warrant parametric testing. Logistic regression analysis was used to produce a predictive model from those recorded variables which are related to PU development. ROC curve analysis was used to show the effects of the Braden scale compared to nurses' clinical judgement in relation to PU development. Baseline differences: **Baseline differences**					

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
for medical diagnosis, protective measures, use of barrier creams and vitamin therapy. Study power/sample size: **A priori sample size calculation indicated a sample size of 108 patients. Final sample size was higher than calculated.** Setting: **Military hospital, Riyadh, Saudi Arabia** Length of study: **eight weeks** Assessment of PUs: **PU were classified according to the US Agency for Health Care Policy and Research (1992). A tissue viability nurse specialist and two trained staff nurses assed the wounds.** Multiple ulcers: **PU at start and patient could have developed a new**					

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
ulcer. If the patient developed more than one PU lesion, only the first one was taken into account. Number of patients with multiple ulcers not reported					

** The authors were contacted for additional information. This publication is part of a doctoral thesis and can be retrieved on https://www.dora.dmu.ac.uk/handle/2086/4343*

Table 14 – Webster 2011

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Webster (2011) **Title:** Pressure ulcers: effectiveness of risk-assessment tools. A randomized controlled trial (the ULCER trial) **Journal:** BMJ Quality & Safety, 20 (4); 297-306 **Study type:** randomized controlled trial **Sequence generation:** a computer-generated randomized list was	**Patient group:** hospitalized patients older than 18 years with or without a PU **All patients** **Randomised N:** 1231 **Completed N:** 1231 **Drop-outs:** 0 **Group 1** **Randomised N:** 411 **Completed N:** 411 **Dropouts:** 0 **Age (mean yrs (SD);**	**Group 1:** the Waterlow scale **Group 2:** the Ramstadius scale **Group 3:** Clinical judgement. **All groups:** prevention measures were documented.	**Outcome 1:** Incidence of PU (all stages) **Outcome 2:** Incidence of PU (stage I) **Outcome 3:** Incidence of PU (stage II)	**Group 1:** 31/411 **Group 2:** 22/410 **Group 3:** 28/410 **P value:** 0.44 **Group 1:** 21/411 **Group 2:** 18/410 **Group 3:** 20/410 **Group 1:** 10/411 **Group 2:** 4/410 **Group 3:** 8/410	**Funding:** / **Limitations:** type of method used for allocation concealment not reported; health care professional not blinded; final sample size lower than a priori calculated; no report on baseline difference regarding presence of PU on admission; patients with PU

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
used to allocate the patients. Block and stratified randomization according to type of patient (medical/oncological), presence/absence of PU on admission and mobility status. **Allocation concealment:** allocation was concealed; method not reported **Blinding:** patient and outcome assessor were blinded to group assignment. **Addressing incomplete outcome data:** Intention-to-treat analysis. 7 missing data on comorbidity; 247 excluded from model because data was not available. **Statistical analysis:** Baseline clinical and demographic characteristics were compared using frequencies or means	**range):** 62.6 (19.6); 18-100 **Gender (m/f):** 200/211 **Ability to turn independently:** 374 **Wheelchair dependent:** 30 **Pressure ulcer on admission:** 25 **Length of stay (mean days (SD); range):** 8.8 (9.5); 1-98 **Group 2** **Randomised N:** 410 **Completed N:** 410 **Dropouts:** 0 **Age (mean yrs (SD); range):** 63.2 (19.2); 18-98 **Gender (m/f):** 205/205 **Ability to turn independently:** 368 **Wheelchair dependent:** 19 **Pressure ulcer on admission:** 25 **Length of stay (mean days (SD); range):** 9.4				before intervention included. **Additional outcomes:** process of care between the three groups were measured. Predictor of pressure injury were calculated. **Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
and standard deviations (SD). The inter-rater agreement was assessed using the percentage agreement between raters. For the primary outcome, the OR and their 95% CIs were calculated for the proportion of patients with pressure ulcers in each group. Logistic regression models were used to determine risk factors associated with patients developing a pressure ulcer after admission. The initial logistic regression model incorporated all variables that were significant in the univariate analyses, and also adjusted for the treatment group. Using this initial model, the backwards elimination was used to the select final model. As the vast majority of inpatient dietician reviews are	(99.9); 1-81 **Group 3** **Randomised N:** 410 **Completed N:** 410 **Dropouts:** 0 **Age (mean yrs (SD); range):** 61.9 (19.0); 19-100 **Gender (m/f):** 214/196 **Ability to turn independently:** 373 **Wheelchair dependent:** 29 **Pressure ulcer on admission:** 21 **Length of stay (mean days (SD); range):** 8.5 (8.5); 1-81 **Inclusion criteria:** admitted through the emergency department or any outpatient department **Exclusion criteria:** hospital stay < 3 days; hospitalized more than 24h before baseline				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
for malnutrition, referral to a dietician was used in the models as a proxy for malnutrition. Regression models are adjusted for potential confounding of treatment group. **Baseline differences:** Statistical difference was calculated for mean hours in emergency department (p=0.56) and average length of stay (p=0.38). **Study power/sample size:** A priori sample size calculation indicated a sample size of 466 patients per group. Final sample size lower than calculated. **Setting:** Internal medicine ward and oncological ward at the Royal Brisbane and Women's Hospital, Australia **Length of study:** not reported; length of	assessment				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
stay: range 1-98 days **Assessment of PUs:** Research assistants trained in pressure ulcer staging asses the wounds using a standardized assessment method (Black et al. 2007). **Multiple ulcers:** not reported					

2. RISK ASSESSMENT – PROGNOSTIC

2.1. Review Protocol

Table 1 – Protocol review question

Protocol	Risk assessment
Review question	What is the predictive ability of risk assessment tools for pressure ulcer development?
Population	Individuals of all ages in all settings without a pressure ulcer
Risk assessment tool	• Clinical judgement based on risk factors • Risk assessment tool (any reported cut-off score): o Braden, o Norton, o Waterlow, o Cubbin-Jackson, o Braden-Q, o Other scales (e.g. Gosnell scale, Knoll scale, Andersen, Pressure Sore Prediction Score, Risk Assessment Pressure Sore, Douglas, Emina, Glamorgan)
Outcomes	**Critical outcomes** • Incidence of pressure ulcers (all grades and grades 2-4)– up to one week • Incidence of pressure ulcers (all grades and grades 2-4) – up to three months
Statistical measures	**Statistical measures** • Area under the ROC (AUC); • Sensitivity for a defined threshold; • Specificity for a defined threshold;
Study design	• High quality systematic reviews of prospective cohort studies. • Prospective cohort studies in which the patients considered had not developed pressure ulcers at the beginning of the study and with a follow-up in a systematic way during an established period
Exclusion	• Non-English, non-French, non-Dutch language papers

Protocol	Risk assessment
Search strategy	**The electronic databases to be searched are:** • Medline (OVID interface), Cinahl (EBSCO-interface), Embase, Library of the Cochrane Collaboration • All years
Review strategy	**How will individual PICO characteristics be combined across studies)** • Population – any population will be combined except those specified in the strata • Risk tool – combine same tools only • Outcomes – same outcomes will be combined • Minimum follow up = no minimum • Minimum total size = no minimum
Analysis	**The following groups will be considered separately if data are present:** • Children (neonates, infants and children); • ICU patients; • Patients with a spinal cord injury; • Palliative patients. The following analyses will be performed • The AUC and 95% CI for each scale (within studies and between studies; if data are available) will be extracted and used to calculate the median AUC and range. • Three cut-off scores will be determined for each scale with an acceptable median AUC, optimising sensitivity (primarily) and specificity

2.2. Search strategy

2.2.1. Search filters

Table 2 – Search filters Medline (OVID)

Date	25/7/12	
Database	**Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R)** 1946 to Present	
Search Strategy	1. Pressure Ulcer/	9139
	2. decubit*.ti,ab.	3957
	3. (pressure adj (sore* or ulcer* or damage)).ti,ab.	6283
	4. (bedsore* or bed-sore*).ti,ab.	506
	5. ((friction or shear) adj2 (sore* or ulcer* or damage or wound* or injur* or lesion*)).ti,ab.	253
	6. OR/1 – 5	
	7. Risk assessment/	13521
	8. Nursing assessment/	152369
	9. nursing assess$.tw	26960
	10. risk assess$.tw	1108
	11. risk-benefit assess$.tw	28820
	12. structured assess$.tw	439
	13. unstructured assess$.tw	580
	14. instrument$.tw	9
	15. tool$.tw	165360
	16. scale$.tw	330115
	17. screening.tw	380195
	18. Risk factor/	289136
	19. risk factor$.tw	498760
	20. risk score$.tw	297520
	21. assess$ score?.tw	5804
	22. Judgment/	1858
	23. clinical judg?ment.tw	11574
	24. Observation/	4103
	25. observation?.tw	4267
	26. OR/7 – 25	479442
	27. Braden$.tw	2222493
	28. Waterlow.tw	327

Date	25/7/12	
	29. Norton.tw	164
	30. OR/27 – 29	450
	31. AND/6, 26, 30	880
	32. Limit year: '2003 – July 2012' and limit language: 'English, Dutch, Flemish, French'	422
		215

Date	25/7/12	
Database	**Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R)** 1946 to Present	
Search Strategy	1. Pressure Ulcer/	9139
	2. decubit*.ti,ab.	3957
	3. (pressure adj (sore* or ulcer* or damage)).ti,ab.	6283
	4. (bedsore* or bed-sore*).ti,ab.	506
	5. ((friction or shear) adj2 (sore* or ulcer* or damage or wound* or injur* or lesion*)).ti,ab.	253
	6. OR/1 – 5	
	7. Risk assessment/	13521
	8. Nursing assessment/	152369
	9. nursing assess$.tw	26960
	10. risk assess$.tw	1108
	11. risk-benefit assess$.tw	28820
	12. structured assess$.tw	439
	13. unstructured assess$.tw	580
	14. instrument$.tw	9
	15. tool$.tw	165360
	16. scale$.tw	330115
	17. screening.tw	380195
	18. Risk factor/	289136
	19. risk factor$.tw	498760
	20. risk score$.tw	297520
	21. assess$ score?.tw	5804
	22. Judgment/	1858
	23. clinical judg?ment.tw	11574
	24. Observation/	4103

Date	25/7/12	
	25. observation?.tw	4267
	26. OR/7 – 25	479442
	27. Sensitivity and Specificity/	2222493
	28. sensitiv:.mp.	253657
	29. predictive value:.mp.	1096653
	30. accuracy:.tw	161212
	31. specificit$.mp	194778
	32. OR/17 – 31	772727
	33. AND/6, 26, 32	1747453
	34. Limit year: '2003 – July 2012' and limit language: 'English, Dutch, Flemish, French'	407
		220

Table 3 – Search filters Embase

Date	25/7/12	
Database	Embase	
Search Strategy (attention, for PubMed, check « Details »)	1. 'decubitus'/exp	6949
	2. decubit*:ti,ab	3631
	3. (pressure NEAR/1 (score* OR ulcer* OR damage)):ab,ti	2357
	4. (bed NEAR/2 sore*):ab,ti OR bedsore*:ti,ab	390
	5. ((friction or shear) near/2 (sore* or ulcer* or damage or wound* or injur* or lesion*)):ti,ab	240
	6. OR/1 – 5	
	7. 'risk assessment'/exp	9754
	8. 'risk assessment$':ti,ab	246481
	9. 'assessment$ risk':ti,ab	26996
	10. 'risk-benefit assessment$':ti,ab	193
	11. 'structured assessment$':ti,ab	458
	12. 'assessment$ structured':ti,ab	519
	13. 'unstructured assessment$':ti,ab	15
	14. 'instrument'/exp	6
	15. 'instrument$':ti,ab	6212
	16. 'tool$':ti,ab	60953
	17. 'scale$':ti,ab	220029
	18. 'screening':ti,ab	323627
	19. 'risk factor'/exp	285932

Date	25/7/12	
	20. ‘risk factor$’:ti,ab	383549
	21. ‘factor risk$’:ti,ab	113655
	22. ‘risk score$’:ti,ab	104
	23. ‘score$ risk’:ti,ab	6423
	24. ‘assessment$ score$’:ti,ab	253
	25. ‘decision making’/exp	1121
	26. ‘clinical judg?ment’:ti,ab	64313
	27. ‘clinical observation’/exp	1312
	28. ‘nursing assessment’/exp	13399
	29. ‘nursing assessment’:ti,ab	250
	30. ‘observation$’:ti,ab	213
	31. OR/7 – 30	190956
	32. ‘braden scale’/exp	1632721
	33. ‘braden$’:ti,ab	39
	34. ‘waterlow’:ti,ab	116
	35. ‘norton’:ti,ab	90
	36. OR/32 – 35	306
	37. AND/6, 31, 36	498
	38. Limit year: ‘2003 – July 2012’ and language: ’English, Dutch, French’	139
		78

Date	25/7/12	
Database	Embase	
Search Strategy (attention, for PubMed, check « Details »)	1. ‘decubitus’/exp	6949
	2. decubit*:ti,ab	3631
	3. (pressure NEAR/1 (score* OR ulcer* OR damage)):ab,ti	2357
	4. (bed NEAR/2 sore*):ab,ti OR bedsore*:ti,ab	390
	5. ((friction or shear) near/2 (sore* or ulcer* or damage or wound* or injur* or lesion*)):ti,ab	240
	6. OR/1 – 5	
	7. 'risk assessment'/exp	9754
	8. ‘risk assessment$’:ti,ab	246481
	9. ‘assessment$ risk’:ti,ab	26996
	10. ‘risk-benefit assessment$’:ti,ab	193

Date	25/7/12	
11.	'structured assessment$':ti,ab	458
12.	'assessment$ structured':ti,ab	519
13.	'unstructured assessment$':ti,ab	15
14.	'instrument'/exp	6
15.	'instrument$':ti,ab	6212
16.	'tool$':ti,ab	60953
17.	'scale$':ti,ab	220029
18.	'screening':ti,ab	323627
19.	'risk factor'/exp	285932
20.	'risk factor$':ti,ab	383549
21.	'factor risk$':ti,ab	113655
22.	'risk score$':ti,ab	104
23.	'score$ risk':ti,ab	6423
24.	'assessment$ score$':ti,ab	253
25.	'decision making'/exp	1121
26.	'clinical judg?ment':ti,ab	64313
27.	'clinical observation'/exp	1312
28.	'nursing assessment'/exp	13399
29.	'nursing assessment':ti,ab	250
30.	'observation$':ti,ab	213
31.	OR/7 – 30	190956
32.	'sensitivity and Specificity'/exp	1632721
33.	'predictive validity'/exp	101683
34.	'Predictive Value'/exp	4404
35.	'sensitive$':ti,ab	19025
36.	'specificit$':ti,ab	444716
37.	'accuracy':ti,ab	3
38.	'Predictive value':ti,ab	178474
39.	'predictive validity':ti,ab	55568
40.	OR/36 – 43	3060
41.	AND/10, 35, 44	724733
42.	Limit year: '2003 – July 2012' and language: 'English, Dutch, French'	105
		73

Table 4 – Search filters Cochrane Library

Date	**25/7/12**	
Database	The Library of the Cochrane Collaboration	
Search Strategy (attention, for PubMed, check « Details »)	1. “Pressure ulcer” [MeSH]	489
	2. Decubit*:ti,ab,kw	349
	3. (pressure near/2 (sore* or ulcer* or damage*)):ti,ab,kw	834
	4. (bedsore* or bed-sore*):ti,ab,kw	33
	5. ((friction or shear) near/2 (sore* or ulcer* or damage or wound* or injur*or lesion*)):ti,ab,kw	3
	6. OR/1 – 5	
	7. “risk assessment”[MeSH]	1115
	8. (risk assess*):ti,ab,kw	5960
	9. (risk-benefit assess*):ti,ab,kw	23877
	10. (structured assessment):ti,ab,kw	132
	11. (unstructured assess*):ti,ab,kw	1872
	12. (instrument*):ti,ab,kw	44
	13. (tool*):ti,ab,kw	21013
	14. (scale*):ti,ab,kw	6381
	15. (screening*):ti,ab,kw	48545
	16. “risk factors”[MeSH]	12029
	17. (risk factor):ti,ab,kw	16190
	18. (risk score):ti,ab,kw	28808
	19. (assessment score):ti,ab,kw	6261
	20. “Judgment”[MeSH]	11419
	21. “nursing assessment”[MeSH]	430
	22. (nurs* assess*):ti,ab,kw	493
	23. (clinical judg?ment):ti,ab,kw	4271
	24. “Observation”[MeSH]	260
	25. (observation*):ti,ab,kw	139
	26. OR/7 – 25	22962
	27. (braden*):ti,ab,kw	145412
	28. (waterlow):ti,ab,kw	27
	29. (Norton):ti,ab,kw	13
	30. OR/27 – 29	32
	31. AND/6, 26, 30	69
	32. Limit year: ‘2003 – July 2012’	43
		21

Date	25/7/12	
Database	The Library of the Cochrane Collaboration	
Search Strategy (attention, for PubMed, check « Details »)	1. “Pressure ulcer” [MeSH]	489
	2. Decubit*:ti,ab,kw	349
	3. (pressure near/2 (sore* or ulcer* or damage*)):ti,ab,kw	834
	4. (bedsore* or bed-sore*):ti,ab,kw	33
	5. ((friction or shear) near/2 (sore* or ulcer* or damage or wound* or injur*or lesion*)):ti,ab,kw	3
	6. OR/1 – 5	
	7. “risk assessment”[MeSH]	1115
	8. (risk assess*):ti,ab,kw	5960
	9. (risk-benefit assess*):ti,ab,kw	23877
	10. (structured assessment):ti,ab,kw	132
	11. (unstructured assess*):ti,ab,kw	1872
	12. (instrument*):ti,ab,kw	44
	13. (tool*):ti,ab,kw	21013
	14. (scale*):ti,ab,kw	6381
	15. (screening*):ti,ab,kw	48545
	16. “risk factors”[MeSH]	12029
	17. (risk factor):ti,ab,kw	16190
	18. (risk score):ti,ab,kw	28808
	19. (assessment score):ti,ab,kw	6261
	20. “Judgment”[MeSH]	11419
	21. “nursing assessment”[MeSH]	430
	22. (nurs* assess*):ti,ab,kw	493
	23. (clinical judg?ment):ti,ab,kw	4271
	24. “Observation”[MeSH]	260
	25. (observation*):ti,ab,kw	139
	26. OR/7 – 25	22962
	27. “Sensitivity and Specificity” [MeSH]	145412
	28. (Sensitive*):ti,ab,kw	13587
	29. (predictive value*):ti,ab,kw	8636
	30. (predictive validity):ti,ab,kw	7144
	31. (accuracy):ti,ab,kw	312
	32. (specificit*):ti,ab,kw	6806
	33. OR/27 – 32	12760

Date	25/7/12	
	34. AND/6, 26, 33	30085
	35. Limit year: '2003 – July 2012'	23
		11
Note		

Table 5 – Search filters CINAHL

Date	25/7/12	
Database	CINAHL (EBSCO-interface)	
Search Strategy (attention, for PubMed, check « Details »)	1. MH "Pressure Ulcer"	7732
	2. bedsore* OR bed-sore*	157
	3. pressure n1 sore* OR pressure n1 ulcer* OR pressure n1 damage*	8512
	4. decubit*	
	5. ((friction or shear) and (sore* or ulcer* or damage or wound* or injur* or lesion*))	482
	6. OR/1 – 5	806
	7. MH "Risk assessment"	
	8. MH "Nursing assessment"	9370
	9. "risk assessment$" or "assessment$ risk"	28426
	10. "nurs$ assessment$ or "assessment$ nurs$"	13700
	11. "risk-benefit assessment$"	30197
	12. "structured assessment$" or "assessment$ structured"	335
	13. "unstructured assessment$"	335
	14. "instrument$"	139
	15. "tool$"	2
	16. "scale$"	31005
	17. "screening"	30123
	18. MH "risk factor"	66388
	19. "risk factor$" or "factor$ risk"	52852
	20. "risk score$" or "score$ risk"	53469
	21. "assessment score$"	13557
	22. MH "Decision Making, Clinical"	917
	23. MH "Judgment"	273
	24. "clinical judg?ment"	13087

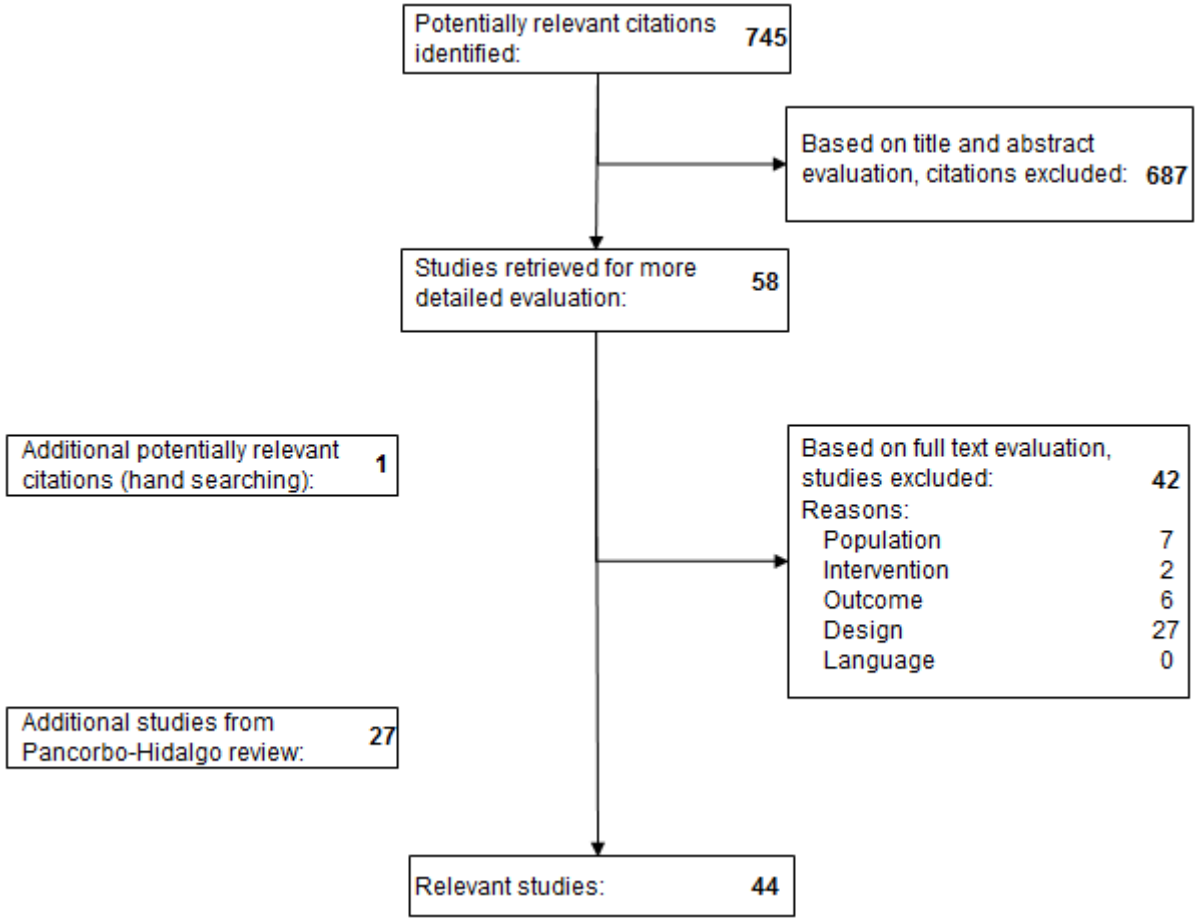
Date	25/7/12	
	25. "observation" or "observations"	1883
	26. OR/7 – 25	273
	27. (MH "Braden Scale for Predicting Pressure Sore Risk")	26519
	28. "Braden$"	281311
	29. "Waterlow"	596
	30. "Norton"	708
	31. OR/27 – 30	115
	32. AND/6, 26, 31	218
	33. Limit year: '2003 – July 2012' and language: 'English, Dutch, French'	976
		806
		451
Note		

Date	25/7/12	
Database	CINAHL (EBSCO-interface)	
Search Strategy (attention, for PubMed, check « Details »)	1. MH "Pressure Ulcer"	7732
	2. bedsore* OR bed-sore*	157
	3. pressure n1 sore* OR pressure n1 ulcer* OR pressure n1 damage*	8512
	4. decubit*	
	5. ((friction or shear) and (sore* or ulcer* or damage or wound* or injur* or lesion*))	482
	6. OR/1 – 5	806
	7. MH "Risk assessment"	
	8. MH "Nursing assessment"	9370
	9. "risk assessment$" or "assessment$ risk"	28426
	10. "nurs$ assessment$ or "assessment$ nurs$"	13700
	11. "risk-benefit assessment$"	30197
	12. "structured assessment$" or "assessment$ structured"	335
	13. "unstructured assessment$"	335
	14. "instrument$"	139
	15. "tool$"	2
	16. "scale$"	31005
	17. "screening"	30123
	18. MH "risk factor"	66388

Date	25/7/12	
	19. “risk factor$” or “factor$ risk”	52852
	20. “risk score$” or “score$ risk”	53469
	21. “assessment score$”	13557
	22. MH "Decision Making, Clinical"	917
	23. MH "Judgment"	273
	24. “clinical judg?ment”	13087
	25. “observation” or “observations”	1883
	26. OR/7 – 25	273
	27. MH "Sensitivity and Specificity"	26519
	28. MH “predictive validity”	281311
	29. MH "Predictive Value of Tests”	23888
	30. “sensitive$”	2056
	31. “Specificit$”	14958
	32. “accuracy”	16366
	33. “Predictive value”	29299
	34. “predictive validity”	15497
	35. OR/27 – 34	17626
	36. AND/6, 26, 35	2626
	37. Limit year: ‘2003 – July 2012’ and language: ’English, Dutch, French’	67412
		265
		146
Note		

2.2.2. Selection of articles

Figure 1 – Flow chart



2.2.3. List of excluded studies

Reference	Reason of exclusion
Anthony 2008	Cross-sectional study
Anthony 2010	No qualitative systematic review
Balzer 2007	Cross-sectional study
Bergstrom 2005	Letter
Bergquist 2001	Retrospective cohort study
Bolton 2007	Abstract; insufficient information
Bolton 2007	No prospective cohort study
Boyle 2001	Patients with PU at start included
Brown 2004	No qualitative systematic review
Cowan 2012	Retrospective study
Defloor 2004	Patients with PU at start included
Fernandes 2008	No predictive validity
Franks 2003	No prospective cohort study
Gherghina 2011	No predictive validity
Gray 2004	Report
Gunningberg 1999	Patients with PU at start included
Hagisawa 1999	Patients with PU at start included
Harris 2010	Abstract; insufficient information
He 2012	Systematic review of a subgroup; reference list screened
Iranmanesh 2012	No predictive validity
Kim 2006	Case-control
Kring 2007	No prospective cohort study
Matuo 2008	Abstract; insufficient information
Mertens 2008	Cross-sectional study
Mertens 2010	Cross-sectional study

Reference	Reason of exclusion
Mitchell 2004	No prospective cohort study
Montague 2009	Abstract; insufficient information
Nonnemacher 2009	Patients with PU at start included
Okuwa 2005	No risk assessment tool
Papanikolaou 2003	Cross-sectional study
Poss 2010	Patients with PU at start included
Price 2005	No predictive validity
Quesada 2009	No predictive validity
Reynolds 2006	No risk assessment tool
Saleh 2009	Patients with PU at start included
Schoonhoven 2005	No prospective cohort study
Serpa 2011	No predictive validity
Sharp 2006	No prospective cohort study
Stausberg 2011	Comment
Stotts 2007	No prospective cohort study
Suddaby 2006	Not only pressure ulcers
Tannen 2010	Cross-sectional study
Thompson 2005	No qualitative systematic review
Walsh 2011	No qualitative systematic review
Webster 2007	Patients with PU at start included
Willock 2009	Patients with PU at start included

2.3. Risk assessment tools

Risk assessment tool	Population*	Risk factors	Scores
Braden scale (Bergstrom 1987a[3])	Skilled nursing facility patients	Sensory perception (completely limited – no impairment) Moisture (constantly – rarely) Activity (bedfast – walks frequently) Mobility (completely immobile – no limitation) Nutrition (very poor – excellent) Friction and shear (problem – no apparent problem)	Score ranges from 6 to 23**
Norton scale (Norton 1962[4])	Elderly hospitalized patients	Physical condition (very bad – good) Mental condition (stupor – alert) Activity (bedfast – ambulant) Mobility (immobile – full) Incontinent (urinary and faecal – not)	Score ranges from 5 to 20**
Waterlow scale (Waterlow 1985[5]; revised Waterlow, 2005[6])	Hospitalized patients on a medical or surgical ward	Build/weight for height (average – below average) Skin type visual risk area (healthy – broken/spots grade 2-4) Sex (male – female) Age (14 – 81+) Continence (complete/catheterised – urinary and faecal incontinence) Mobility (fully – chair bound) Malnutrition screening tool (MST) (nutrition score) Special risk: tissue malnutrition (terminal cachexia, multiple/single organ failure, peripheral vascular disease, anaemia, smoking); neurological deficit (diabetes, MS, CVA, motor/sensory, paraplegia); major surgery/trauma (orthopaedic/spinal, on table ≥2hrs/6hrs); medication (cytotoxic, long term/high dose steroids, anti-inflammatory)	Score ranges from 2 to 20+***
Cubbin-Jackson scale (Cubbin 1991[7]; revised Jackson 1999[8])	Intensive care patients	Age Weight Skin condition of the whole body Mental state	Score ranges from 10 to 40**

Risk assessment tool	Population*	Risk factors	Scores
		Mobility Nutrition Respiration Incontinence Hygiene Hemodynamic state	
Braden-Q scale (Quigley 1996[9])	Paediatric patients	Mobility (completely immobile – no limitations) Activity (bedfast – all patients too young to ambulate or walks frequently) Sensory perception (completely limited – no impairment) Moisture (constantly – rarely) Friction and shear (problem – no apparent problem) Nutrition (very poor – excellent) Tissue perfusion and oxygenation (extremely compromised – excellent)	Scores ranges from 7 to 28**

** Population for which the scale was originally developed*
*** Lowest score indicates the highest risk*
**** Lowest score indicates the lowest risk*

2.4. Clinical evidence

2.4.1. Search strategy

A systematic review by Pancorbo-Hidalgo et al. (2006)[10] was identified and adapted for this review. We updated the review by Pancorbo-Hidalgo et al. (2006) [10] through a systematic search of multiple electronic databases. This resulted in 1053 records: 369 in Medline (OVID), 515 in CINAHL, 138 in Embase and 30 in the Cochrane Library. 308 duplicates were removed. Based on screening of title and/or abstract 687 records were excluded. 58 records were reviewed in detail and an additional 42 records were excluded. The remaining 16 studies were included in this review. One additional study was retrieved trough screening of reference lists.

The review by Pancorbo-Hidalgo et al. (2006)[10] included 32 studies, of which five were excluded because they didn't meet the inclusion criteria of our review:

- One was excluded as it was a retrospective cohort study[11];
- Another study was removed as it was written in Spanish[12];
- Three other studies were excluded as they included patients with a pressure ulcer at start of the study[13-15].

The update of the Pancorbo-Hidalgo (2006)[10] review yielded 16 additional articles resulting in a final inclusion of 44 studies[3 , 16 , 17 , 18 , 19 , 20 , 21 , 22 , 23 , 24 , 25 , 26 , 27 , 28 , 29 , 30 , 31 , 32 , 33 , 34 , 35 , 36 , 37 , 38 , 39 , 40 , 41 , 42 , 43 , 44 , 45 , 46 , 47 , 48 , 49 , 50 , 51 , 52 , 53 , 54 , 55 , 56 , 57]

2.4.2. Clinical evidence

The systematic review by Pancorbo-Hidalgo (2006) [10]was used as a reference for this review. All studies included in the Pancorbo-Hidalgo (2006) [10] review, identified through the update and meeting the criteria of our review were reviewed in detail. Sensitivity and specificity of each scale and cut-off score were re-calculated by using the raw data as presented in the individual studies. Some adjustments were made to the Pancorbo-Hidalgo review[10].

2.4.3. Summary table

Table 2 – Summary of included studies

Study	Risk tool Outcome	Population	Length of follow-up	Number of patients	Number of events
Andersen 1982[16]	Andersen scale Pressure ulcer development	Patients in an acute observation ward	Maximum three months	3398	40
Anthony 2003[17]	Waterlow scale Pressure ulcer development	Hospitalized patients	Not reported (median days in hospital two days for PU free patients versus 22 days for PU patients)	45735	203
Barnes 1993[18]	Braden scale Pressure ulcer development	Nursing home patients	Maximum two weeks	361	22
Bergstrom 1987a[3] **(1)** **(2)**	Braden scale Pressure ulcer development	Medical/surgical patients Medical/surgical patients (unit with higher acuity levels and longer expected length of stay than group 1)	Maximum six weeks Maximum 12 weeks	99 100	7 9
Bergstrom 1987b[19]	Braden scale Pressure ulcer development	Intensive care patients	Maximum two weeks	60	24
Bergstrom 1998[20] **(1)** **(2)** **(3)**	Braden scale Pressure ulcer development	Patients in a tertiary care hospital Patients in a Veteran Medical Centre Patients in a skilled nursing facility	48-72 hours and maximum 11 days	306 282 255	26 21 61
Braden 1994[21]	Braden scale Pressure ulcer development	Patients in a skilled nursing facility	Maximum four weeks	102	28

Study	Risk tool Outcome	Population	Length of follow-up	Number of patients	Number of events
Capobianco 1996[22]	Braden scale Pressure ulcer development	Medical/surgical patients	Maximum two weeks	50	14
Chan 2009[23]	(1) Braden scale (2) Modified Braden scale Pressure ulcer development	Orthopaedic patients	Maximum nine days	197	18
Compton 2008[24]	Waterlow scale Pressure ulcer grade II+ development	Intensive care patients	Maximum 13 days	698	121
Curley 2003[25]	Braden-Q Pressure ulcer development	Paediatric intensive care patients	Maximum 10 days	322	86
de Souza 2010[26]	Braden scale Pressure ulcer development	Patients in a long-term care facility; aged 60 years and older; a Braden score < 19	Three months	233	44
Edwards 1995[27]	Waterlow scale Pressure ulcer development	Home care patients	Eight weeks	31	2
Feuchtinger 2007[28]	(1) Braden scale (2) Modified Norton scale (3) 4-factor model PU development	Intensive care patients (cardiac surgery patients)	Maximum four days	53	26
Goodridge 1998[29]	Braden scale Pressure ulcer development	Patients from the medical and geriatric unit of a tertiary care hospital and long-term care facility; aged 65 years and older	Maximum three months	330	32
Halfens 2000[30]	(1) Braden scale (2) Extended Braden	Surgical, neurological, orthopaedic and internal	Not reported	320	186

Study	Risk tool Outcome	Population	Length of follow-up	Number of patients	Number of events
	scale Pressure ulcer development and/or use of preventive measures	medicine patients			
Hatanaka 2008[31]	Braden scale Pressure ulcer development	Bedridden hospitalized patients with a respiratory disorder	Maximum 79 days	149	38
Jalali 2005[32]	(1) Braden scale (2) Norton scale (3) Waterlow scale (4) Gosnell scale Pressure ulcer development	Neurological, intensive care, orthopaedic and medical care patients.	Maximum 14 days	230	74
Kim 2009[33]	(1) Braden scale (2) Cubbin-Jackson scale (3) Song and Choi scale Pressure ulcer development	Surgical intensive care patients	Maximum 90 days	219	40
Kwong 2005[34]	(1) Braden scale (2) Modified Braden scale (3) Norton scale Pressure ulcer development	Acute care patients	Maximum 21 days	429	9
Langemo 1991[35] **(1)** **(2)**	Braden scale Pressure ulcer development	Hospitalized patients Patients in a long-term care facility	Maximum 16 days Maximum 31 days	74 25	11 7
Lewicki 2000[36]	Braden scale Pressure ulcer development	Elective cardiac surgery patients	Five days	337	7
Lincoln 1986[37]	Norton scale Pressure ulcer	Medical/surgical patients; aged 65 years and older	Maximum 26 days	36	5

Study	Risk tool Outcome	Population	Length of follow-up	Number of patients	Number of events
	development				
Lindgren 2002[38]	Risk Assessment Pressure Sore scale (RAPS) Pressure ulcer development	Acute care patients	Maximum 12 weeks	488	54
Lothian 1989[39]	Pressure Sore Prediction Score (PSPS) Pressure ulcer development	Orthopaedic patients	Maximum three weeks	1244	53
Lyder 1999[40]	Braden scale Pressure ulcer development	Patients from a tertiary hospital	Not reported	177	24
Ongoma 2006[41]	(1) Sunderland Pressure Sore Risk Calculator (modified Cubbin-Jackson scale) (2) Modified Norton scale Pressure ulcer development	Intensive care patients	Three weeks	66	25
Page 2011[42]	The Northern Hospital Pressure Ulcer Prevention Plan (TNH-PUPP) Pressure ulcer development	Acute care patients	Not reported	165	7
Pang 1998[43]	(1) Braden scale (2) Norton scale (3) Waterlow scale Pressure ulcer development	Medical and orthopaedic patients	Maximum 14 days	106	21

Study	Risk tool Outcome	Population	Length of follow-up	Number of patients	Number of events
Perneger 2002[44]	(1) Braden scale (2) Norton scale (3) Fragmment scale Pressure ulcer development	Internal medicine, abdominal surgery, orthopaedic, neurosurgery, intensive care, and dermatological patients	Maximum three weeks	1190	170
Ramundo 1995[45]	Braden scale Pressure ulcer grade II development	Home care patients	Maximum four weeks	48	7
Salvadalena 1992[46]	(1) Braden scale (2) Clinical judgement Pressure ulcer development	Acute medical care patients	Maximum six months	99	20
Schoonhoven 2002[47]	(1) Braden scale (2) Norton scale (3) Waterlow scale Pressure ulcer development	Surgical, internal care, neurological, and geriatric patients	Maximum 12 weeks	1229	135
Seongsook 2004[48]	(1) Braden scale (2) Cubbin-Jackson scale (3) Douglas scale Pressure ulcer development	Internal, surgical and neurological intensive care patients	Study duration of 1 year	112	35
Serpa 2009[49]	Waterlow scale Pressure ulcer development	Hospitalized patients; a Braden score < 19 and/or a Waterlow score > 15	Maximum six days	98	7
Serpa 2011[58]	Braden scale Pressure ulcer development	Intensive care patients; a Braden score < 19	Maximum six days	72	8
Smith 1989[50]	(1) Norton scale (2) Waterlow scale	Hospitalized patients	Nor reported	101	30

Study	Risk tool Outcome	Population	Length of follow-up	Number of patients	Number of events
	Pressure ulcer development				
Stotts 1988[51]	Norton scale Pressure ulcer development	Cardiovascular surgery and neurosurgery patients	Maximum three weeks	387	67
Suriadi 2006[52]	Braden scale PU development	Intensive care patients	Maximum 22 days	105	35
Suriadi 2008[53]	Suriadi and Sanada scale (SS) Pressure ulcer development	Intensive care patients	Not reported	253	47
Towey 1988[54]	Knoll scale Pressure ulcer development	Patients in a long-term care facility; aged 65 years and older	Fourteen and 38 days	60	28
VandenBosch 1996[55]	(1) Braden scale (2) Clinical judgement Pressure ulcer development	General and intensive care patients and rehabilitation inpatients	Maximum two weeks	103	29
Wai-Han 1997[56]	(1) Norton scale (2) Waterlow scale Pressure ulcer development	Geriatric hospitalized patients; aged 70 years and older	Four weeks	185	8
Weststrate 1998[57]	Waterlow scale Pressure ulcer grade II+ development	Surgical intensive care patients	Maximum of 183 days	594	47

2.4.4. Median Area under the ROC curve

Table 3 – Braden scale

Study	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of patients (range)	Number of events (range)	Median AUC (%) (range)	Acceptability of values*	Quality
All populations									
9 (Schoonhoven 2002; Perneger 2002; Seongsook 2004**; Suriadi 2006; Hatanaka 2007; Chan 2009; Kim 2009; de Souza 2010**; Serpa 2011)	Very serious[1]	Serious[2]	No serious indirectness	Serious[3]	72-1229	8-170	74.0 (55.0 – 88.0)	Fair discrimination	⊕○○○ VERY LOW
General population									
5 (Schoonhoven 2002; Perneger 2002; Hatanaka 2007; Chan 2009; de Souza 2010**)	Very serious[1]	Serious[2]	No serious indirectness	Serious[3]	149-1229	38-170	68.0 (55.0 – 81.0)	Poor discrimination	⊕○○○ VERY LOW
Intensive care patients									
4 (Seongsook 2004**; Suriadi 2006; Kim 2009; Serpa 2011)	Very serious[1]	No serious inconsistency	No serious indirectness	Serious[3]	72-219	8-40	79.0 (71.0 – 88.0)	Fair discrimination	⊕○○○ VERY LOW

** 90.0-100.0: very good discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*
*** Unclear if patients with a pressure ulcer at start of the study were included.*
1 All studies had high to very high risks of bias (see quality table)
2 Wide variation in AUC across the studies
3 Low event rates (< 100), except for the study of Schoonhoven 2002 and Perneger 2002

Table 4 – Modified Braden scale

Study	Risk of bias	Inconsistency	Indirectness	Imprecision	Number	Number	Median	Acceptability	Quality

					of patients	of events	AUC (%) (range)	of values*	
General population									
1 (Chan 2009)	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	197	18	74.0 (95% CI: 63.0-84.0)	Fair discrimination	⊕⊕○○ LOW

** 90.0-100.0: perfect discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*
1 Study had high risks of bias (see quality table)
2 Low event rates (< 100)

Table 5 – Braden-Q scale

Study	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of patients	Number of events	Median AUC (%) (range)	Acceptability of values*	Quality
Paediatric ICU									
1 (Curley 2003)	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	322	86	83.0 (95% CI: 76.0-91.0)	Good discrimination	⊕⊕○○ LOW

** 90.0-100.0: perfect discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*
1 Study had high risks of bias (see quality table)
2 Low event rates (< 100)

Table 6 – Norton scale

Study	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of patients (range)	Number of events (range)	Median AUC[3] (%) (range)	Acceptability of values*	Quality
General population									
2 (Schoonhoven 2002; Perneger 2002)	Serious[1]	Serious[2]	No serious indirectness	No serious imprecision	1190-1229	135-170	65.0 (56.0 – 74.0)	Poor discrimination	⊕⊕○○ LOW

** 90.0-100.0: perfect discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*
1 Studies had high risks of bias (see quality table)

2 Wide variation in AUC across the two studies
3 Mean AUC: only two studies

Table 7 – Waterlow scale

Study	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of patients (range)	Number of events (range)	Median AUC (%) (range)	Acceptability of values*	Quality
All populations									
4 (Schoonhoven 2002; Anthony 2003; Compton 2008; Serpa 2009)	Very serious[1]	Serious[2]	No serious indirectness	Serious[3]	98-45735	7-203	60.0 (54.0 – 90.0)	Poor discrimination	⊕○○○ VERY LOW
General population									
3 (Schoonhoven 2002; Anthony 2003; Serpa 2009)	Very serious[1]	Serious[2]	No serious indirectness	Serious[3]	98-45735	7-203	61.0 (54.0 – 90.0)	Poor discrimination	⊕○○○ VERY LOW
Intensive care patients									
1 (Compton 2008)	Very serious[1]	No serious inconsistency	No serious indirectness	No serious imprecision	698	121	59.0 (95% CI: 54.0-65.0)	Fail discrimination	⊕⊕○○ LOW

** 90.0-100.0: perfect discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*
1 The studies had high to very high risks of bias (see quality table)
2 Wide variation in AUC across the studies
3 Very low event rates (< 100) for the study of Serpa 2009. The other studies had an event rate > 100

Table 8 – Cubbin-Jackson scale

Study	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of patients (range)	Number of events (range)	Median AUC[3] (%) (range)	Acceptability of values*	Quality
Intensive care patients									
2 (Kim 2009; Seongsook 2004**)	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	112-219	35-40	87.0 (83.0-90.0)	Good discrimination	⊕⊕○○ LOW

** 90.0-100.0: perfect discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*
*** Unclear if patients with a pressure ulcer at start of the study were included.*
1 The studies had high risks of bias (see quality table)
2 Low event rates (< 100); no confidence intervals
3 Mean AUC: only two studies

Table 9 – Douglas scale

Study	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of patients	Number of events	Median AUC (%) (range)	Acceptability of values*	Quality
Intensive care patients									
1 (Seongsook 2004**)	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	112	170	79.0	Fair discrimination	⊕⊕○○ LOW

** 90.0-100.0: perfect discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*
*** Unclear if patients with a pressure ulcer at start of the study were included.*
1 Study had high risks of bias (see quality table)
2 Low event rates (< 100); no confidence interval

Table 10 – Fragmment scale

Study	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of patients	Number of events	Median AUC (%) (range)	Acceptability of values*	Quality
General population and intensive care patients									
1 (Perneger 2002)	Serious[1]	No serious inconsistency	No serious indirectness	No serious imprecision	1190	170	79.0 (95% CI: 75.0-82.0)	Fair discrimination	⊕⊕○○ LOW

** 90.0-100.0: perfect discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*
1 Study had high risks of bias (see quality table)

Table 11 – Song and Choi scale

Study	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of patients	Number of events	Median AUC (%) (range)	Acceptability of values*	Quality
Intensive care patients									
1 (Kim 2009)	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	219	40	89.0	Good discrimination	⊕⊕○○ LOW

** 90.0-100.0: perfect discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*
1 Study had high risks of bias (see quality table)
2 Low event rates (< 100); no confidence interval

Table 12 – The Northern Hospital Pressure Ulcer Prevention Plan (TNH-PUPP)

Study	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of patients	Number of events	Median AUC (%) (range)	Acceptability of values*	Quality
Intensive care patients									
1 (Page 2011)	Very serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	165	7	90.0 (95% CI: 82.0-99.0)	Perfect discrimination	⊕○○○ VERY LOW

** 90.0-100.0: perfect discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*
1 Study had very high risks of bias (see quality table)
2 Very low event rates (< 100)

2.4.5. AUC within studies

Table 13 – Schoonhoven 2002

Study	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of patients	Number of events	AUC (%) (95% CI)	Acceptability of values*	Quality
General population									
Braden scale	Serious[1]	No serious inconsistency	No serious indirectness	No serious imprecision	1129	135	55.0 (95% CI 49.0-60.0)	Fail	⊕⊕⊕○ MODERATE
Norton scale							56.0 (95% CI 51.0-61.0)	Fail	
Waterlow scale							61.0 (95% CI 56.0-66.0)	Poor	

** 90.0-100.0: perfect discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*
1 The study had high risks of bias (see quality table)

Table 14 – Perneger 2002

Study	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of patients	Number of events	AUC (%) (95% CI)	Acceptability of values*	Quality
General population and intensive care patients									
Braden scale	Serious[1]	No serious inconsistency	No serious indirectness	No serious imprecision	1190	170	74.0 (95% CI 70.0-78.0)	Fair	⊕⊕⊕○ MODERATE
Norton scale							74.0 (95% CI 70.0-78.0)	Fair	
Fragmment scale							79.0 (95% CI 75.0-82.0)	Fair	

** 90.0-100.0: perfect discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*
1 The study had high risks of bias (see quality table)

Table 15 – Seongsook 2004**

Study	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of patients	Number of events	AUC (%) (95% CI)	Acceptability of values*	Quality
Intensive care patients									
Braden scale Cubbin-Jackson scale Douglas scale	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	112	35	71.0 83.0 79.0	Fair Good Fair	⊕⊕○○ LOW

** 90.0-100.0: perfect discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*
*** Unclear if patients with a pressure ulcer at start of the study were included.*
1 The study had high risks of bias (see quality table)
2 Low event rates (< 100); no confidence interval

Table 16 – Chan 2009

Study	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of patients	Number of events	AUC (%) (95% CI)	Acceptability of values*	Quality
General population									
Braden scale Modified Braden scale	Serious[1]	No serious inconsistency	No serious indirectness	Very serious[2]	197	18	73.0 (95% CI 63.0-84.0) 68.0 (95% CI 51.0-79.0)	Fair Poor	⊕○○○ VERY LOW

** 90.0-100.0: perfect discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*
1 The study had high risks of bias (see quality table)
2 Low event rates (< 100); wide confidence interval

Table 17 – Kim 2009

Study	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of patients	Number of events	AUC (%) (95% CI)	Acceptability of values*	Quality
Intensive care patients									
Braden scale	Serious[1]	No serious inconsistency	No serious indirectness	Serious[2]	219	40	88.0	Good	⊕⊕○○ LOW
Cubbin-Jackson scale							91.0	Excellent	
Song and Choi scale							89.0	Good	

** 90.0-100.0: perfect discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*
1 The study had high risks of bias (see quality table)
2 Low event rates (< 100); no confidence interval

Table 18 – Serpa 2009

Study	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of patients	Number of events	AUC (%) (95% CI)	Acceptability of values*	Quality
General population									
Waterlow scale (48 hours)	Very serious[1]	No serious inconsistency	No serious indirectness	Very serious[2]	98	7	64.0 (95% CI 35.0-93.0)	Poor	⊕○○○ VERY LOW
Waterlow scale (4 days)							59.0 (95% CI 34.0-83.0)	Fail	
Waterlow scale (6 days)							54.0 (95% CI 35.0-74.0)	Poor	

** 90.0-100.0: perfect discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*
1 The study had very high risks of bias (see quality table)
2 Very low event rates (< 100); very wide confidence intervals

Table 19 – Serpa 2011

Study	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of patients	Number of events	AUC (%) (95% CI)	Acceptability of values*	Quality
Intensive care patients									
Braden scale (48 hours) Braden scale (4 days) Braden scale (6 days)	Very serious[1]	No serious inconsistency	No serious indirectness	Very serious[2]	72	8	79.0 (95% CI 29.0-100.0) 79.0 (95% CI 27.0-100.0) 80.0 (95% CI 28.0-100.0)	Fair Fair Good	⊕○○○ VERY LOW

** 90.0-100.0: perfect discrimination; 80.0-89.0: good discrimination; 70.0-79.0: fair discrimination; 60.0-69.0: poor discrimination;50.0-59.0: fail to discriminate*
1 The study had very high risks of bias (see quality table)
2 Very ow event rates (< 100); very wide confidence intervals

2.4.6. Predictive ability

Table 20 – Braden scale

Study	Cut-off score*	Median sensitivity** (range)	Specificity**‡ (range)
Follow-up < 1 week – all stages – general population			
2 (Bergstrom 1998[a]; Braden 1994)[a]	≤ 17	59.0 (50.0-78.0)	70.5 (52.0-81.0)
2 (Bergstrom 1998[a]; Braden 1994)[a]	≤ 18	70.0 (60.0-88.0)	58.0 (48.0-81.0)
2 (Bergstrom 1998[a]; Braden 1994)[a]	≤ 19	83.5 (51.0-100.0)	60.5 (42.0-73.0)
Follow-up < 1 week – all stages – ICU			
1 (Serpa 2011 – 48 hours)	≤ 12	87.5	64.1
1 (Serpa 2011 – 4 days and 6 days)	≤ 13	75.0 (75.0-75.0)	82.1 (81.3-82.8)
1 (Feuchtinger 2007)	≤ 16	76.9	29.6
Follow-up > 1 week – all stages – general population			

Study	Cut-off score*	Median sensitivity** (range)	Specificity**‡ (range)
10 (Bergstrom 1987a; Bergstrom 1998[a]; Braden 1994[a]; Capobianco 1996; Chan 2009; Goodridge 1998; Langemo 1991; Lyder 1999; Pang 1998; Salvadalena 1992)	≤ 18	79.5 [b] (46.2-100.0)	73.6 [b] (14.0-100.0)
5 (Bergstrom 1987a; Bergstrom 1998[a]; Braden 1994[a]; Capobianco 1996;Salvadalena 1992)	≤ 19	86.3 [c] (71.4-100.0)	67.5 [c] (42.9-77.8)
5 (Bergstrom 1987a; Bergstrom 1998[a]; Braden 1994[a]; Capobianco 1996; Salvadalena 1992)	≤ 20	93.2[d] (43.2-100.0)	53.5 [d] (31.6-66.7)
Follow-up > 1 week – all stages – ICU			
1 (Braden 1994)	≤ 15	75.0	66.7
2 (Braden 1994[a]; Seongsook 2004[a]***)	≤ 16	90.2 (83.3-97.1)	45.0 (26.0-63.9)
1 (Braden 1994)	≤ 17	87.5	50.0
Follow-up > 1 week – stage 2+ – general population			
1 (Ramundo 1995) [e]	≤ 17	42.9	63.4
1 (Ramundo 1995) [e]	≤ 18	100.0	34.1
1 (Ramundo 1995) [e]	≤ 19	100.0	22.0

** The reported thresholds are these with the highest values for median sensitivity and specificity*
*** Percentage*
**** Unclear if patients with a pressure ulcer at start of the study were included.*
‡ Specificity corresponding to the median sensitivity
a Study of which sensitivity and specificity are presented.
b Sensitivity analysis without studies with < 10 events (Bergstrom 1987a and Langemo 1991) revealed a median sensitivity of 78.6 (r ange: 46.2-90.5) and a corresponding 74.3 (range: 14.0-100.0)
c Sensitivity analysis without study with < 10 events (Bergstrom 1987a) revealed a median sensitivity of 85.7 (range: 71.4-100.0) and a corresponding 59.1 (range: 43.0-77.8)

d Sensitivity analysis without study with < 10 events (Bergstrom 1987a) revealed a median sensitivity of 91.7 (range: 43.2 -100.0) and a corresponding 40.1 (range: 31.6-66.7)
e The study of Ramundo 1995 had 7 events

Table 21 – Braden-Q scale

Study	Cut-off score*	Median sensitivity**	Specificity**‡
Follow-up > 1 week – all stages – paediatric ICU patients			
1 (Curley 2003)	≤ 15	75.6	67.8
1 (Curley 2003)	≤ 16	88.4	58.1
1 (Curley 2003)	≤ 17	91.9	44.1

** The reported thresholds are these with the highest values for median sensitivity and specificity*
*** Percentage*
‡ Specificity corresponding to the median sensitivity

Table 22 – Norton scale

Study	Cut-off score*	Median sensitivity**	Specificity**‡
Follow-up > 1 week – all stages – general population			
4 (Kwong 2005; Lincoln 1986; Stotts 1998[a]***; Wai-Han 1997[a])	≤ 14	45.7 [b] (0.0-88.9)	80.6 [b] (61.0-94.4)
1 (Schoonhoven 2002) [c]	≤ 15	45.9	60.3
2 (Pang 1998[a]; Smith 1989[a]***)	≤ 16	70.5 (60.0-81.0)	44.9 (31.0-58.8)

** The reported thresholds are these with the highest values for median sensitivity and specificity*
*** Percentage*
**** Unclear if patients with a pressure ulcer at start of the study were included.*
‡ Specificity corresponding to the median sensitivity
a Study of which sensitivity and specificity are presented.
b Sensitivity analysis without studies with < 10 events (Kwong 2005 and Lincoln 1986) revealed a median sensitivity of 45.7 (range: 16.4-75.0) and a corresponding 80.6 (range: 66.7-94.4)
c The study of Schoonhoven 2002 had 135 events

Table 23 – Waterlow scale

Study	Cut-off score*	Median sensitivity**	Specificity*‡
Follow-up < 1 week – all stages – general population			
1 (Serpa 2009 – 48 hours) [b]	≥ 17	71.4	67.0
1 (Serpa 2009 – 4 days and 6 days) [b]	≥ 20	85.7 (85.7-85.7)	36.9 (33.0-40.7)
Follow-up > 1 week – all stages – general population			
3 (Anthony 2003[a]; Schoonhoven 2002; Wai-Han 1997)	≥ 10	87.5 [c] (82.3-89.6)	28.2 [c] (22.4-85.2)
1 (Anthony 2003) [d]	≥ 15	48.8	94.4
2 (Pang 1998[a]; Smith 1989[a]***)	≥ 16	84.3 (73.3-95.2)	40.8 (38.0-43.5)
Follow-up < 1 week – stage 2+ – ICU			
1 (Weststrate 1998)	≥ 15	80.9	28.5

** The reported thresholds are these with the highest values for median sensitivity and specificity*
*** Percentage*
**** Unclear if patients with a pressure ulcer at start of the study were included.*
‡ Specificity corresponding to the median sensitivity
a Study of which sensitivity and specificity are presented.
b The study of Serpa 2009 had 7 events
c Sensitivity analysis with only studies with > 100 events (Antony 2003 and Schoonhoven 2002) revealed a median sensitivity o f 86.0 (range: 82.3-89.6) and a corresponding 53.8 (range: 22.4-85.2)
d The study of Antony 2003 had 203 events

Table 24 – Cubbin-Jackson scale

Study	Cut-off score*	Median sensitivity**	Specificity*‡
Follow-up > 1 week – all stages – ICU			
1 (Seongsook 2004***)	≤ 24	88.6	61.0
1 (Kim 2009)	≤ 28	95.0	81.6

** The reported thresholds are these with the highest values for median sensitivity and specificity*
*** Percentage*
**** Unclear if patients with a pressure ulcer at start of the study were included.*
‡ Specificity corresponding to the median sensitivity

Table 25 – Fragmment scale

Study	Cut-off score*	Median sensitivity**	Specificity*‡
Follow-up > 1 week – all stages – general population			
1 (Perneger 2002) [a]	≤ 1	78.7	53.5
1 (Perneger 2002) [a]	≤ 2	76.7	71.9
1 (Perneger 2002) [a]	≤ 3	62.1	85.0

** The reported thresholds are these with the highest values for median sensitivity and specificity*
*** Percentage*
‡ Specificity corresponding to the median sensitivity
a The study of Perneger 2002 had 170 events

Table 26 – Douglas scale

Study	Cut-off score*	Median sensitivity**	Specificity*‡
Follow-up > 1 week – all stages – ICU			
1 (Seongsook 2004***)	≤ 18	100.0	18.2

** The reported thresholds are these with the highest values for median sensitivity and specificity*
*** Percentage*
**** Unclear if patients with a pressure ulcer at start of the study were included.*
‡ Specificity corresponding to the median sensitivity

Table 27 – The Northern Hospital Pressure Ulcer Prevention Plan

Study	Cut-off score*	Median sensitivity**	Specificity**‡
Follow-up > 1 week – all stages – general population			
1 (Page 2011) [a]	≥ 2	85.7	62.0
1 (Page 2011) [a]	≥ 3	71.4	81.0
1 (Page 2011) [a]	≥ 4	71.4	88.0

** The reported thresholds are these with the highest values for median sensitivity and specificity*
*** Percentage*
‡ Specificity corresponding to the median sensitivity
a The study of Page 2011 had a 7 events

Table 28 – Song and Choi scale

Study	Cut-off score*	Median sensitivity**	Specificity**‡
Follow-up > 1 week – all stages – ICU			
1 (Kim 2009)	≤ 21	95.0	69.3

** The reported thresholds are these with the highest values for median sensitivity and specificity*
*** Percentage*
‡ Specificity corresponding to the median sensitivity

Table 29 – Suriadi and Sanada scale

Study	Cut-off score*	Median sensitivity**	Specificity**‡
Follow-up > 1 week – all stages – ICU			
1 (Suriadi 2008)	≥ 3	97.2	53.0
1 (Suriadi 2008)	≥ 4	80.6	82.9
1 (Suriadi 2008)	≥ 5	72.2	86.7

** The reported thresholds are these with the highest values for median sensitivity and specificity*
*** Percentage*
‡ Specificity corresponding to the median sensitivity

Table 30 – Clinical judgement

Study	Cut-off score	Median sensitivity**	Specificity*‡
Follow-up > 1 week – all stages – ICU			
2 (Salvadalena 1992[a]; VandenBosch 1996 [a])	Yes/no	50.9 (50.0-51.7)	68.9 (58.1-79.7)

*** Percentage*
‡ Specificity corresponding to the median sensitivity
a Study of which sensitivity and specificity are presented.

2.4.7. Quality of the studies

Table 31 – Quality of the studies

Study	Selection bias*	Risk tool bias**	Outcome bias***	Analysis bias****
Andersen 1982	Low	High	Low	High
Anthony 2003	High	High	Low	High
Barnes 1993	High	High	Low	High
Bergstrom 1987a	Low	High	Low	Very high
Bergstrom 1987b	Low	High	Low	High
Bergstrom 1998	Low	High	Low	High
Braden 1994	Low	High	Low	High
Capobianco 1996	Low	High	Low	High
Chan 2009	High	High	Low	High
Compton 2008	Very high	High	Low	High
Curley 2003	Low	High	Low	High
de Souza 2010	Very high	High	Low	High
Edwards 1995	Low	High	Low	Very high
Feuchtinger 2007	Low	High	Low	High
Goodridge 1998	High	High	Low	High
Halfens 2000	High	High	Low	High
Hatanaka 2008	High	High	High	High
Jalali 2005	High	Very high	Low	High
Kim 2009	High	High	Low	High
Kwong 2005	High	High	Low	Very high
Langemo 1991	High	High	Low	Very high
Lewicki 2000	High	High	Low	Very high
Lincoln 1986	High	High	Low	Very high
Lindgren 2002	High	High	Low	High
Lothian 1989	Very high	Very high	Very high	High

Study	Selection bias*	Risk tool bias**	Outcome bias***	Analysis bias****
Lyder 1999	High	High	High	High
Ongoma 2006	High	Very high	Very high	High
Page 2011	Very high	High	High	Very high
Pang 1998	High	High	Low	High
Perneger 2002	High	High	Low	High
Ramundo 1995	High	High	Low	Very high
Salvadalena 1992	High	High	Low	High
Schoonhoven 2002	High	High	Low	Low
Seongsook 2004	Very high	High	Low	High
Serpa 2009	High	High	High	Very high
Serpa 2011	High	High	High	Very high
Smith 1989	Very high	High	High	High
Stotts 1988	Very high	High	Low	High
Suriadi 2006	High	High	Low	High
Suriadi 2008	High	High	Low	High
Towey 1988	Low	High	High	High
VandenBosch 1996	High	High	Low	High
Wai-Han 1997	High	High	High	High
Weststrate 1998	High	High	High	High

** inappropriate patient enrolment, inappropriate study design, not representative population*
*** unclear definition and measurement of index test, absence of imputation technique or unclear description of exclusion, inadequate threshold*
**** unclear definition and measurement of reference test, inappropriate duration*
***** no use of time to event analysis, number of events < 100, reason for missing data not reported*

2.5. Incidence and predictive ability of risk assessment scales

2.5.1. Sensitivity and specificity of risk assessment tools

Table 36 – Braden scale

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Barnes 1993	2 weeks	6.1	≤ 16	72.7	90.6
Braden 1994	48-72 hours‡	NR	≤ 14	29.0	97.0
			≤ 15	43.0	95.0
			≤ 16	46.0	84.0
			≤ 17	61.0	78.0
			≤ 18	79.0	68.0
			≤ 19	93.0	51.0
			≤ 20	96.0	35.0
	4 weeks	27.5	≤ 14	21.4	95.9
			≤ 15	32.1	94.6
			≤ 16	50.0	89.2
			≤ 17	57.1	85.1
			≤ 18	78.6	74.3
			≤ 19	85.7	59.3
			≤ 20	92.9	43.2
Bergstrom 1987a (a)	6 weeks	7.1	≤ 9	14.3	100.0
			≤ 10	14.3	98.9
			≤ 13	28.6	98.9
			≤ 14	42.9	98.9
			≤ 15	71.4	94.6
			≤ 16	100.0	90.2
			≤ 17	100.0	88.0
			≤ 18	100.0	82.6
			≤ 19	100.0	73.9
			≤ 20	100.0	65.2
			≤ 21	100.0	50.0
			≤ 22	100.0	35.9
			≤ 23	100.0	0.0

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
(b)	12 weeks	9.0	≤ 8	11.1	95.6
			≤ 9	11.1	91.2
			≤ 11	22.2	89.0
			≤ 12	44.4	86.8
			≤ 13	55.6	83.5
			≤ 14	66.7	78.0
			≤ 15	77.8	73.
			≤ 16	100.0	63.7
			≤ 17	100.0	60.4
			≤ 18	100.0	50.5
			≤ 19	100.0	42.9
			≤ 20	100.0	31.9
			≤ 21	100.0	26.4
			≤ 22	100.0	9.9
			≤ 23	100.0	0.0
Bergstrom 1987	2 weeks	40.0	≤ 9	8.3	100.0
			≤ 10	8.3	97.2
			≤ 11	16.7	91.7
			≤ 12	33.3	88.9
			≤ 13	58.3	77.8
			≤ 14	70.8	75.0
			≤ 15	75.0	66.7
			≤ 16	83.3	63.9
			≤ 17	87.5	50.0
			≤ 18	91.7	38.9
			≤ 19	91.7	25.0
			≤ 20	95.8	13.9
			≤ 21	95.8	5.6
			≤ 22	100.0	0.0
Bergstrom 1998 (c)	48-72 hours‡	NR	≤ 9	4.0	100.0
			≤ 10	12.0	100.0

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
			≤ 11	19.0	99.0
			≤ 12	31.0	99.0
			≤ 13	38.0	98.0
			≤ 14	38.0	95.0
			≤ 15	46.0	90.0
			≤ 16	58.0	84.0
			≤ 17	62.0	76.0
			≤ 18	88.0	68.0
			≤ 19	100.0	59.0
			≤ 20	100.0	40.0
			≤ 21	100.0	23.0
	11 days	8.5	≤ 9	7.7	100.0
			≤ 10	11.5	100.0
			≤ 11	11.5	98.9
			≤ 12	15.4	98.9
			≤ 13	15.4	97.9
			≤ 14	15.4	97.1
			≤ 15	23.1	92.9
			≤ 16	30.8	88.9
			≤ 17	38.5	83.9
			≤ 18	46.2	68.9
			≤ 19	100.0	58.9
			≤ 20	100.0	40.0
			≤ 21	100.0	22.9
(d)	48-72 hours‡	NR	≤ 9	0.0	99.0
			≤ 10	10.0	99.0
			≤ 11	10.0	98.0
			≤ 12	10.0	98.0
			≤ 13	10.0	97.0
			≤ 14	20.0	96.0
			≤ 15	20.0	94.0

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
			≤ 16	30.0	90.0
			≤ 17	50.0	85.0
			≤ 18	60.0	81.0
			≤ 19	80.0	73.0
			≤ 20	80.0	69.0
			≤ 21	90.0	41.0
	11 days	7.4	≤ 9	0.0	99.2
			≤ 10	0.0	99.2
			≤ 11	0.0	99.2
			≤ 12	0.0	98.1
			≤ 13	28.6	98.1
			≤ 14	28.6	96.9
			≤ 15	52.4	93.9
			≤ 16	52.4	92.0
			≤ 17	61.9	87.0
			≤ 18	71.4	78.9
			≤ 19	71.4	70.9
			≤ 20	90.5	50.2
			≤ 21	90.5	32.2
(e)	48-72 hours‡	NR	≤ 9	0.0	99.0
			≤ 10	2.0	99.0
			≤ 11	2.0	99.0
			≤ 12	5.0	99.0
			≤ 13	13.0	99.0
			≤ 14	23.0	97.0
			≤ 15	33.0	93.0
			≤ 16	41.0	88.0
			≤ 17	56.0	81.0
			≤ 18	72.0	68.0
			≤ 19	67.0	48.0
			≤ 20	83.0	34.0

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
			≤ 21	97.0	17.0
	11 days	23.9	≤ 9	0.0	99.0
			≤ 10	19.7	99.0
			≤ 11	29.5	97.9
			≤ 12	8.2	97.9
			≤ 13	13.1	97.9
			≤ 14	19.7	95.9
			≤ 15	31.1	94.8
			≤ 16	49.2	90.2
			≤ 17	60.7	86.1
			≤ 18	80.3	73.2
			≤ 19	86.9	57.2
			≤ 20	93.4	40.2
			≤ 21	98.4	25.3
Capobianco 1996	2 weeks	28.0	≤ 12	28.6	97.2
			≤ 13	28.6	97.2
			≤ 14	28.6	97.2
			≤ 15	35.7	94.4
			≤ 16	42.9	91.7
			≤ 17	57.1	91.7
			≤ 18	71.4	83.3
			≤ 19	85.7	77.8
			≤ 20	92.9	66.7
Chan 2009	9 days	9.1	≤ 16	66.7	64.2
			≤ 17	72.2	40.8
			≤ 18	88.9	21.2
de Souza 2010 (f)	3 months	3.9	≤ 13	56.8	71.9
(g)	3 months	3.9	≤ 17	71.4	75.8
Feuchtinger 2007	4 days	62.3	≤ 9	19.2	100.0
			≤ 10	23.1	100.0
			≤ 11	30.8	100.0

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
			≤ 16	76.9	29.6
			≤ 20	96.2	3.7
Goodridge 1998	3 months	9.7	≤ 11	12.5	97.3
			≤ 16	25.0	85.6
			≤ 18	50.0	52.3
Halfens 2000	NR	58.1	≤ 10	1.1	100.0
			≤ 11	3.2	100.0
			≤ 12	5.4	99.3
			≤ 13	11.8	97.8
			≤ 14	17.7	97.0
			≤ 15	22.0	94.8
			≤ 16	32.3	91.8
			≤ 17	40.9	90.3
			≤ 18	51.1	85.8
			≤ 19	61.3	79.9
			≤ 20	73.7	70.1
			≤ 21	78.5	56.7
			≤ 22	88.2	42.5
			≤ 23	100.0	29.9
Jalali 2005	14 days	9.1	NR	52.7	100.0
Kim 2009	90 days	18.3	≤ 14	92.5	69.8
Kwong 2005	21 days	2.1	≤ 14	88.9	71.9
Langemo 1991 (h)	16 days	14.9	≤ 15	54.5	93.7
			≤ 16	63.6	87.3
(i)	31 days	28.0	≤ 18	57.1	61.1
Pang 1998	2 weeks	19.8	≤ 18	90.5	62.4
Lyder 1999 (j)	NR‡	NR	≤ 18	81.0	100.0
(k)	NR‡	NR	≤ 16	77.0	50.0
(l)	NR‡	NR	≤ 18	90.0	14.0
Ramundo 1995	4 weeks	14.6	≤ 11	14.3	97.6

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
			≤ 12	14.3	95.1
			≤ 13	14.3	95.1
			≤ 14	14.3	90.2
			≤ 15	14.3	82.9
			≤ 16	28.6	80.5
			≤ 17	42.9	63.4
			≤ 18	100.0	34.1
			≤ 19	100.0	22.0
			≤ 20	100.0	12.2
			≤ 21	100.0	4.9
			≤ 22	100.0	0.0
Salavadalena 1992	6 months	20.2	≤ 9	0.0	98.7
			≤ 10	5.0	97.5
			≤ 11	5.0	91.1
			≤ 12	15.0	89.9
			≤ 13	20.0	86.1
			≤ 14	30.0	79.
			≤ 15	30.0	77.2
			≤ 16	40.0	69.6
			≤ 17	45.0	63.3
			≤ 18	60.0	54.4
			≤ 19	80.0	43.0
			≤ 20	85.0	31.6
			≤ 21	95.0	13.9
			≤ 22	100.0	1.3
			≤ 23	100.0	0.0
Schoonhoven 2002	12 weeks	11.0	≤ 17	43.7	67.8
Seongsook 2004	NR	31.3	≤ 16	97.1	26.0
Serpa 2011	48 hours	11.1	≤ 12	87.5	64.1
	4 days	11.1	≤ 13	75.0	81.3
	6 days	11.1	≤ 13	75.0	82.8

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Suriadi 2006	21 days	33.3	≤ 14	80.0	54.3
VandenBosch 1996	2 weeks	28.8	≤ 17	59.0	NR
			≤ 18	NR	79.0

** Percentage*
‡ No raw data was available to recalculate the sensitivity and specificity
NR: not reported
(a) ward one in Bergstrom 1987a study; (b) ward two in Bergstrom 1987a study; (c) tertiary care hospitals; (d) veteran medical centres; (e) skilled nursing facilities; (f) group of patients with a Braden score < 18 on admission; (g) group of patients with a Braden score < 19 on admission; (h) hospitalized patients ; (i) long-term care patients; (j) black elders ≥ 75 yrs; (k) black elders < 75 yrs; (l) Latino/Hispanic < 75 yrs

Table 37 – Extended Braden scale

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Halfens 2000	NR	58.1	≤ 11	0.5	100.0
			≤ 12	1.6	100.0
			≤ 13	2.2	100.0
			≤ 14	3.8	99.3
			≤ 15	6.5	98.5
			≤ 16	12.4	97.9
			≤ 17	17.7	96.3
			≤ 18	24.2	94.8
			≤ 19	32.8	91.0
			≤ 20	40.9	88.8
			≤ 21	51.1	85.1
			≤ 22	62.9	79.1
			≤ 23	73.7	69.4
			≤ 24	78.5	55.2
			≤ 25	88.2	42.5
			≤ 26	100.0	29.1

** Percentage*
NR: not reported

Table 38 – Modified Braden scale

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Chan 2009	9 days	9.1	≤ 17	38.9	79.9
			≤ 18	55.6	72.6
			≤ 19	88.9	62.0
Kwong 2005	21 days	2.1	≤ 16	88.9	75.0

** Percentage*

Table 39 – Braden-Q scale

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Curley 2003	10 days	26.7	≤ 10	3.5	100.0
			≤ 11	16.3	97.0
			≤ 12	47.7	92.8
			≤ 13	67.4	89.0
			≤ 14	72.1	78.8
			≤ 15	75.6	67.8
			≤ 16	88.4	58.1
			≤ 17	91.9	44.1
			≤ 18	100.0	30.1
			≤ 19	100.0	19.9
			≤ 20	100.0	8.1

** Percentage*

Table 40 – Norton scale

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Kwong 2005	21 days	2.1	≤ 14	88.9	61.0
Lincoln 1986	26 days	13.9	≤ 14	0.0	93.5
Pang 1998	2 weeks	19.8	≤ 16	81.0	58.8
Schoonhoven 2002	12 weeks	11.0	≤ 15	45.9	60.3
Smith 1989	NR	29.7	≤ 16	60.0	31.0

Stotts 1988	3 weeks	17.3	≤ 14	16.4	94.4
Wai-Hang 1997	4 weeks	4.3	≤ 14	75.0	66.7

** Percentage*
NR: Not reported

Table 41 – Modified Norton scale (ICU)

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Feuchtinger 2007	4 days	62.3	≤ 19	26.9	100.0
			≤ 21	34.6	92.6
			≤ 23	42.3	88.9
			≤ 25	57.7	48.1

** Percentage*

Table 42 – Modified Norton scale (South African Hospital)

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Ongoma 2005	1 week	37.9	≤ 20	92.0	29.3

** Percentage*

Table 43 – Waterlow scale

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Anthony 2003	NR	0.4	≥ 10	82.3	85.2
			≥ 15	48.8	94.5
			≥ 20	16.7	98.1
Compton 2008	13 days	17.3	NR	37.2	94.6
Edwards 1995	8 weeks	6.5	NR	100.0	10.3
Jalali 2005	14 days	9.1	NR	63.5	83.3
Pang 1998	2 weeks	19.8	≥ 16	95.2	43.5
Serpa 2009	48 hours	7.1	≥ 17	71.4	67.0
	4 days	7.1	≥ 20	85.7	40.7
	6 days	7.1	≥ 20	85.7	33.0

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Schoonhoven 2002	12 weeks	11.0	≥ 10	89.6	22.4
Smith 1989	NR	29.7	≥ 16	73.3	38.0
Wai-Han 1997	4 weeks	4.3	≥ 10	87.5	28.2
Weststrate 1998	183 days	7.9	≥ 15	80.9	28.5

** Percentage; NR: not reported*

Table 44 – Andersen scale

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Andersen 1982	3 months	1.2	≥ 2	87.5	86.7

** Percentage*

Table 45 – Pressure Sore Prediction Score scale (PSPS)

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Lothian 1989	3 weeks	4.3	> 6	88.7	76.0

** Percentage*

Table 46 – Knoll scale

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Towey 1988	28 days	46.7	≥ 12	85.7	56.3

** Percentage*

Table 47 – Cubbin-Jackson scale

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Kim 2009	90 days	18.3	≤ 28	95.0	81.6
Seongsook 2004	NR	31.3	≤ 24	88.6	61.0

** Percentage -NR: not reported*

Table 48 – Sunderland Pressure Sore Risk Calculator (modified Cubbin-Jackson)

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Ongoma 2005	1 week	37.9	≤ 34	80.0	70.7

** Percentage*

Table 49 – Risk Assessment Pressure Sore scale (RAPS)

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Lindgren 2002	12 weeks	11.7	≤ 31	31.5	84.6
			≤ 32	33.3	80.2
			≤ 33	38.9	75.3
			≤ 34	46.3	69.4
			≤ 35	50.0	64.3
			≤ 36	57.4	57.6
			≤ 37	70.4	46.5
			≤ 38	77.8	34.8

** Percentage*

Table 50 – Fragmment scale

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Perneger 2002	3 weeks	29.9	= 0	91.6	34.2
			≤ 1	78.7	53.5
			≤ 2	76.7	71.9
			≤ 3	62.1	85.0
			≤ 4	49.7	91.0
			≤ 5	40.2	94.2
			≤ 6	27.0	97.6
			≤ 7	17.7	98.9
			≤ 8	2.2	99.5

** Percentage*

Table 51 – Douglas scale

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Seongsook 2004	NR	31.3	≤ 18	100.0	18.2

** Percentage*
NR: Not reported

Table 52 – Grosnell scale

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Jalali 2005	2 weeks	9.1	NR	85.1	83.3

** Percentage*
NR: not reported

Table 53 – Song and Choi scale

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Kim 2009	90 days	18.3	≤ 21	95.0	69.3

** Percentage*

Table 54 – 4-factor model

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Feuchtinger 2007	4 days	62.3	≥ 2	84.6	29.6

** Percentage*

Table 55 – Suriadi and Sanada scale (SS)

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Suriadi 2008	NR	28.5	≥ 0	100.0	0.0
			≥ 2	97.2	42.0
			≥ 3	97.2	53.0
			≥ 4	80.6	82.9
			≥ 5	72.2	86.7
			≥ 6	61.1	92.3
			≥ 7	58.3	95.0
			≥ 9	6.9	100.0

** Percentage*
NR: not reported

Table 56 – The Northern Hospital Pressure Ulcer Prevention Plan (TNH-PUPP)

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Page 2011	NR	4.2	≥ 1	100.0	34.2
			≥ 2	85.7	62.0
			≥ 3	71.4	81.0
			≥ 4	71.4	88.0
			≥ 5	42.9	96.2
			≥ 6	57.1	99.4

** Percentage*
NR: not reported

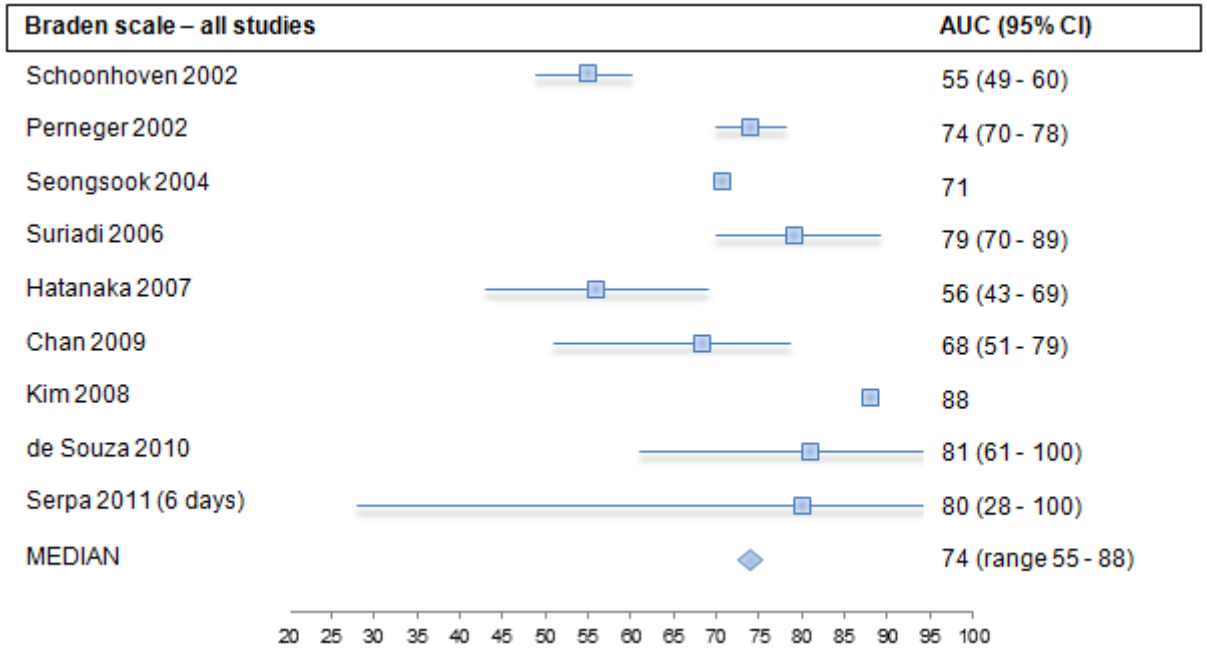
Table 57 – Clinical judgement

Study	Time point	Incidence*	Cut-off score	Sensitivity*	Specificity*
Salvadalena 1992	6 months	20.2	Yes/no	50.0	79.7
VandenBosch 1996	2 weeks	28.2	Yes/no	51.7	58.1

** Percentage*

2.5.2. Forest plots area under the receiver operating characteristics curve (AUC)

Figure 2: Braden scale



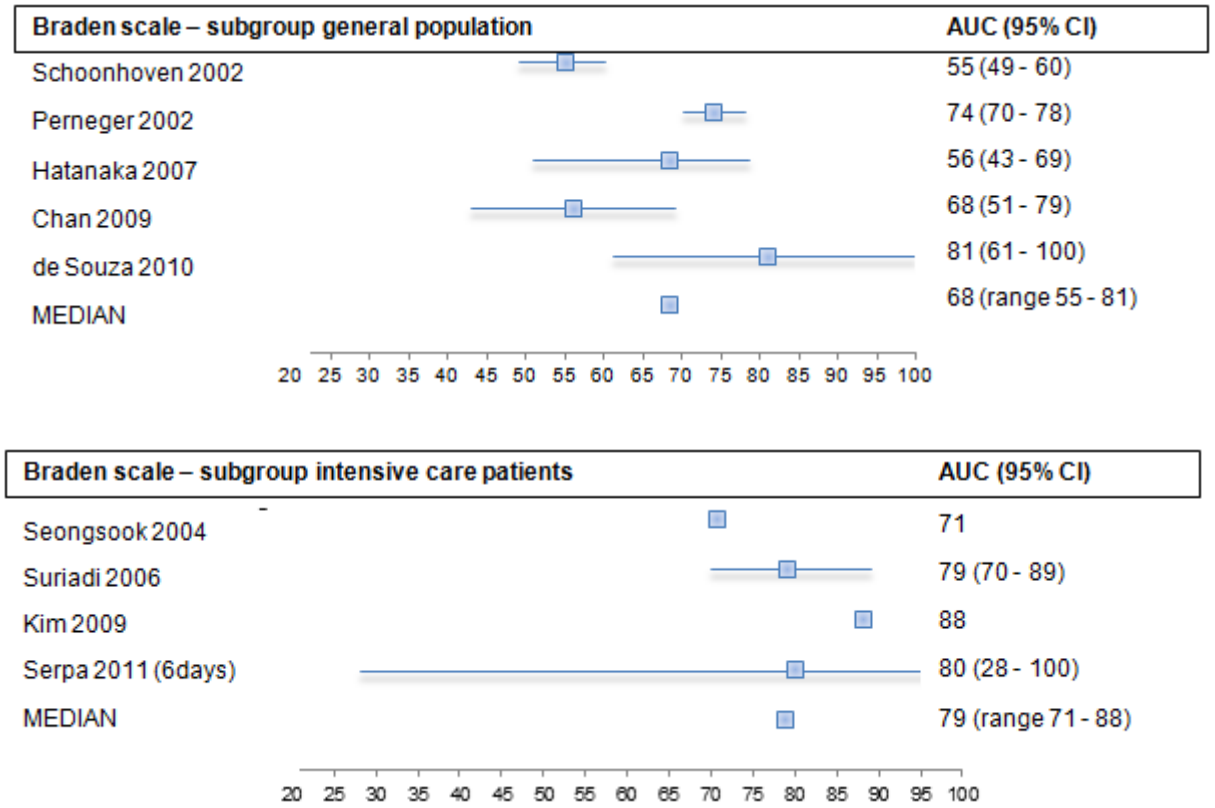


Figure 3 – Modified Braden scale

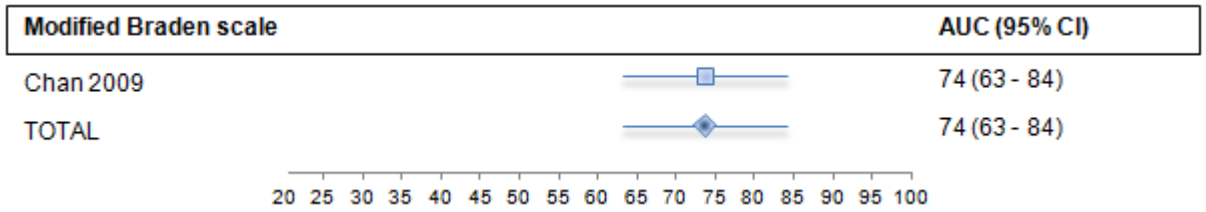


Figure 4 – Braden-Q scale

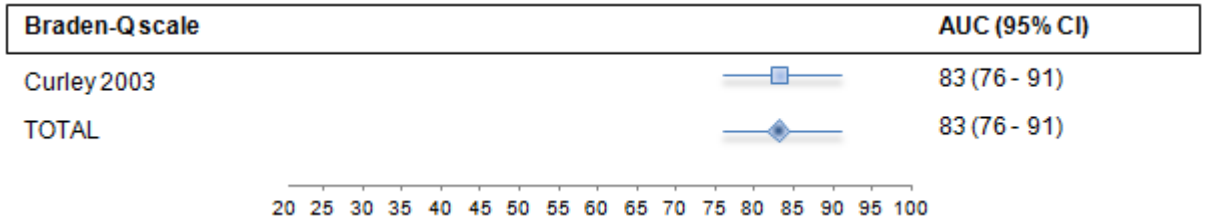


Figure 5 – Norton scale

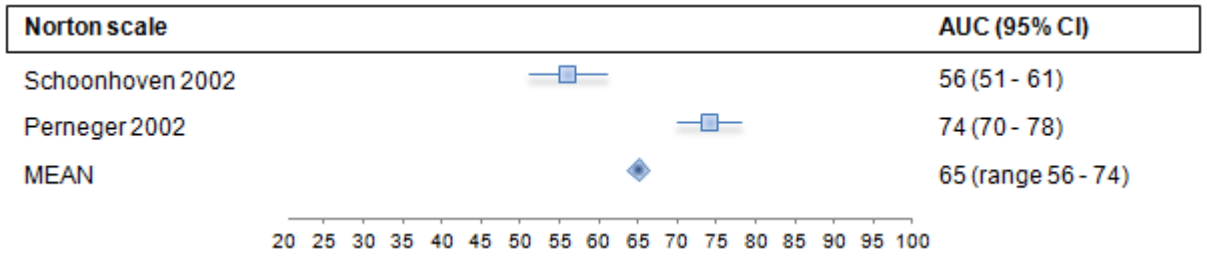
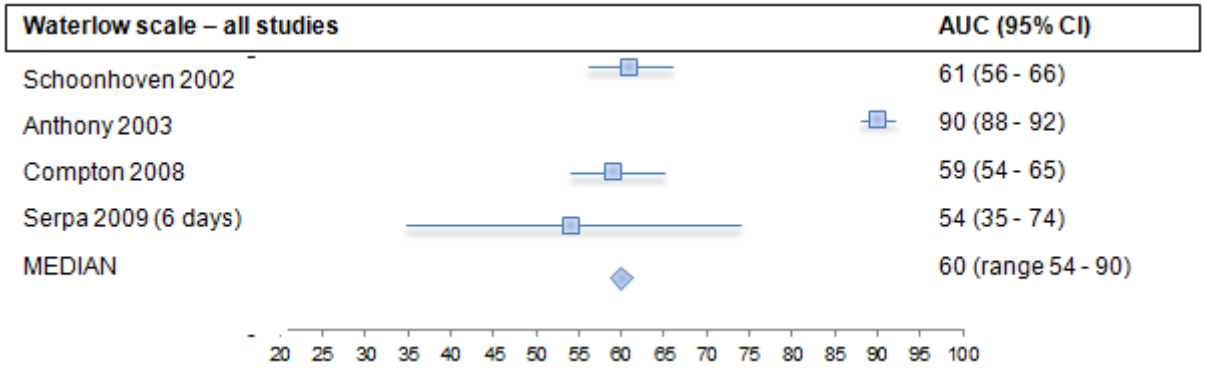


Figure 6 – Waterlow scale



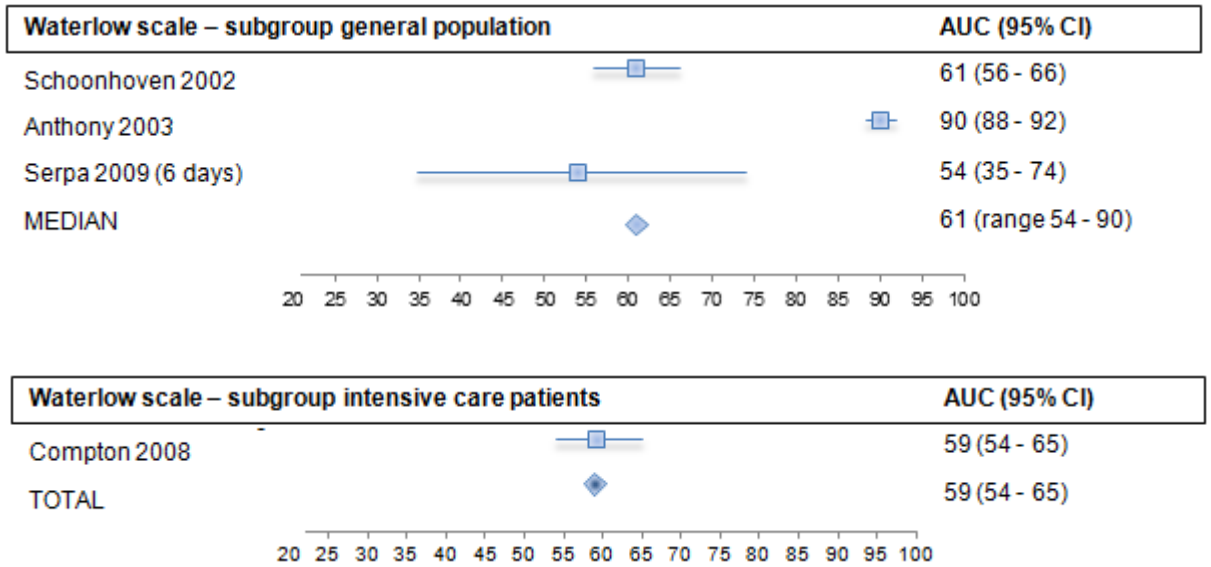


Figure 7 – Cubbin-Jackson scale

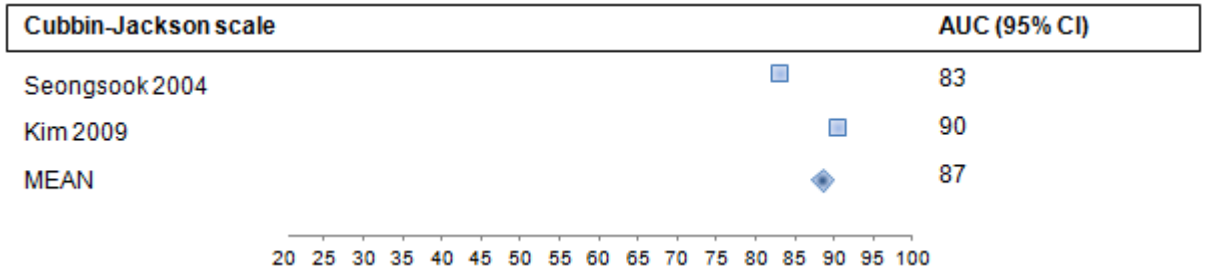


Figure 8 – Douglas scale

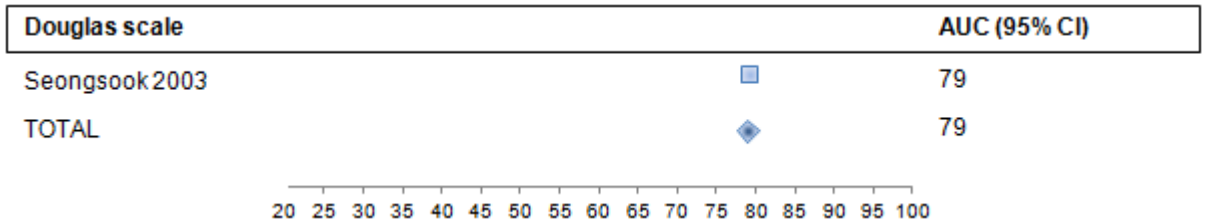


Figure 9 – Fragmment scale

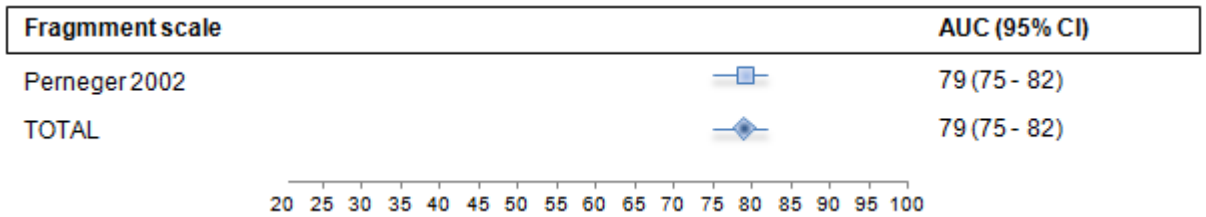


Figure 10 – Song and Choi scale

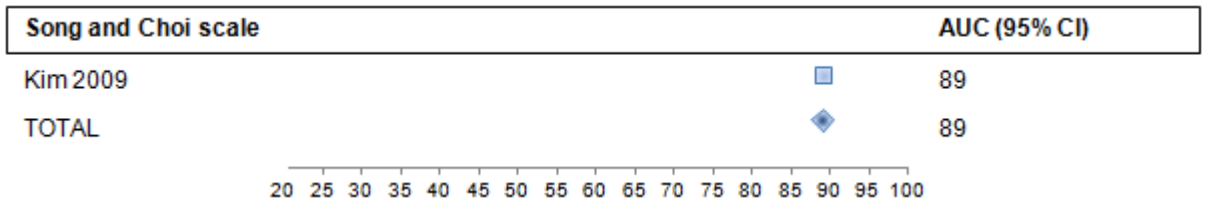


Figure 11 – The Northern Hospital Pressure Ulcer Prevention Plan

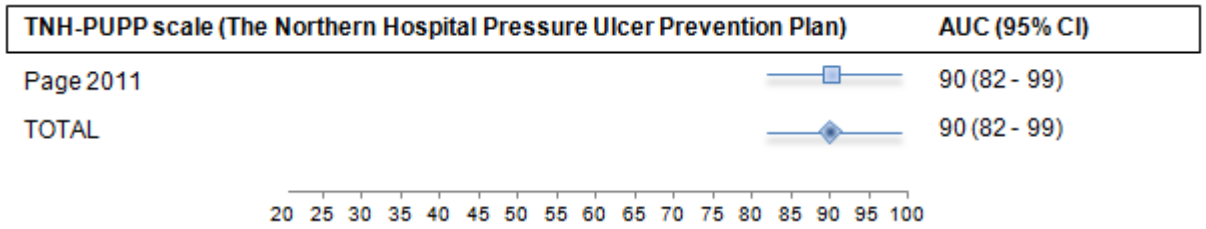


Figure 12 – Schoonhoven 2002

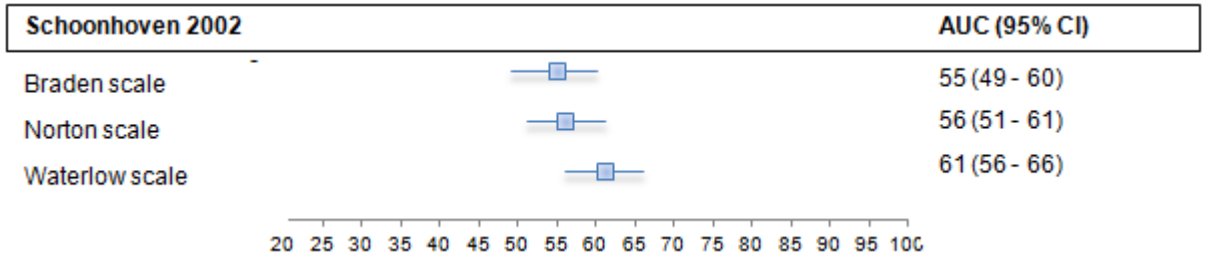


Figure 13 – Perneger 2002

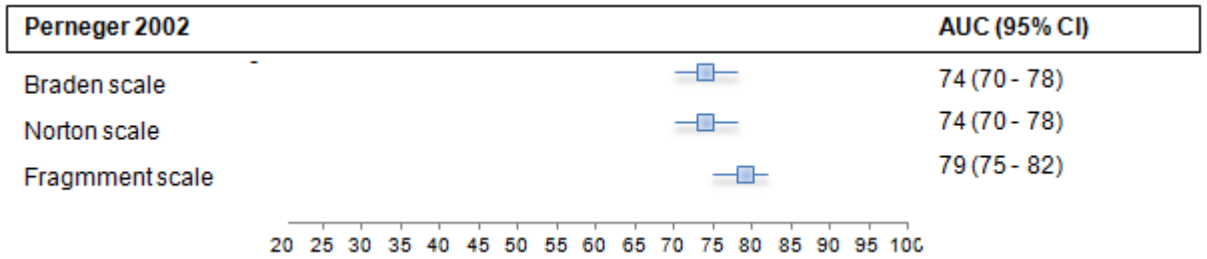


Figure 14 – Seongsook 2004

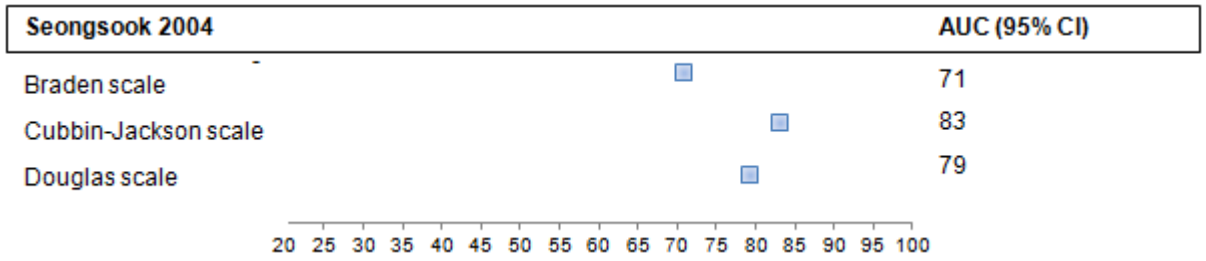


Figure 15 – Chan 2009

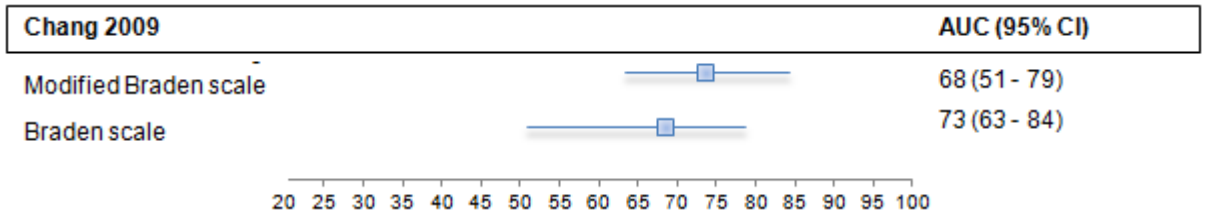


Figure 16 – Kim 2009

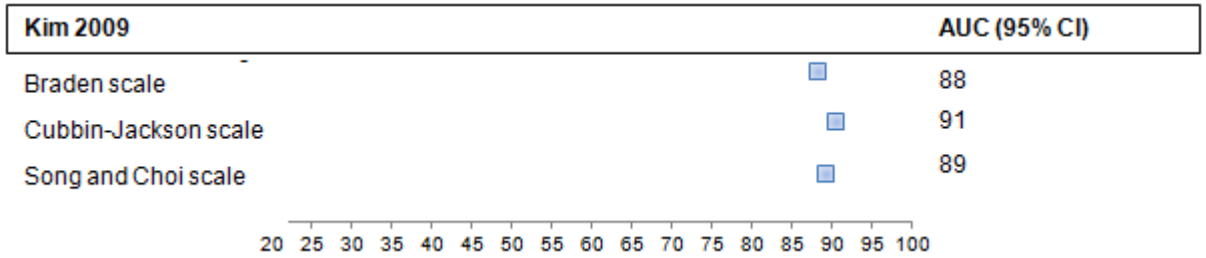


Figure 17 – Serpa 2009

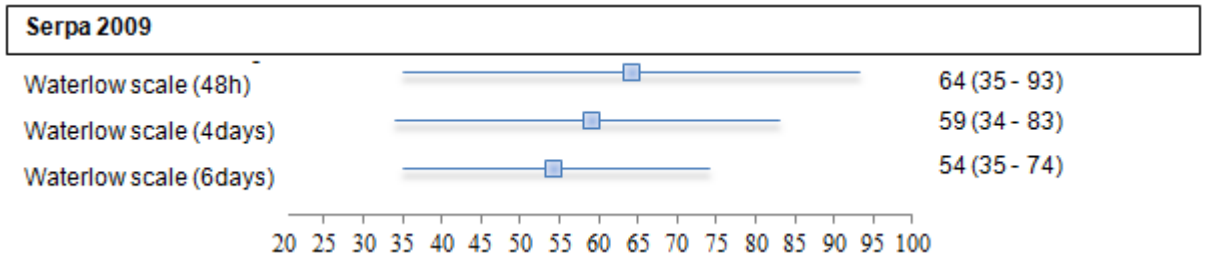
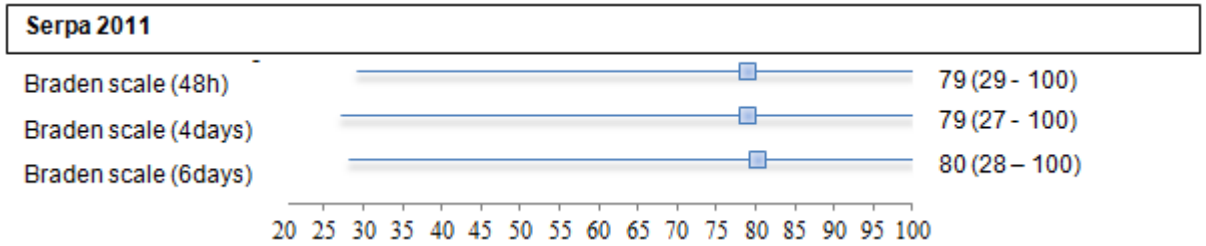
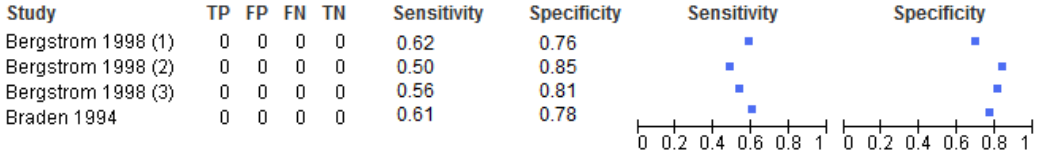


Figure 18 – Serpa 2011



2.5.3. Forest plots sensitivity and specificity

Figure 19 – Braden scale cut-off score 17 – follow-up < 1 week – general population – all grades

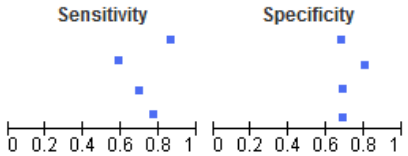


No raw data available

Bergstrom 1998 (1): tertiary hospital; Bergstrom 1998 (2): veteran medical centre; Bergstrom 1998 (3): skilled nursing facili ty

Figure 20 – Braden scale cut-off score 18 – follow-up < 1 week – general population – all grades

Study	TP	FP	FN	TN	Sensitivity	Specificity
Bergstrom 1998 (1)	0	0	0	0	0.88	0.68
Bergstrom 1998 (2)	0	0	0	0	0.60	0.81
Bergstrom 1998 (3)	0	0	0	0	0.72	0.68
Braden 1994	0	0	0	0	0.79	0.68

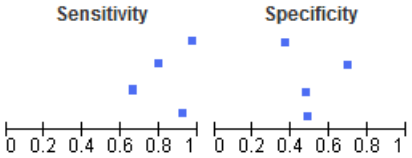


No raw data available

Bergstrom 1998 (1): tertiary hospital; Bergstrom 1998 (2): veteran medical centre; Bergstrom 1998 (3): skilled nursing facili ty

Figure 21 – Braden scale cut-off score 19 – follow-up < 1 week – general population – all grades

Study	TP	FP	FN	TN	Sensitivity	Specificity
Bergstrom 1998 (1)	0	0	0	0	1.00	0.40
Bergstrom 1998 (2)	0	0	0	0	0.80	0.73
Bergstrom 1998 (3)	0	0	0	0	0.67	0.48
Braden 1994	0	0	0	0	0.93	0.51



No raw data available

Bergstrom 1998 (1): tertiary hospital; Bergstrom 1998 (2): veteran medical centre; Bergstrom 1998 (3): skilled nursing facili ty

Figure 22 – Braden scale cut-off score 12 – follow-up 48 hours – ICU – all grades

Study	TP	FP	FN	TN	Sensitivity	Specificity
Serpa 2011	7	23	1	41	0.88 [0.47, 1.00]	0.64 [0.51, 0.76]

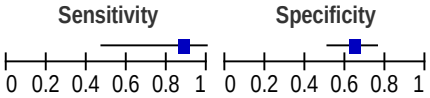
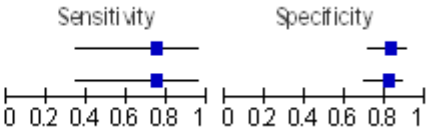


Figure 23 – Braden scale cut-off score 13 – follow-up 4 and 6 days – ICU – all grades

Study	TP	FP	FN	TN	Sensitivity	Specificity
Serpa 2011 [1]	6	11	2	53	0.75 [0.35, 0.97]	0.83 [0.71, 0.91]
Serpa 2011 [2]	6	12	2	52	0.75 [0.35, 0.97]	0.81 [0.70, 0.90]



Serpa 2011 [1]: 4 days; Serpa 2011 [2]: 6 days

Figure 24 – Braden scale cut-off score 16 – follow-up < 1 week – ICU – all grades

Study	TP	FP	FN	TN	Sensitivity	Specificity
Feuchtinger 2007	20	19	6	8	0.77 [0.56, 0.91]	0.30 [0.14, 0.50]

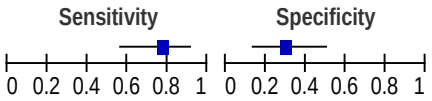
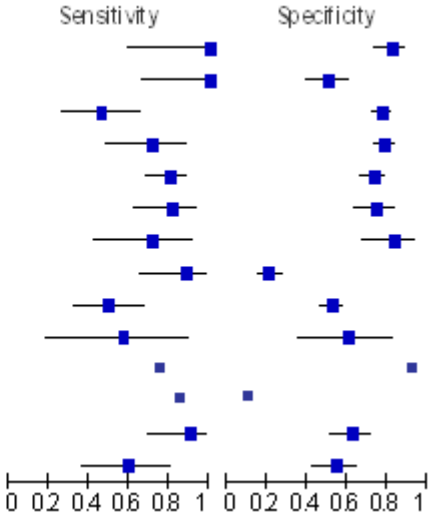


Figure 25 – Braden scale cut-off score 18 – follow-up > 1 week – general population – all grades

Study	TP	FP	FN	TN	Sensitivity	Specificity
Bergstrom 1987a (1)	7	16	0	76	1.00 [0.59, 1.00]	0.83 [0.73, 0.90]
Bergstrom 1987a (2)	9	45	0	46	1.00 [0.66, 1.00]	0.51 [0.40, 0.61]
Bergstrom 1998 (1)	12	62	14	218	0.46 [0.27, 0.67]	0.78 [0.73, 0.83]
Bergstrom 1998 (2)	15	55	6	206	0.71 [0.48, 0.89]	0.79 [0.73, 0.84]
Bergstrom 1998 (3)	49	52	12	142	0.80 [0.68, 0.89]	0.73 [0.66, 0.79]
Braden 1994	22	19	5	55	0.81 [0.62, 0.94]	0.74 [0.63, 0.84]
Capobianco 1996	10	6	4	30	0.71 [0.42, 0.92]	0.83 [0.67, 0.94]
Chan 2009	16	141	2	38	0.89 [0.65, 0.99]	0.21 [0.15, 0.28]
Goodridge 1998	16	142	16	156	0.50 [0.32, 0.68]	0.52 [0.47, 0.58]
Langemo 1991 (2)	4	7	3	11	0.57 [0.18, 0.90]	0.61 [0.36, 0.83]
Lyder 1999 (1)	0	0	0	0	0.81	1.00
Lyder 1999 (3)	0	0	0	0	0.90	0.14
Pang 1998	19	32	2	53	0.90 [0.70, 0.99]	0.62 [0.51, 0.73]
Salvadalena 1992	12	36	8	43	0.60 [0.36, 0.81]	0.54 [0.43, 0.66]

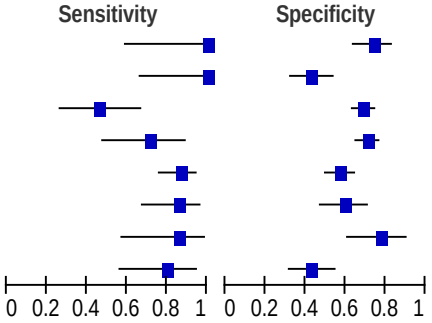


No raw data for Lyder 1991

Bergstrom 1987a (1): ward one; Bergstrom 1987a (2): ward two; Bergstrom 1998 (1): tertiary hospital; Bergstrom 1998 (2): vete ran medical centre; Bergstrom 1998 (3): skilled nursing facility; Langemo 1991 (2): skilled nursing facility; Lyder 1999 (1): black elders ≥ 75 yrs; Lyder 1999 (2): Latino/Hispanic < 75 yrs

Figure 26 – Braden scale cut-off score 19 – follow-up > 1 week – general population – all grades

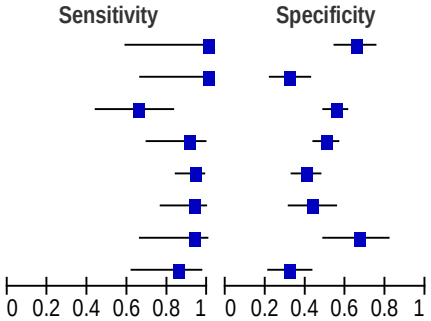
Study	TP	FP	FN	TN	Sensitivity	Specificity
Bergstrom 1987a (1)	7	24	0	68	1.00 [0.59, 1.00]	0.74 [0.64, 0.83]
Bergstrom 1987a (2)	9	52	0	39	1.00 [0.66, 1.00]	0.43 [0.33, 0.54]
Bergstrom 1998 (1)	12	87	14	193	0.46 [0.27, 0.67]	0.69 [0.63, 0.74]
Bergstrom 1998 (2)	15	76	6	185	0.71 [0.48, 0.89]	0.71 [0.65, 0.76]
Bergstrom 1998 (3)	53	83	8	111	0.87 [0.76, 0.94]	0.57 [0.50, 0.64]
Braden 1994	24	30	4	44	0.86 [0.67, 0.96]	0.59 [0.47, 0.71]
Capobianco 1996	12	8	2	28	0.86 [0.57, 0.98]	0.78 [0.61, 0.90]
Salvadalena 1992	16	45	4	34	0.80 [0.56, 0.94]	0.43 [0.32, 0.55]



Bergstrom 1987a (1): ward one; Bergstrom 1987a (2): ward two; Bergstrom 1998 (1): tertiary hospital; Berg strom 1998 (2): veteran medical centre; Bergstrom 1998 (3): skilled nursing facility

Figure 27 – Braden scale cut-off score 20 – follow-up > 1 week – general population – all grades

Study	TP	FP	FN	TN	Sensitivity	Specificity
Bergstrom 1987a (1)	7	32	0	60	1.00 [0.59, 1.00]	0.65 [0.55, 0.75]
Bergstrom 1987a (2)	9	62	0	29	1.00 [0.66, 1.00]	0.32 [0.22, 0.42]
Bergstrom 1998 (1)	17	126	9	154	0.65 [0.44, 0.83]	0.55 [0.49, 0.61]
Bergstrom 1998 (2)	19	130	2	131	0.90 [0.70, 0.99]	0.50 [0.44, 0.56]
Bergstrom 1998 (3)	57	116	4	78	0.93 [0.84, 0.98]	0.40 [0.33, 0.47]
Braden 1994	26	42	2	32	0.93 [0.76, 0.99]	0.43 [0.32, 0.55]
Capobianco 1996	13	12	1	24	0.93 [0.66, 1.00]	0.67 [0.49, 0.81]
Salvadalena 1992	17	54	3	25	0.85 [0.62, 0.97]	0.32 [0.22, 0.43]



Bergstrom 1987a (1): ward one; Bergstrom 1987a (2): ward two; Bergstrom 1998 (1): tertiary hospital; Bergstrom 1998 (2): veteran medical centre; Bergstrom 1998 (3): skilled nursing facility

Figure 28 – Braden scale cut-off score 15 – follow-up > 1 week – ICU – all grades

Study	TP	FP	FN	TN	Sensitivity	Specificity
Braden 1994	9	4	19	70	0.32 [0.16, 0.52]	0.95 [0.87, 0.99]

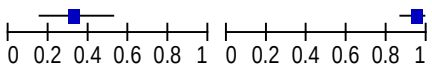


Figure 29 – Braden scale cut-off score 16 – follow-up > 1 week – ICU – all grades

Study	TP	FP	FN	TN	Sensitivity	Specificity
Braden 1994	14	8	14	66	0.50 [0.31, 0.69]	0.89 [0.80, 0.95]
Seongsook 2004	34	57	1	20	0.97 [0.85, 1.00]	0.26 [0.17, 0.37]

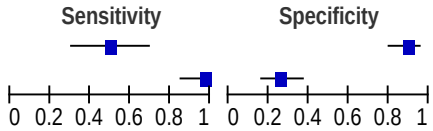


Figure 30 – Braden scale cut-off score 12 – follow-up > 1 week – ICU – all grades

Study	TP	FP	FN	TN	Sensitivity	Specificity
Braden 1994	16	11	12	63	0.57 [0.37, 0.76]	0.85 [0.75, 0.92]

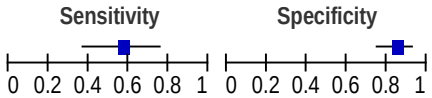


Figure 31 – Braden scale cut-off score 17 – follow-up > 1 week – general population – stage 2+

Study	TP	FP	FN	TN	Sensitivity	Specificity
Ramundo 1995	3	15	4	26	0.43 [0.10, 0.82]	0.63 [0.47, 0.78]

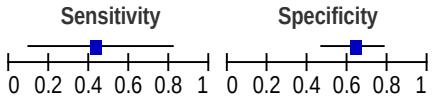


Figure 32 – Braden scale cut-off score 18 – follow-up > 1 week – general population – stage 2+

Study	TP	FP	FN	TN	Sensitivity	Specificity
Ramundo 1995	7	27	0	14	1.00 [0.59, 1.00]	0.34 [0.20, 0.51]

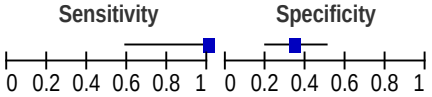


Figure 33 – Braden scale cut-off score 19 – follow-up > 1 week – general population – stage 2+

Study	TP	FP	FN	TN	Sensitivity	Specificity
Ramundo 1995	7	32	0	9	1.00 [0.59, 1.00]	0.22 [0.11, 0.38]

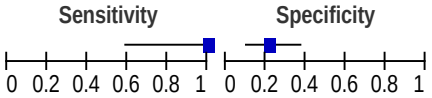


Figure 34 – Braden-Q scale cut-off score 15 – follow-up > 1 week – paediatric ICU – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Curley 2003	65	76	21	160	0.76 [0.65, 0.84]	0.68 [0.61, 0.74]

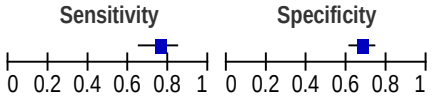


Figure 35 – Braden-Q scale cut-off score 16 – follow-up > 1 week – paediatric ICU – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Curley 2003	76	99	10	137	0.88 [0.80, 0.94]	0.58 [0.51, 0.64]

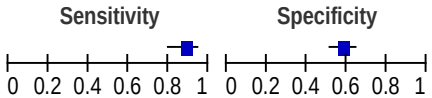


Figure 36 – Braden-Q scale cut-off score 17 – follow-up > 1 week – paediatric ICU – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Curley 2003	79	132	7	104	0.92 [0.84, 0.97]	0.44 [0.38, 0.51]

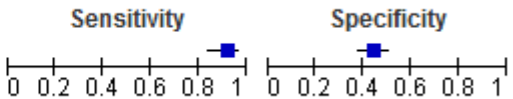


Figure 37 – Norton scale cut-off score 14 – follow-up > 1 week – general population – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Kwong 2005	8	164	1	256	0.89 [0.52, 1.00]	0.61 [0.56, 0.66]
Lincoln 1986	0	2	5	29	0.00 [0.00, 0.52]	0.94 [0.79, 0.99]
Stotts 1988	11	18	56	302	0.16 [0.08, 0.27]	0.94 [0.91, 0.97]
Wai-Han 1997	6	59	2	118	0.75 [0.35, 0.97]	0.67 [0.59, 0.74]

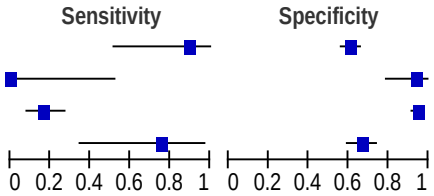


Figure 38 – Norton scale cut-off score 15 – follow-up > 1 week – general population – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Schoonhoven 2002	62	434	73	660	0.46 [0.37, 0.55]	0.60 [0.57, 0.63]

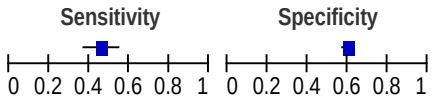


Figure 39 – Norton scale cut-off score 16 – follow-up > 1 week – general population – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Pang 1998	17	35	4	50	0.81 [0.58, 0.95]	0.59 [0.48, 0.69]
Smith 1989	18	49	12	22	0.60 [0.41, 0.77]	0.31 [0.21, 0.43]

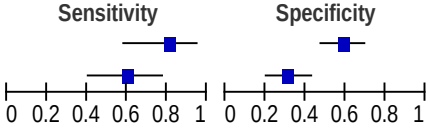


Figure 40 – Waterlow scale cut-off score 17 – follow-up 48 hours – general population – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Serpa 2009	5	30	2	61	0.71 [0.29, 0.96]	0.67 [0.56, 0.77]

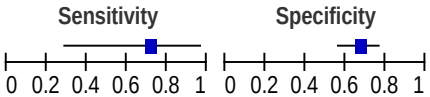
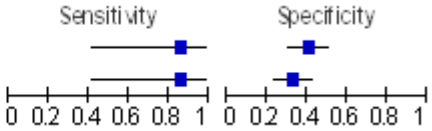


Figure 41 – Waterlow scale cut-off score 20 – follow-up 4 days and 6 days – general population – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Serpa 2009 [1]	6	54	1	37	0.86 [0.42, 1.00]	0.41 [0.30, 0.51]
Serpa 2009 [2]	6	61	1	30	0.86 [0.42, 1.00]	0.33 [0.23, 0.44]



Serpa 2009 [1]: 4 days; Serpa 2009 [2]: 6 days

Figure 42 – Waterlow scale cut-off score 10 – follow-up > 1 week – general population – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Anthony 2003	167	6757	36	38775	0.82 [0.76, 0.87]	0.85 [0.85, 0.85]
Schoonhoven 2002	121	849	14	245	0.90 [0.83, 0.94]	0.22 [0.20, 0.25]
Wai-Han 1997	7	127	1	50	0.88 [0.47, 1.00]	0.28 [0.22, 0.35]

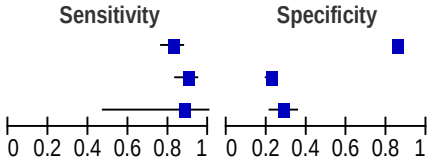


Figure 43 – Waterlow scale cut-off score 15 – follow-up > 1 week – general population – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Anthony 2003	99	2519	104	43013	0.49 [0.42, 0.56]	0.94 [0.94, 0.95]

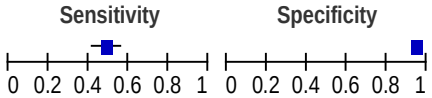


Figure 44 – Waterlow scale cut-off score 16 – follow-up > 1 week – general population – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Pang 1998	20	48	1	37	0.95 [0.76, 1.00]	0.44 [0.33, 0.55]
Smith 1989	22	44	8	27	0.73 [0.54, 0.88]	0.38 [0.27, 0.50]

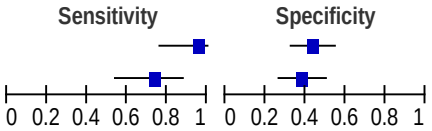


Figure 45 – Waterlow scale cut-off score 15 – follow-up > 1 week – ICU – stage 2+

Study	TP	FP	FN	TN	Sensitivity	Specificity
Weststrate 1998	38	391	9	156	0.81 [0.67, 0.91]	0.29 [0.25, 0.33]

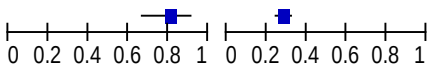


Figure 46 – Cubbin-Jackson scale cut-off score 24 – follow-up > 1 week – ICU – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Seongsook 2004	31	30	4	47	0.89 [0.73, 0.97]	0.61 [0.49, 0.72]

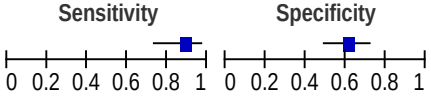


Figure 47 – Cubbin-Jackson scale cut-off score 28 – follow-up > 1 week – ICU – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Kim 2009	38	33	2	146	0.95 [0.83, 0.99]	0.82 [0.75, 0.87]

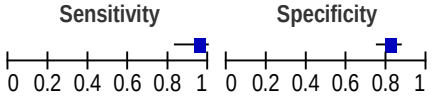


Figure 48 – Fragmment scale cut-off score 1 – follow-up > 1 week – general population– all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Perneger 2002	280	388	76	446	0.79 [0.74, 0.83]	0.53 [0.50, 0.57]

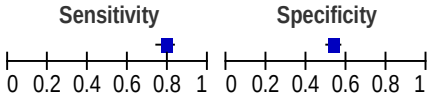


Figure 49 – Fragmment scale cut-off score 2 – follow-up > 1 week – general population– all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Perneger 2002	273	234	83	600	0.77 [0.72, 0.81]	0.72 [0.69, 0.75]

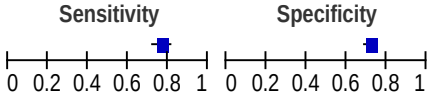


Figure 50 – Fragmment scale cut-off score 3 – follow-up > 1 week – general population– all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Perneger 2002	221	125	135	709	0.62 [0.57, 0.67]	0.85 [0.82, 0.87]

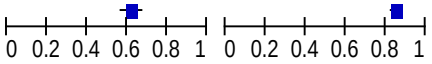


Figure 51 – The Northern Hospital Pressure Ulcer Prevention plan cut-off score 2 – follow-up > 1 week – general population– all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Page 2011	6	60	1	98	0.86 [0.42, 1.00]	0.62 [0.54, 0.70]

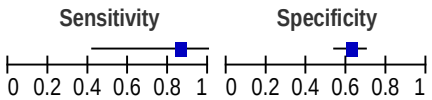


Figure 52 – The Northern Hospital Pressure Ulcer Prevention plan cut-off score 3 – follow-up > 1 week – general population– all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Page 2011	5	30	2	128	0.71 [0.29, 0.96]	0.81 [0.74, 0.87]

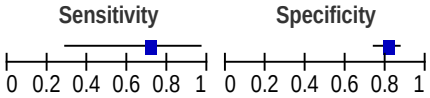


Figure 53 – The Northern Hospital Pressure Ulcer Prevention plan cut-off score 4 – follow-up > 1 week – general population– all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Page 2011	5	19	2	139	0.71 [0.29, 0.96]	0.88 [0.82, 0.93]

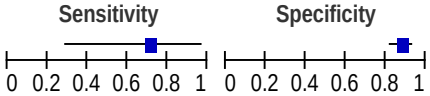


Figure 54 – Douglas scale cut-off score 18 – follow-up > 1 week – ICU – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Seongsook 2004	35	63	0	14	1.00 [0.90, 1.00]	0.18 [0.10, 0.29]

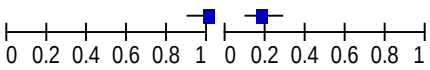


Figure 55 – Song and Choi scale cut-off score 2 – follow-up > 1 week – ICU – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Kim 2009	38	55	2	124	0.95 [0.83, 0.99]	0.69 [0.62, 0.76]

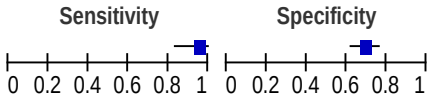


Figure 56 – Suriadi and Sanada scale cut-off score 3 – follow-up > 1 week – ICU – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Suriadi 2008	70	85	2	96	0.97 [0.90, 1.00]	0.53 [0.45, 0.60]

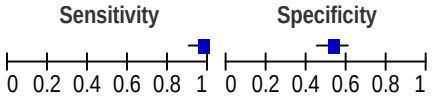


Figure 57 – Suriadi and Sanada scale cut-off score 4 – follow-up > 1 week – ICU – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Suriadi 2008	58	31	14	150	0.81 [0.70, 0.89]	0.83 [0.77, 0.88]

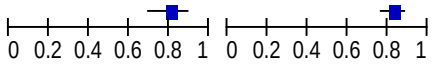


Figure 58 – Suriadi and Sanada scale cut-off score 5 – follow-up > 1 week – ICU – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Suriadi 2008	52	24	20	157	0.72 [0.60, 0.82]	0.87 [0.81, 0.91]

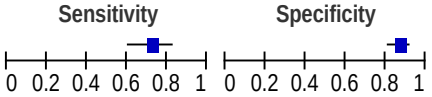
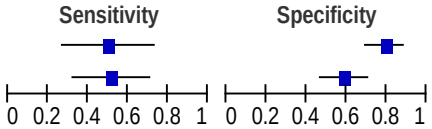


Figure 59 – Clinical judgement – follow-up > 1 week – general population – all stages

Study	TP	FP	FN	TN	Sensitivity	Specificity
Salvadalena 1992	10	16	10	63	0.50 [0.27, 0.73]	0.80 [0.69, 0.88]
VandeBosch 1996	15	30	14	43	0.52 [0.33, 0.71]	0.59 [0.47, 0.70]



2.5.4. Clinical evidence tables

Table 58 – Pancorbo 2006

Reference	Method	Patient characteristics	Intervention	Results	Critical appraisal of review quality
Author and year: **Pancorbo (2006)** Title: **Risk assessment scales for pressure ulcer prevention: a systematic review.** Journal: **Journal of Advanced Nursing, 54 (1); 94-110.**	**Design:** systematic review and meta-analysis **Source of funding:** grant from the Health Institute Carlos III, Ministry of Health and Consumer (Spain) **Search date**: 1966-2003 Searched databases: DARE; CINAHL; Medline; Current contents clinical medicine, social and behaviour science, life sciences; indice medico	Eligibility criteria: all types of patients **Patient characteristics** Hospitalized patients (acute ward, medical ward, surgical ward, orthopaedic ward, internal medicine, geriatric ward, cardiovascular surgery, neurosurgery, orthopaedic surgery), ICU patients, home care patients, LTCF patients, rehabilitation patients, geriatric centre	**Index test** Braden scale; Norton scale; Waterlow scale; Andersen scale; Pressure Sore Prediction Score; Knoll scale; Modified Norton scale; Emina scale; Cubbin-Jackson scale; Risk Assessment Pressure Sore; Fragmment scale; Douglas scale; Clinical judgement	See Appendix 2.5	The critical assessment guide developed for clinical practice guide for PU assessment and prevention (Rycroft-Malone & McInness 2002) was used to assess the quality of prospective cohort studies. Results of the assessment of the methodological quality are not reported.

Reference	Method	Patient characteristics	Intervention	Results	Critical appraisal of review quality
	español; cuiden; centro Latinoamericano y del caribe de información en Ciencias de la Salud; Cochrane Library; EBSCO; ScienceDirect; Springer; InterSciencia; ProQuest; Pascal **Included study designs:** prospective cohort studies **Inclusion criteria:** the patients considered had no PU at the beginning of the study; drop-out rate of patients did not exceed 25 %; studies in French, Spanish, English or Portuguese **Number of included studies:** 32		**Reference standard:** Pressure ulcer development		

Table 59 – Anthony 2003

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: **Anthony (2003)** Title: **A regression analysis of the Waterlow score in pressure ulcer risk assessment.** Journal: **Clinical**	**Patient group:** hospitalised patients of all ages **All patients** **Included N:** 45735 **Completed N:** 45735	**Index test 1:** the Waterlow scale **Reference standard:** development of pressure ulcer stage I or above, according to the Torrance grading (Torrance, 1983)	**Outcome 1:** Incidence of PU **Outcome 2:** Area under the ROC	**Value:** 0.4% **AUC:** 0.901 **95% CI:** 0.883-0.919	**Funding:** / **Limitations:** database cohort study; no report on re-assessment of index test; no

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Intervention
Comparison</th><th>Outcome measures</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>Rehabilitation, 17(2): 216-23.

Study type: Database cohort study but participants followed prospectively
Selection patient:
Hospitalized patients. All patients admitted between 1996 and 2000 with a compatible Waterlow score on admission.
Index test: Waterlow scale was used to assess PU risk at admission. Re-assessment unclear. Health professional were trained to screen the patients.
Reference standard: The Torrance score was used to grade the PU. Health professional were trained to screen the patients.
Imputation: no imputation, no exclusion
Number of events: 203 patients developed</td>
<td>Drop-outs: 0

Group with hospital acquired PU
Number of patients with a PU: 203 had no PU on admission; 74 had a PU on admission
Age (mean years; median age (IQR); range): 63.24; 64.70 (17.22); 0 to > 81
Gender (m/f): 81/122
Days in hospital (mean days; median days (IQR)): 31.98; 22.00 (34.50)

Group without hospital acquired PU
Age (mean years; median age (IQR); range): 41.84; 44.50 (28.33); 0 to > 81
Gender (m/f): 21732/23800
Days in hospital (mean days; median days (IQR)): 3.40; 2.00 (2.00)

Inclusion criteria: not reported</td>
<td>Preventive methods: not reported</td>
<td>Outcome 3:
Sensitivity and specificity
Waterlow scale cut-off 10

Outcome 4:
Sensitivity and specificity
Waterlow scale cut-off 15

Outcome 5:
Sensitivity and specificity
Braden scale cut-off 20</td>
<td>Sensitivity: 82.3%
Specificity: 85.2%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>167</td><td>6757</td><td>6924</td></tr>
<tr><td>No</td><td>36</td><td>38775</td><td>38811</td></tr>
<tr><td></td><td>203</td><td>45532</td><td>45735</td></tr>
</table>
Sensitivity: 48.8%
Specificity: 94.5%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>99</td><td>2519</td><td>2618</td></tr>
<tr><td>No</td><td>104</td><td>43013</td><td>43117</td></tr>
<tr><td></td><td>203</td><td>45532</td><td>45735</td></tr>
</table>
Sensitivity: 16.7%
Specificity: 98.1%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>34</td><td>846</td><td>880</td></tr>
<tr><td>No</td><td>169</td><td>44686</td><td>44855</td></tr>
<tr><td></td><td>203</td><td>45532</td><td>45735</td></tr>
</table>
</td>
<td>report on duration of follow-up; no report on blinding; no imputation, no exclusion; not reported when patients dropped from the study; no report on inclusion and exclusion criteria; no report on use of preventive measures; no sub-analyses according to preventive measures.

Additional outcomes: /

Notes: /</td>
</tr>
</table>

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
ulcers Addressing missing data: **not reported when patients dropped from the study** Statistical analysis: **An ROC curve is a plot of the true positive rate (sensitivity) against the false positive rate (1–specificity) for given thresholds. A system that performs as one might expect would show a differing ratio of sensitivity to specificity as the threshold increases.** Setting: **the Queen's Hospital in Burton.** Blinding: **not reported**	**Exclusion criteria:** not reported				

Table 60 – Chan 2009

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Intervention
Comparison</th><th>Outcome measures</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>Author and year: Chan (2009)
Title: Assessing predictive validity of the modified Braden scale for prediction of pressure ulcer risk of orthopaedic patients in an acute care setting.
Journal: Journal of Clinical Nursing, 18: 1565-73

Study type: prospective cohort study
Selection patient:
Chinese patients aged 18 or above without a pressure ulcer on admission. Recruitment unclear.
Index test: Braden and modified Braden were used to assess PU risk at admission. Researcher, a trained nurse, screened the patients.
Reference standard:</td>
<td>Patient group: hospitalised patients aged 18 or above

All patients
Included N: 197
Completed N: 197
Drop-outs: 0
Age (mean years (SD); range): 79.4 (10.88); 35-98
Gender (m/f): 30/167
Number of patients with a PU: 18
Number of patients without a PU: 179

Inclusion criteria: Chinese;
aged 18 or above;
an expected stay of five days or more following admission;
not ambulant;
no PU on admission.
Exclusion criteria: none</td>
<td>Index test 1: the Braden scale
Index test 2: modified Braden scale (Kwong et al. 2005)
Reference standard: development of pressure ulcer stage I or above, according to the NPUAP (2007) classification.

Preventive methods: preventive nursing intervention were performed but not described..</td>
<td>Outcome 1:
Incidence of PU
(> 1 week; 9 days)

Outcome 2:
Area under the ROC

Outcome 3:
Sensitivity and specificity Braden scale cut-off 16

Outcome 4:
Sensitivity and specificity Braden scale cut-off 17</td>
<td>Value: 9.10%

Value: 0.736
95% CI: 0.632-0.841

Sensitivity: 66.7%
Specificity: 64.2%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>12</td><td>64</td><td>76</td></tr>
<tr><td>No</td><td>6</td><td>115</td><td>121</td></tr>
<tr><td></td><td>18</td><td>179</td><td>197</td></tr>
</table>
Sensitivity: 72.2%
Specificity: 40.8%
Raw data
<table>
<tr><td></td><td></td><td>Reference standard</td><td></td></tr>
</table>
</td>
<td>Funding: /

Limitations: index test measured only at admission; no report on blinding of researcher toward index test and reference standard; no imputation, no exclusion; low event rate; not reported when patients dropped from the study; no sub-analyses according to preventive measures.

Additional outcomes: /

Notes: /</td>
</tr>
</table>

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments

skin assessment to detect PUs were performed daily. Researcher, a trained nurse, screened the patients. Patient were observed until PU development, discharge, transfer or death. Observation period of maximum 9 days.

Imputation: **no imputation, no exclusion**

Number of events: **18 patients developed ulcers**

Addressing missing data: **not reported when patients dropped from the study**

Statistical analysis: **The receiver operating characteristic (ROC) curve determined the predictive validity of the Braden and modified Braden scales.**

		Yes	No	
Index test	Yes	13	106	119
	No	5	73	78
		18	179	197

Outcome 5:

Sensitivity and specificity Braden scale cut-off 18

Sensitivity: 88.9%

Specificity: 21.2%

Raw data

		Reference standard		
		Yes	No	
Index test	Yes	16	141	157
	No	2	38	40
		18	179	197

Outcome 6:

Sensitivity and specificity modified-Braden scale cut-off 17

Sensitivity: 38.9%

Specificity: 79.9%

Raw data

		Reference standard		
		Yes	No	
Index test	Yes	7	36	43
	No	11	143	154

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Intervention
Comparison</th><th>Outcome measures</th><th>Results</th><th>Comments</th></tr>
<tr><td>Setting: two orthopaedic wards of an acute care hospital in Hong Kong
Blinding: blinding of researcher who assess risk and PU development not reported. Nurses performed preventive measures without knowing the scores of the Braden and modified Braden.</td><td></td><td></td><td>Outcome 7:
Sensitivity and specificity modified-Braden scale cut-off 18</td><td>
<table>
<tr><td></td><td></td><td>18</td><td>179</td><td>197</td></tr>
</table>
Sensitivity: 55.6%
Specificity: 72.6%
Raw data
<table>
<tr><td></td><td></td><td>Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>10</td><td>49</td><td>59</td></tr>
<tr><td>No</td><td>8</td><td>130</td><td>138</td></tr>
<tr><td></td><td>18</td><td>179</td><td>197</td></tr>
</table>
Outcome 8:
Sensitivity and specificity modified-Braden scale cut-off 19</td><td>Sensitivity: 88.9%
Specificity: 62.0%
Raw data
<table>
<tr><td></td><td></td><td>Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>16</td><td>68</td><td>84</td></tr>
<tr><td>No</td><td>2</td><td>111</td><td>113</td></tr>
<tr><td></td><td>18</td><td>179</td><td>197</td></tr>
</table>
</td><td></td></tr>
</table>

Table 61 – Compton 2008

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: **Compton (2008)** Title: **Pressure ulcer predictors in ICU patients: nursing skin assessment versus objective parameters** Journal: **Journal of Wound Care, 17(10): 417-24.** Study type: database **cohort but participants were followed prospectively** Selection patient: **All patients admitted to the medical ICU between April 2001 and December 2004.** Index test: **Waterlow score at admission. The admitting nurse screened the patients** Reference standard: **Occurrence of PU were recorded during the ICU treatment (median stay (IQ) before PU occurrence: 7 (4.13))** Imputation: **no imputation, no**	**Patient group:** patients hospitalised in ICU. **All patients** **Included N:** 698 **Completed N:** 698 **Drop-outs:** 0 **Age (median yrs (IQ)):** 66 (56, 75, 25) **Gender (m/f):** 392/306 **Number of patients with a PU:** 121 **Number of patients without a PU:** 577 **Number of days before occurrence of PU (median days (IQ)):** 7 (4, 13) **Inclusion criteria:** patients admitted to the ICU for at least 72 hours; no pressure ulcer on admission **Exclusion criteria:** /	**Index test 1:** the Waterlow scale **Reference standard:** development of pressure ulcer stage II or above, according to the NPUAP (1999) classification. **Preventive methods:** not reported.	**Outcome 1:** Incidence of PU **Outcome 2:** Area under the ROC	**Value:** 17.3% **AUC:** 0.59 **95% CI:** 0.54-0.65	**Funding:** / **Limitations:** database cohort study; index test only assessed on admission; no report on maximum duration of follow-up; no report on blinding; no imputation, no exclusion; not reported when patients dropped from the study; no report on use of preventive measures; no sub-analyses according to preventive measures; cut-off score of 0.5 does not exist **Additional outcomes:** logistic regression of 32

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
exclusion Number of events: **121 patients developed ulcers** Addressing missing data: **not reported when patients dropped from the study** Statistical analysis: **The predictive capacity of the logistic regression function was assessed and compared with the Waterlow score by calculating the area under the curve of a receiving-operator characteristics curve. AUC, sensitivity specificity were displayed with 95% CI** Setting: **medical ICU of the Charité Campus Benjamin Franklin Berlin** Blinding: **not reported**					variables. Five parameters were identified as predictors and sensitivity and specificity was calculated. **Notes:** /

Table 62 – Curley 2003

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Intervention
Comparison</th><th>Outcome measures</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>Author and year: Curley (2003)
Title: Predicting pressure ulcer risk in pediatric patients: the Braden Q Scale
Journal: Nursing Research, 52(1): 22-33.

Study type: prospective cohort study
Selection patient:
PICU patients. Consecutive sample.
Index test: Braden-Q was used to assess PU risk at enrolment. A trained nurse screened the patients. Patients were observed up to 3 times a week for 2 weeks, then once a week until discharge (stay: 3 – 12 days).
Reference standard: The skin assessment tool (Braden &</td>
<td>Patient group: paediatric patients hospitalised in PICU.

All patients
Included N: 322
Completed N: 322
Drop-outs: 0
Age (mean months (SD)): 36 (29)
Gender (m/f): 193/129
Number of patients with a PU: 277
Number of patients without a PU: 45

Inclusion criteria: bedrest for at least 24 hours;
age between 21 days and 8 years.
Exclusion criteria: patients admitted to the PICU with a pre-existing PU;
intra-cardiac shunting; unrepaired congenital heart disease</td>
<td>Index test 1: the Braden-Q scale (Quigley & Curley, 1996)
Reference standard: development of pressure ulcer stage II or above, according to the NPUAP (1989) classification.

Preventive methods: not reported.</td>
<td>Outcome 1:
Incidence of PU
(> 1 week; 12 days)

Outcome 2:
Area under the ROC

Outcome 3:
Sensitivity and specificity Braden-Q scale cut-off 10

Outcome 4:
Sensitivity and specificity Braden-Q scale cut-off 11</td>
<td>Value: 26.71%

AUC: 0.830
95% CI: 0.76-0.91

Sensitivity: 3.5%
Specificity: 100%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>3</td><td>0</td><td>3</td></tr>
<tr><td>No</td><td>83</td><td>236</td><td>319</td></tr>
<tr><td></td><td>86</td><td>236</td><td>322</td></tr>
</table>
Sensitivity: 16.3%
Specificity: 97.0%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
</table>
</td>
<td>Funding: /

Limitations: no imputation, no exclusion; low event rate; not reported when patients dropped from the study; no report on preventive measures; no sub-analyses according to preventive measures.

Additional outcomes: /

Notes: /</td>
</tr>
</table>

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Bergstorm, 1997) was used to detect the presence or absence of PUs. **A trained nurse screened the patients. Patients were observed up to 3 times a week for 2 weeks, then once a week until discharge (stay: 3 – 12 days).** Imputation: **no imputation, no exclusion** Number of events: **86 patients developed ulcers** Addressing missing data: **not reported when patients dropped from the study** Statistical analysis: **Diagnostic probabilities** **(sensitivity, specificity, positive predictive value, and negative predicative value) were calculated over a**					

Index test	Yes	14	7	21
	No	72	229	301
		86	236	322

Outcome 5:

Sensitivity and specificity Braden-Q scale cut-off 12

Sensitivity: 47.7%

Specificity: 92.8%

Raw data

		Reference standard		
		Yes	No	
Index test	Yes	41	17	58
	No	45	219	264
		86	236	322

Outcome 6:

Sensitivity and specificity Braden-Q scale cut-off 13

Sensitivity: 67.4%

Specificity: 89.0%

Raw data

		Reference standard		
		Yes	No	
Index test	Yes	58	26	84
	No	28	210	238
		86	236	322

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Intervention
Comparison</th><th>Outcome measures</th><th>Results</th><th>Comments</th></tr>
<tr><td>range of possible Braden Q score.
Receiver operator characteristic (ROC) curve analysis
plotting sensitivity against 1 – specificity over the range of
Braden Q scores was constructed to confirm the critical value of the Braden Q Scale. The optimal cutoff point was determined by that which provided high sensitivity and adequate specificity. The likelihood ratio (LR) was measured to identify the ratio of the probabilities that a positive test results from a patient with pressure ulcers to that for a patient without pressure ulcers.
Setting: three PICUs of three different hospitals in the US</td><td></td><td></td><td>Outcome 7:
Sensitivity and specificity Braden-Q scale cut-off 14</td><td>Sensitivity: 72.1%
Specificity: 78.8%
Raw data<table><tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Index test</td><td>Yes</td><td>62</td><td>50</td><td>112</td></tr><tr><td>No</td><td>24</td><td>186</td><td>210</td></tr><tr><td></td><td>86</td><td>236</td><td>322</td></tr></table>Sensitivity: 75.6%
Specificity: 67.8%
Raw data<table><tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Index test</td><td>Yes</td><td>65</td><td>76</td><td>141</td></tr><tr><td>No</td><td>21</td><td>160</td><td>181</td></tr><tr><td></td><td>86</td><td>236</td><td>322</td></tr></table>Sensitivity: 88.4%
Specificity: 58.1%
Raw data<table><tr><td></td><td></td><td>Reference</td><td></td></tr></table></td><td></td></tr>
</table>

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Blinding: **the two nurses were blinded to other's assessment. Nurse I rated the Braden Q and nurse II rated the skin assessment tool.**			cut-off 16	<table><tr><td></td><td></td><td colspan="2">standard</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Index test</td><td>Yes</td><td>76</td><td>99</td><td>175</td></tr><tr><td>No</td><td>10</td><td>137</td><td>147</td></tr><tr><td></td><td>86</td><td>236</td><td>322</td></tr></table>	
			Outcome 10: Sensitivity and specificity Braden-Q scale cut-off 17	**Sensitivity:** 91.9% **Specificity**: 44.1% **Raw data** <table><tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Index test</td><td>Yes</td><td>79</td><td>132</td><td>211</td></tr><tr><td>No</td><td>7</td><td>104</td><td>111</td></tr><tr><td></td><td>86</td><td>236</td><td>322</td></tr></table>	
			Outcome 11: Sensitivity and specificity Braden-Q scale cut-off 18	**Sensitivity:** 100.0% **Specificity**: 30.1% **Raw data** <table><tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="2">Index test</td><td>Yes</td><td>86</td><td>165</td><td>251</td></tr><tr><td>No</td><td>0</td><td>71</td><td>71</td></tr></table>	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments

		86	236	322

Outcome 12:
Sensitivity and specificity Braden-Q scale cut-off 19

Sensitivity: 100.0%
Specificity: 19.9%
Raw data

		Reference standard		
		Yes	No	
Index test	Yes	86	189	275
	No	0	47	47
		86	236	322

Outcome 13:
Sensitivity and specificity Braden-Q scale cut-off 120

Sensitivity: 100.0%
Specificity: 8.1%
Raw data

		Reference standard		
		Yes	No	
Index test	Yes	86	217	303
	No	0	19	19
		86	236	322

Table 63 – de Souza 2010

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Intervention
Comparison</th><th>Outcome measures</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>Author and year: de Souza (2010)
Title: Predictive validity of the Braden scale for pressure ulcer risk in elderly residents of long-term care facilities
Journal: Geriatric nursing, 31(2): 95-104.

Study type: prospective cohort study (secondary analysis)
Selection patient:
Elderly patients residing in LTCF with a Braden score < 19. Recruitment strategy not reported.
Index test: Braden scale was used to assess PU risk every 2 days for 3 months. Assessment were carried out by trained observers.
Reference standard: Skin assessment</td>
<td>Patient group: elderly patients residing in LTCFs.

All patients
Included N: 233
Completed N: 233
Drop-outs: 0
Age (mean years (SD)): 76.6 (9.2)
Gender (m/f): 104/129
Length of stay (mean days (SD); range): 3685.37 (4266.4); 1-23360
Number of patients with a PU: 44
Number of patients without a PU: 189

Subgroup (Braden score < 18)
Included N: 94
Completed N: 94
Drop-outs: 0
Age (mean years (SD)): 79.1 (9.6)
Gender (m/f): 35/52</td>
<td>Index test 1: the Braden scale (Braden and Bergstrom 1994)

Reference standard: development of pressure ulcer grade 1 or above, according to the EPUAP (2008) classification.

Preventive methods:
change of the patient’s position and minimization
of skin exposure to moisture</td>
<td>Outcome 1:
Incidence of PU in total group
(not reported)

Outcome 2:
Incidence of PU in subgroup
(not reported)

Outcome 3:
Sensitivity and specificity Braden scale cut-off 17 in total group // last assessment (3 months?)

Outcome 4:
Sensitivity and specificity Braden scale cut-off 17 in subgroup // last</td>
<td>Value: 18.9%

Value: 39.4%

Sensitivity: 75.0%
Specificity: 75.7%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>33</td><td>46</td><td>79</td></tr>
<tr><td>No</td><td>11</td><td>143</td><td>154</td></tr>
<tr><td></td><td>44</td><td>189</td><td>233</td></tr>
</table>
Sensitivity: 56.8%
Specificity: 71.9%
Raw data
<table>
<tr><td></td><td></td><td>Reference standard</td><td></td></tr>
</table>
</td>
<td>Funding: /

Limitations: no imputation, no exclusion; low event rate; not reported when patients dropped from the study; no report on blinding; no sub-analyses according to preventive measures. Only patients with a Braden score < 19 were included! Unclear if patients with a pressure ulcer at start of the study were included.

Additional outcomes: sensitivity and specificity on day 0</td>
</tr>
</table>

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
was performed every 2 days for 3 months. Assessment were carried out by trained observers. Imputation: **no imputation, no exclusion** Number of events: **44 patients developed ulcers** Addressing missing data: **not reported when patients dropped from the study** Statistical analysis: **The predictive validity of a test is determined by the sensitivity and specificity of the test. Sensitivity and specificity can be graphically represented by the receiver operating characteristic (ROC) curve that plots the true-positive rate (sensitivity) against the false-positive**	Length of stay (mean days (SD)): 3979.51 (5371.3) **Number of patients with a PU:** 37 **Number of patients without a PU:** 57 **Inclusion criteria:** aged 60 years and older; Braden score < 19; agreement to participate **Exclusion criteria:** /		assessment (3 months?)	<table><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Index test</td><td>Yes</td><td>21</td><td>16</td><td>37</td></tr><tr><td>No</td><td>16</td><td>41</td><td>57</td></tr><tr><td></td><td>37</td><td>57</td><td>94</td></tr></table>	**Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
rate (1-specificity). The test is considered good when the ROC curve falls above the diagonal line. There is a quantitative and qualitative relationship between the area under the curve (AUC) and accuracy, which may be classified as **excellent (0.80–0.90), very good (0.70–0.79), good (0.60–0.69), and poor (0.50–0.59). The patients were assessed for 3 consecutive months, and data from the first and last (before any of the aforementioned outcomes) assessments were used for statistical analysis.** Setting: **4 LTCFs located in 3 cities in Southern Minas Gerais, Brazil.** Blinding: **no blinding**					

Table 64 – Feuchtinger 2007

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Intervention
Comparison</th><th>Outcome measures</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>Author and year: Feuchtinger (2007)
Title: Pressure ulcer risk assessment immediately after cardiac surgery--does it make a difference? A comparison of three pressure ulcer risk assessment instruments within a cardiac surgery population
Journal: Nursing in Critical Care, 12(1): 42-49.
Study type: prospective cohort study
Selection patient:
ICU patients consecutively recruited after cardiac surgery.
Index test: Braden scale, modified</td>
<td>Patient group: cardiac surgery ICU patients.

All patients
Included N: 53
Completed N: 53 completed assessment on admission to the ICU and day 1. 36 patients completed the assessment after day 2, 20 after day 3 and 17 after day 4.
Drop-outs: 0 for assessment on admission to the ICU and day 1. 17 for assessment on day 2, another 16 for assessment on day 3 and another 3 for assessment on day 4.
Age (mean years (SD); range): 62 (12.1); 25-83
Gender (m/f): 31/22
Number of patients with a PU: 33
Number of patients</td>
<td>Index test 1: the Braden scale (Bergstorm et al. 1987)
Index test 2: the modified Norton scale (Bienstein, 1991)
Index test 2: the four-factor model (Halfens et al. 2000)

Reference standard: development of pressure ulcer grade 1 or above, according to the EPUAP (2005a) classification.

Preventive methods:
Not reported</td>
<td>Outcome 1:
Incidence of PU (1 day)

Outcome 2:
Incidence of PU (1 week)

Outcome 3:
Sensitivity and specificity Braden scale cut-off 9 // day 1

Outcome 4:
Sensitivity and specificity Braden scale cut-off 10 // day</td>
<td>Value: 49%

Value: 62.3%

Sensitivity: 19.2%
Specificity: 100.0%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>5</td><td>0</td><td>5</td></tr>
<tr><td>No</td><td>21</td><td>27</td><td>48</td></tr>
<tr><td></td><td>26</td><td>27</td><td>53</td></tr>
</table>
Sensitivity: 23.1%
Specificity: 100.0%
Raw data
<table>
<tr><td></td><td></td><td>Reference standard</td><td></td></tr>
</table>
</td>
<td>Funding: /

Limitations: no imputation, no exclusion; low event rate; no report on blinding; no report on preventive measures; no report on statistical analysis; no sub-analyses according to preventive measures.

Additional outcomes: /

Notes: /</td>
</tr>
</table>

<table>
<tr><th>Reference</th><th>Patient Characteristics

Intervention

Comparison</th><th>Outcome measures</th><th>Results</th><th>Comments</th></tr>
<tr><td>Norton scale and 4-factor model of Halfens (2000) were used to assess PU risk after surgery and the four following days. Assessment were carried out by trained observers.

Reference standard: Skin assessment was performed preoperative, postoperative and the four following days. Assessment were carried out by trained observers.

Imputation: no imputation, no exclusion

Number of events: 26 patients developed ulcers

Addressing missing data: 53 patients were assessed postoperative and on day 1. 36 patients were assessed on day 2, 20 on day 3 and 14 on day 4.

Statistical analysis:</td><td>without a PU: 20

Inclusion criteria: cardiac surgery patients with a length of stay of ≥24h in ICU

Exclusion criteria: /</td><td>1

Outcome 5:
Sensitivity and specificity Braden scale cut-off 11 // day 1

Outcome 6:
Sensitivity and specificity Braden scale cut-off 16 // day 1</td><td>
<table>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>6</td><td>0</td><td>6</td></tr>
<tr><td>No</td><td>20</td><td>27</td><td>47</td></tr>
<tr><td></td><td>26</td><td>27</td><td>53</td></tr>
</table>
Sensitivity: 30.8%
Specificity: 100.0%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>8</td><td>0</td><td>8</td></tr>
<tr><td>No</td><td>18</td><td>27</td><td>45</td></tr>
<tr><td></td><td>26</td><td>27</td><td>53</td></tr>
</table>
Sensitivity: 76.9%
Specificity: 29.6%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="2">Index test</td><td>Yes</td><td>20</td><td>19</td><td>39</td></tr>
<tr><td>No</td><td>6</td><td>8</td><td>14</td></tr>
</table>
</td><td></td></tr>
</table>

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Not reported Setting: **ICU; no further information.** Blinding: **no blinding**					

		26	27	53

Outcome 7:
Sensitivity and specificity Braden scale cut-off 20 // day 1

Sensitivity: 96.2%
Specificity: 3.7%
Raw data

		Reference standard		
		Yes	No	
Index test	Yes	25	26	51
	No	1	1	2
		26	27	53

Outcome 8:
Sensitivity and specificity modified Norton scale cut-off 19 // day 1

Sensitivity: 26.9%
Specificity: 100%
Raw data

		Reference standard		
		Yes	No	
Index test	Yes	7	0	7
	No	19	27	46
		26	27	53

Sensitivity: 34.6%
Specificity: 92.6%

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments

Outcome 9:

Sensitivity and specificity modified Norton scale cut-off 21 // day 1

Raw data

		Reference standard		
		Yes	No	
Index test	Yes	9	2	11
	No	17	25	42
		26	27	53

Sensitivity: 42.3%
Specificity: 88.9%

Outcome 10:

Sensitivity and specificity modified Norton scale cut-off 23 // day 1

Raw data

		Reference standard		
		Yes	No	
Index test	Yes	11	3	14
	No	15	24	39
		26	27	53

Sensitivity: 57.7%
Specificity: 48.1%

Outcome 11:

Sensitivity and specificity modified Norton scale cut-off 25

Raw data

		Reference standard		
		Yes	No	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
			// day 1		

Index test	Yes	15	14	29
	No	11	13	24
		26	27	53

Sensitivity: 84.6%
Specificity: 29.6%

Outcome 12:
Sensitivity and specificity 4-factor model cut-off 25 // day 1

Raw data

		Reference standard		
		Yes	No	
Index test	Yes	22	19	41
	No	4	8	12
		26	27	53

Table 65 – Hatanaka 2007

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: **Hatanaka (2007)** Title: **A new predictive indicator for development of pressure ulcers in bedridden patients based on common**	**Patient group:** bedridden hospitalized patients. **All patients** **Included N:** 149 **Completed N:149**	**Index test 1:** the Braden scale **Reference standard:** development of pressure ulcer was defined as more than grade 1 (closed-persistent erythema)	**Outcome 1:** Incidence of PU (5-79 days) **Outcome 2:** Area under the ROC Braden	**Value:** 25.5% **Value:** 0.56	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; not reported when patients

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
laboratory tests results Journal **Journal of Clinical Pathology, 61: 514-518.** Study type: **prospective cohort study** Selection patient: **Bedridden patients hospitalized for a respiratory disorder.** **Recruitment strategy not reported.** Index test: **Braden scale was used to assess PU risk on admission.** Reference standard: **Pressure ulcer development was observed over a three months period, hospital discharge or PU development.** Imputation: **no imputation, no exclusion** Number of events: **38 patients developed**	**Drop-outs:** 0 **Age (mean years (SD)):** 71.6 (11.3) **Gender (m/f):** 104/45 **Number of patients with a PU:** 38 **Number of patients without a PU:** 111 **Inclusion criteria:** Required constant attentive care or need of a considerable amount of assisted care **Exclusion criteria:** /	**Preventive methods:** All patients were given a standard pressure-relieving mattress during hospitalization.	scale		dropped from the study; index test only on admission; no report on blinding; no description of preventive measures; no sub-analyses according to preventive measures. **Additional outcomes:** AUC of new indicator based on laboratory results **Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
ulcers Addressing missing data: **not reported when patients dropped from the study** Statistical analysis: **A receiver operating characteristic (ROC) curves analysis was performed.** Setting: **One hospital, Nara, Japan.** Blinding: **no blinding**					

Table 66 – Jalali 2005

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: **Jalali (2005)** Title: **Predicting pressure ulcer risk: comparing the predictive validity of 4 scales** Journal **Advances in Skin & Wound Care,**	**Patient group:** hospitalized patients. **All patients** **Included N:** 230 **Completed N:** 230 **Drop-outs:** 0 **Age (mean years;**	**Index test 1:** the Braden scale (Bergstorm et al. 1987) **Index test 2:** the Norton scale (Norton, 1962) **Index test 3:** the Gosnell scale (Gosnell, 1973) **Index test 4:** the Waterlow scale (Waterlow 1985)	**Outcome 1:** Incidence of PU (> 1 week; 2 weeks) **Outcome 2:** Area under the ROC Braden scale	**Value:** 9.10% **Sensitivity:** 52.7% **Specificity**: 100.0% **Raw data**	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; not reported when patients dropped from

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Intervention
Comparison</th><th>Outcome measures</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>18(2): 92-97.

Study type: prospective cohort study
Selection patient:
Patients from a neurology, intensive care, orthopaedic and medical unit.
Recruitment strategy not reported.
Index test: Braden scale, Norton scale, Gosnell scale and Waterlow scale were used to assess PU risk within 48h of admission. Patients were screened by trained research staff.
Reference standard: Skin assessment was performed once every 24h for a maximum of 14 days to assess the presence or absence of a PU. Patients were screened by trained research</td>
<td>range): 60; 21-89
Gender (m/f): 100/130
Number of patients with a PU:
Stage I: 18
Stage II: 48
Stage III: 8
Pressure ulcer location:
Sacrum: 54
Buttocks: 10
Heels: 6
Scapula: 4
Number of patients without a PU: 156

Inclusion criteria:
age of 21 years or older;
admitted to the hospital within the past 48h;
expected stay of 14days or longer;
no PU during initial skin assessment
Exclusion criteria: /</td>
<td>Reference standard: development of pressure ulcer according to criteria of Bergstorm et al. (1994)

Preventive methods:
Common preventive and nursing measures were recorded.</td>
<td>Outcome 3:
Sensitivity and specificity
Norton scale cut-off not reported

Outcome 4:
Sensitivity and specificity
Grosnell scale cut-off not reported</td>
<td>
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>39</td><td>0</td><td>39</td></tr>
<tr><td>No</td><td>35</td><td>156</td><td>191</td></tr>
<tr><td></td><td>74</td><td>156</td><td>230</td></tr>
</table>
Sensitivity: 48.6%
Specificity: 100.0%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>36</td><td>0</td><td>36</td></tr>
<tr><td>No</td><td>38</td><td>156</td><td>194</td></tr>
<tr><td></td><td>74</td><td>156</td><td>230</td></tr>
</table>
Sensitivity: 85.1%
Specificity: 83.3%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td>Index</td><td>Yes</td><td>63</td><td>26</td><td>89</td></tr>
</table>
</td>
<td>the study; index test only within 48h of admission; no report on blinding concerning skin assessment; unclear what is meant with assessment by 4 independent nurses; no description of preventive measures; no sub-analyses according to preventive measures; no report on thresholds of risk assessment tools.

Additional outcomes: /

Notes: /</td>
</tr>
</table>

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments

staff.

Imputation: **no imputation, no exclusion**

Number of events: **74 patients developed ulcers**

Addressing missing data: **not reported when patients dropped from the study**

Statistical analysis: **Predictive power was measured by the overall considerations of sensitivity, specificity,**

positive predictive value, and negative predictive value.

Setting: **three educational hospitals in Kermanshah, Iran.**

Blinding: **the four risk assessment tool were assessed by four independent research nurses; no information for skin assessment.**

test	No	11	130	141
		74	156	230

Outcome 5:

Sensitivity and specificity Waterlow scale cut-off not reported

Sensitivity: 63.5%

Specificity: 83.3%

Raw data

		Reference standard		
		Yes	No	
Index test	Yes	47	26	73
	No	27	130	157
		74	156	230

Table 67 – Kim 2009

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: **Kim (2009)** Title: **Comparison of the predictive validity among pressure ulcer risk assessment scales for surgical ICU patients** Journal **Australian Journal of Advanced Nursing, 26(4): 87-94.** Study type: **prospective study** Selection patient: **Patients from a surgical intensive care unit.** **Recruitment strategy not reported.** Index test: **Braden scale, Song and Choi scale, Cubbin and Jackson scale were used to assess PU risk at admission. Patients were screened by a**	**Patient group:** surgical ICU patients ≥ 16 years. **All patients** **Included N:** 219 **Completed N:** 219 **Drop-outs:** 0 **Age (mean years (SD); range):** 58.1 (1.2); 16-98 **Gender (m/f):** 145/74 **Number of patients with a PU:** Stage I: 15 Stage II: 25 **Pressure ulcer location:** Coccyx: 25 Other: 15 **Number of patients without a PU:** 179 **Inclusion criteria:** age of 16 years or older; no existing PU on admission;	**Index test 1:** the Braden scale **Index test 2:** the Song and Choi scale (Song and Choi, 1991) **Index test 3:** the Cubbin and Jackson scale (Cubbin and Jackson, 1991) **Reference standard:** development of pressure ulcer according to criteria of AHRQ (1994) **Preventive methods:** All patients received ordinary nursing interventions, especially those related to pressure ulcer prevention. Their position was changed every two hours and they were dried, cleaned and friction/shear managed to prevent pressure ulcers.	**Outcome 1:** Incidence of PU (> 1 week; 90 days) **Outcome 2:** Area under the ROC Braden scale **Outcome 3:** Area under the ROC Song and Choi scale **Outcome 4:** Area under the ROC Cubbin and Jackson scale **Outcome 5:** Sensitivity and specificity Braden scale cut-off 14	**Value:** 18.3% **Value:** 0.881 **Value:** 0.890 **Value:** 0.903 **Sensitivity:** 92.5% **Specificity**: 69.8% **Raw data** Reference standard	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; not reported when patients dropped from the study; index test only at admission; blinding unclear; no sub-analyses according to preventive measures. **Additional outcomes:** / **Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
trained research nurse. Reference standard: **Skin assessment was performed daily between 10:00 and 11:00 am until discharge (stay: 3-90 days). Patients were screened by a trained research nurse.** Imputation: **no imputation, no exclusion** Number of events: **40 patients developed ulcers** Addressing missing data: **not reported when patients dropped from the study** Statistical analysis: **The parameters for evaluating the predictive validity of each assessment scale included sensitivity, specificity, PVP and PVN. The**	admitted to the SICU **Exclusion criteria:** /			<table><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Index test</td><td>Yes</td><td>37</td><td>54</td><td>91</td></tr><tr><td>No</td><td>3</td><td>125</td><td>128</td></tr><tr><td></td><td>40</td><td>179</td><td>219</td></tr></table>	
			Outcome 6: Sensitivity and specificity Song and Choi scale cut-off 21	**Sensitivity:** 95.0% **Specificity**: 69.3% **Raw data** <table><tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Index test</td><td>Yes</td><td>38</td><td>55</td><td>93</td></tr><tr><td>No</td><td>2</td><td>124</td><td>126</td></tr><tr><td></td><td>40</td><td>179</td><td>219</td></tr></table>	
			Outcome 7: Sensitivity and specificity Cubbin and Jackson cut-off 28	**Sensitivity:** 95.0% **Specificity**: 81.6% **Raw data** <table><tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="2">Index test</td><td>Yes</td><td>38</td><td>33</td><td>71</td></tr><tr><td>No</td><td>2</td><td>146</td><td>148</td></tr></table>	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
ROC curve shows how the sensitivity proportion (vertical axis) varies with the false-positive proportion (horizontal axis, 1-specificity) as the decision criterion is varied. Setting: **one surgical ICU of a South-Korean hospital.** Blinding: **the head-nurse assessed each scale and skin assessment tool.**				<table><tr><td></td><td></td><td>40</td><td>179</td><td>219</td></tr></table>	

Table 68 – Kwong 2005

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: **Kwong (2005)** Title: **Predicting pressure ulcer risk with the modified Braden, Braden, and Norton scales in acute care hospitals in Mainland China**	**Patient group:** hospitalized patients of all ages. **All patients** **Included N:** 429 **Completed N:** 429 **Drop-outs:** 0	**Index test 1:** the Braden scale (Braden and Bergstrom, 1987) **Index test 2:** the modified Braden scale (Pand and Wong, 1998) **Index test 3:** the Norton scale (Norton et al., 1975) **Reference standard:**	**Outcome 1:** Incidence of PU (> 1 week; 21 days) **Outcome 2:** Sensitivity and specificity	**Value:** 2.1% **Sensitivity:** 88.9% **Specificity**: 71.9% **Raw data**	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; not reported when patients dropped from

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Intervention

Comparison</th><th>Outcome measures</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>Journal: Applied Nursing Research, 18 (2); 122-128.

Study type: prospective study
Selection patient:
Patients from any ward in two acute care hospitals.
Recruitment strategy not reported.
Index test: Braden scale, modified Braden scale and Norton scale were used to assess PU risk at admission. Patients were screened by trained nurses.
Reference standard: Skin assessment was performed daily until discharge, transfer or 21-day hospitalisation. Patients were screened by trained nurses.
Imputation: no</td>
<td>Age (mean years (SD); range): 54.07 (16.9); 5-93
Gender (m/f): 253/176
Number of patients with a PU:
Stage I: 8
Stage II: 1
Pressure ulcer location:
Sacral area: 4
Right iliac region: 2
Abdomen: 1
Left knee: 1
Right ankle: 1
Number of patients without a PU: 420

Inclusion criteria:
Free of PU within 24h of admission
Exclusion criteria: /</td>
<td>development of pressure ulcer according to criteria of the NPUAP (1989)

Preventive methods:
Nurses working in the ward relied on their clinical judgment to determine and perform preventive nursing interventions on the subjects. Preventive measures could be: turning every 2h, use of material to reduce pressure, keeping bed linen clean, dry, and smooth, keeping skin clean and dry, positioning, use of draw sheet for lifting patients, and massage of pressure points.</td>
<td>Braden scale cut-off 14

Outcome 3:
Sensitivity and specificity modified Braden scale cut-off 16

Outcome 4:
Sensitivity and specificity Norton scale cut-off 14</td>
<td>
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>8</td><td>118</td><td>126</td></tr>
<tr><td>No</td><td>1</td><td>302</td><td>303</td></tr>
<tr><td></td><td>9</td><td>420</td><td>429</td></tr>
</table>
Sensitivity: 88.9%
Specificity: 75.0%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>8</td><td>105</td><td>113</td></tr>
<tr><td>No</td><td>1</td><td>315</td><td>316</td></tr>
<tr><td></td><td>9</td><td>420</td><td>429</td></tr>
</table>
Sensitivity: 88.9%
Specificity: 61.0%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
</table>
</td>
<td>the study; index test only at admission; no blinding of scales and skin assessment; no sub-analyses according to preventive measures.

Additional outcomes: /

Notes: Pressure ulcers located to the iliac region and abdomen could be the result of medical devices. However, this is not stated in the article.</td>
</tr>
</table>

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments

imputation, no exclusion

Number of events: **9 patients developed ulcers**

Addressing missing data: **not reported when patients dropped from the study**

Statistical analysis: **not reported**

Setting: **two acute care hospitals in Mainland China.**

Blinding: **three nurses form each ward assessed the three scales and skin condition independent of each other. No blinding between scale and PU development as one of the three nurses performed this assessment.**

Index test	Yes	8	164	172
	No	1	256	257
		9	420	429

Table 69 – Lincoln 1986

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: **Lincoln (1986)** Title: **Use of the Norton Pressure Sore risk assessment scoring system with elderly patients in acute care** Journal: **Journal of Enterostomy Therapy, 13; 132-138.** Study type: **prospective study** Selection patient: **Hospitalized surgical-medical patients.** **Recruitment strategy not reported.** Index test: **Norton scale was used to assess PU risk at admission and every 3 days until discharge or death. Patients were screened by research assistants.** Reference standard:	**Patient group:** hospitalized medical-surgical patients aged 65 years and older. **All patients** **Included N:** 50 **Completed N:** 36 **Drop-outs:** 14 (stayed 3 days or less) **Age (mean years (SD); range):** 72.2 (15.8); 65-89 **Gender (m/f):** 23/27 **Length of stay (mean days; range):** 7.88; 2-26 **Number of patients with a PU:** 5 of the 36 **Pressure ulcer location:** Primarily on heels and elbows, and one sacral lesion **Number of patients without a PU:** 31 **Inclusion criteria:**	**Index test 1:** the Norton scale (assessment on admission used) **Reference standard:** development of pressure ulcer according to a 5-point scale: 0 = no change, 1 = erythema, 2 = superficial skin opening, 3 = a lesion extending into underlying tissue, 4 = involvement of muscle and bone **Preventive methods:** Preventive measures were given but not reported. Nurses giving prevention were unaware of Norton score	**Outcome 1:** Incidence of PU (max. 26 days) **Outcome 2:** Sensitivity and specificity Norton scale cut-off 14	**Value:** 13.9% **Sensitivity:** 0.0% **Specificity**: 93.5% **Raw data** Reference standard: Yes / No Index test: Yes: 0 / 2 / 2 No: 5 / 29 / 34 5 / 31 / 36	**Funding:** the research was funded by the Dean's Research fund, Frances Payne Bolton School of Nursing, Case Western Reserve University **Limitations:** no imputation, no exclusion; low event rate; not reported when patients dropped from the study; index test assessed on admission used; no blinding of; no sub-analyses according to preventive measures. **Additional**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Skin assessment was performed at admission and every 3 days until discharge or death. Patients were screened by research assistants. Imputation: **no imputation, no exclusion** Number of events: **5 patients developed ulcers** Addressing missing data: **not reported when patients dropped from the study** Statistical analysis: **not reported** Setting: **two divisions in a teaching hospital in the Midwest.** Blinding: **not reported**	Age over 65 years; absence of pressure sores on admission **Exclusion criteria:** /				**outcomes:** / **Notes:** /

Table 70 – Ongoma 2005

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Intervention
Comparison</th><th>Outcome measures</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>Author and year: Ongoma (2009)
Title: Predictive validity of pressure risk assessment scales in a private sector trauma intensive care unit
Journal: Southern African Journal of Critical Care, 21 (2); 78-86.

Study type: prospective study
Selection patient:
Patients admitted to the ICU of a private institution.
Purposive sampling; not further specified.
Index test: Sunderland Pressure Sore Risk Calculator (modified Cubbin and Jackson) and a modified Norton scale were used to assess PU risk at admission and on a</td>
<td>Patient group: ICU patients older than 18 years.

All patients
Included N: 66
Completed N: 66 completed assessment on admission and after one week. 34 patients completed the assessment after 2 weeks and 17 after 3 weeks.
Drop-outs: 0 for assessment on admission and after one week. 32 for assessment on week 2 and another 17 for assessment on week 3.
Age (range): 18-65
Gender (m/f): 56/10
Number of patients with a PU: 25
Pressure ulcer location (total of 44 PU):
Heels: 19</td>
<td>Index test 1: the Sunderland Pressure Sore Risk Calculator (modified Cubbin and Jackson) (Lowery 1995)
Index test 2: a modified Norton scale (hospital South Africa)
Reference standard: development of pressure ulcer; criteria not specified

Preventive methods:
Not reported</td>
<td>Outcome 1:
Incidence of PU
(1 week)

Outcome 2:
Sensitivity and specificity Sunderland Pressure Sore Risk Calculator cut-off 35 // week 1

Outcome 3:
Sensitivity and specificity modified Norton scale cut-off 20 / week 1</td>
<td>Value: 37.9%

Sensitivity: 80.0%
Specificity: 70.7%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>20</td><td>12</td><td>32</td></tr>
<tr><td>No</td><td>5</td><td>29</td><td>34</td></tr>
<tr><td></td><td>25</td><td>41</td><td>66</td></tr>
</table>
Sensitivity: 92.0%
Specificity: 29.3%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>23</td><td>29</td><td>52</td></tr>
<tr><td>No</td><td>2</td><td>12</td><td>14</td></tr>
<tr><td></td><td>25</td><td>41</td><td>66</td></tr>
</table>
</td>
<td>Funding: /

Limitations: no imputation, no exclusion; low event rate; no report on blinding; unclear which is the modified Norton scale; no report on criteria of PU classification nor assessment; no report on preventive measure; no report no sub-analyses according to preventive measures.

Additional outcomes: sensitivity and specificity on day 0</td>
</tr>
</table>

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
weekly basis for three weeks or until discharge or death. Reference standard: **PU development based on record review was performed daily.** Imputation: **no imputation, no exclusion** Number of events: **25 patients developed ulcers** Addressing missing data: **66 patients were assessed on admission and after one week. 34 patients were assessed after 2 weeks and 17 after 3 weeks.** Statistical analysis: **Inferential statistics were used to compare the total scores** **(predicted risk) with the outcome (pressure ulcer development), in**	Occiput: 7 Buttocks: 7 Sacrum: 3 Ankles: 2 Knees: 2 Elbows: 1 Ears: 1 Nose: 1 Forehead: 1 **Number of patients without a PU:** 41 **Inclusion criteria:** Age between 18 and 65 years; no pressure ulcer on admission; total bedrest due to injuries or medical interventions **Exclusion criteria:** extensive burns in the back, buttocks and legs				**Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
order to determine their predictive values. Setting: **the ICU of a private sector health care institution, South Africa.** Blinding: **not reported**					

Table 71 – Page 2011

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: **Page (2011)** Title: **Development and validation of pressure ulcer risk assessment tool for acute hospital patients** Journal: **Wound Repair and Regeneration, 19; 31-37.** Study type: **prospective study** Selection patient:	**Patient group:** hospitalized patients. **All patients** **Included N:** 165 **Completed N:** 165 **Drop-outs:** 0 **Number of patients > 65 years:** 107 **Gender (m/f):** 87/78 **Length of stay (mean days (SD)):** 14.97 (22.29) **Number of patients with a PU:** 7	**Index test 1:** The Northern Hospital Pressure Ulcer Prevention Plan (TNH-PUPP) (Page 2011) **Reference standard:** development of pressure ulcer grade 1; not further specified **Preventive methods:** A prevention protocol was implemented.	**Outcome 1:** Incidence of PU (not reported) **Outcome 2:** Area under the ROC TNH-PUPP **Outcome 3:** Sensitivity and specificity TNH-PUPP cut-off 1	**Value:** 4.2% **Value:** 0.90 **95% CI:** 0.82-0.99 **Sensitivity:** 100.0% **Specificity**: 34.2% **Raw data** Reference standard	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; no report on time of assessment of index test and reference standard; not reported when patients dropped from the study; no inclusion and exclusion

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Patients admitted to a general ward, critical care or emergency department of a hospital. **Recruitment strategy not reported.** Index test: **The Northern Hospital Pressure Ulcer Prevention Plan was used to assess PU risk. Patients were screened by trained nurses.** Reference standard: **PU development was identified by the nursing staff who received an education session of 30 minutes.** Imputation: **no imputation, no exclusion** Number of events: **7 patients developed ulcers** Addressing missing data: **not reported when patients**	**Number of patients without a PU:** 158 **Inclusion criteria:** / **Exclusion criteria:** /		**Outcome 4:** Sensitivity and specificity TNH-PUPP cut-off 2 **Outcome 5:** Sensitivity and specificity TNH-PUPP cut-off 3	<table><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Index test</td><td>Yes</td><td>7</td><td>104</td><td>111</td></tr><tr><td>No</td><td>0</td><td>54</td><td>54</td></tr><tr><td></td><td>7</td><td>158</td><td>165</td></tr></table> **Sensitivity:** 85.7% **Specificity**: 62.0% **Raw data** <table><tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Index test</td><td>Yes</td><td>6</td><td>60</td><td>66</td></tr><tr><td>No</td><td>1</td><td>98</td><td>99</td></tr><tr><td></td><td>7</td><td>158</td><td>165</td></tr></table> **Sensitivity:** 71.4% **Specificity**: 81.0% **Raw data** <table><tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="2">Index test</td><td>Yes</td><td>5</td><td>30</td><td>35</td></tr><tr><td>No</td><td>2</td><td>128</td><td>130</td></tr></table>	criteria reported; no report on blinding; no report on criteria of PU classification; no report no sub-analyses according to preventive measures. **Additional outcomes:** **Notes:** /

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
dropped from the study Statistical analysis: **The predictive accuracy of the TNH-PUPP was measured by the parameters area under the receiver operating curve (AUC), sensitivity, specificity, PPV, NPV, Youden Index, and prognostic separation index. An AUC of 1 indicates perfect prediction, whereas 0.5 represents the prediction expected by chance. Sensitivity, specificity, PPV, and NPV values > 0.70 are reported to be evidence of high predictive accuracy.** Setting: **the general wards, critical care and emergency department of an acute, metropolitan, public teaching**			**Outcome 6:** Sensitivity and specificity TNH-PUPP cut-off 4 **Outcome 7:** Sensitivity and specificity TNH-PUPP cut-off 5 **Outcome 8:** Sensitivity and specificity TNH-PUPP cut-off 6	<table><tr><td></td><td></td><td>7</td><td>158</td><td>165</td></tr></table> **Sensitivity:** 71.4% **Specificity**: 88.0% **Raw data** <table><tr><td></td><td></td><td>Reference standard</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Index test</td><td>Yes</td><td>5</td><td>19</td><td>24</td></tr><tr><td>No</td><td>2</td><td>139</td><td>141</td></tr><tr><td></td><td>7</td><td>158</td><td>165</td></tr></table> **Sensitivity:** 42.9% **Specificity**: 96.2% **Raw data** <table><tr><td></td><td></td><td>Reference standard</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Index test</td><td>Yes</td><td>3</td><td>6</td><td>9</td></tr><tr><td>No</td><td>4</td><td>152</td><td>156</td></tr><tr><td></td><td>7</td><td>158</td><td>165</td></tr></table> **Sensitivity:** 57.1% **Specificity**: 99.4%	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
hospital in Melbourne, Australia. Blinding: **not reported**				**Raw data** Reference standard: Yes / No Index test: Yes: 4 / 1 / 5 Index test: No: 3 / 157 / 160 7 / 158 / 165	

Table 72 – Serpa 2009

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: **Serpa (2009)** Title: **Predictive validity of Waterlow Scale for pressure ulcer development risk in hospitalized patients.** Journal: **Journal of Wound Ostomy & Continence Nursing, 36(6); 640-646.** Study type: **prospective study**	**Patient group:** hospitalized patients older than 18 years. **All patients** **Included N:** 98 **Completed N:** 98 **Drop-outs:** 0 before three consecutive assessments **Age (mean years (SD); range):** 71.1 (15.5); 29-96 **Number of patients with a PU:**	**Index test 1:** the Portuguese Waterlow scale (Paranhos & Santos, 1999) **Reference standard:** development of pressure ulcer; not further specified. **Preventive methods:** Not reported	**Outcome 1:** Incidence of PU (< 1 week; 2 days) **Outcome 2:** Area under the ROC first assessment (48h) **Outcome 3:** Area under the ROC second	**Value:** 7.1% **Value:** 0.64 **95% CI:** 0.35-0.93 **Value:** 0.59 **95% CI:** 0.34-0.83	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; no report on blinding; no report on skin assessment and criteria of classification; no report on preventive measures; no sub-analyses

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Intervention
Comparison</th><th>Outcome measures</th><th>Results</th><th>Comments</th></tr>
<tr><td>(secondary analysis)
Selection patient:
Patients at risk for PU from any ward in a general private hospital.
Recruitment strategy not reported.
Index test: Portuguese Waterlow scale was used to assess PU risk at admission. The patient was assessed for the first time and then at 48-hours intervals as long as the patient remained at risk or until PU development, discharge, transfer or death.
Reference standard: PU development; no further information.
Imputation: no imputation, no exclusion
Number of events: 7 patients developed ulcers</td><td>Stage I: 6
Stage II: 1
Number of patients without a PU: 91

Inclusion criteria:
Age equal to 18 years or older;
absence of PU at first assessment;
hospitalized for a minimum period of 24 hours and a maximum period of 48 hours at first assessment;
a total Braden Scale score equal to 18 or less and a Waterlow Scale score equal to 16 or more.
Exclusion criteria:
Additional criteria (data from another study): patients with chronic renal failure; patients on dialyse for more than 1 month; patients with liver insufficiency accompanied with ascites.</td><td></td><td>assessment (4 days)

Outcome 4:
Area under the ROC third assessment (6 days)

Outcome 5:
Sensitivity and specificity Waterlow scale cut-off 17 // 48h

Outcome 6:
Sensitivity and specificity Waterlow scale cut-off 20 // 4 days</td><td>Value: 0.54
95% CI: 0.35-0.74

Sensitivity: 71.4%
Specificity: 67.0%
Raw data<table><tr><td></td><td></td><td>Reference standard</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Index test</td><td>Yes</td><td>5</td><td>30</td><td>35</td></tr><tr><td>No</td><td>2</td><td>61</td><td>63</td></tr><tr><td></td><td>7</td><td>91</td><td>98</td></tr></table>Sensitivity: 85.7%
Specificity: 40.7%
Raw data<table><tr><td></td><td></td><td>Reference standard</td><td></td></tr></table></td><td>according to preventive measures.
Only patients at risk were included!

Additional outcomes: /

Notes: Braden scale scores were also collected, but no results of these scores were reported.</td></tr>
</table>

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Intervention
Comparison</th><th>Outcome measures</th><th>Results</th><th>Comments</th></tr>
<tr><td>Addressing missing data: not reported when patients dropped from the study
Statistical analysis: The predictive validity of the Waterlow Scale for the development
of PU in hospitalized patients was analyzed by using 2 methods: receiver operating characteristic (ROC)
curve and likelihood ratio (LR).
Setting: a medium-size general private hospital in the city of São Paulo, Brazil.
Blinding: not reported.</td><td></td><td></td><td>Outcome 7:
Sensitivity and specificity Waterlow scale cut-off 20 // 6 days</td><td>
<table>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>6</td><td>54</td><td>60</td></tr>
<tr><td>No</td><td>1</td><td>37</td><td>38</td></tr>
<tr><td></td><td>7</td><td>91</td><td>98</td></tr>
</table>
Sensitivity: 85.7%
Specificity: 33.0%
Raw data
<table>
<tr><td></td><td></td><td>Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>6</td><td>61</td><td>67</td></tr>
<tr><td>No</td><td>1</td><td>30</td><td>31</td></tr>
<tr><td></td><td>7</td><td>91</td><td>98</td></tr>
</table>
</td><td></td></tr>
</table>

Table 73 – Serpa 2011

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: **Serpa (2011)** Title: **Predictive validity of the Braden scale for pressure ulcer risk on critical care patients.** Journal: **Revista Latino-Americana de Enfermagem, 19(1); 50-57.** Study type: **prospective study (secondary analysis)** Selection patient: **Patients at risk for PU from an ICU.** **Recruitment strategy not reported.** Index test: **Portuguese Braden scale was used to assess PU risk at admission. The patient was assessed for the first time and then at 48-hours intervals as long as the patient remained**	**Patient group:** ICU patients older than 18 years. **All patients** **Included N:** 72 **Completed N:** 72 **Drop-outs:** 0 before three consecutive assessments **Age (mean years (SD);):** 60.9 (16.5) **Number of patients with a PU:** Stage I: 3 Stage II: 5 **Number of patients without a PU:** 64 **Inclusion criteria:** Admitted to one of the four ICUs; age equal to 18 years or older; absence of PU at first assessment; hospitalized for a minimum period of 24 hours and a maximum period of 48 hours at	**Index test 1:** the Portuguese Braden scale (Paranhos & Santos, 1999) **Reference standard:** development of pressure ulcer; not further specified. **Preventive methods:** Not reported	**Outcome 1:** Incidence of PU (< 1 week; 2 days) **Outcome 2:** Area under the ROC first assessment (48h) **Outcome 3:** Area under the ROC second assessment (4 days) **Outcome 4:** Area under the ROC third assessment (6 days) **Outcome 5:** Sensitivity and specificity Braden scale cut-off 12 // 48h	**Value:** 11.1% **Value:** 0.788 **95% CI:** 0.29-1.00 **Value:** 0.789 **95% CI:** 0.28-1.00 **Value:** 0.800 **95% CI:** 0.28-1.00 **Sensitivity:** 87.5% **Specificity**: 64.1% **Raw data** Reference	**Funding:** / **Limitations:** no imputation, no exclusion; low event rate; no report on blinding; no report on skin assessment and criteria of classification; no report on preventive measures; no sub-analyses according to preventive measures. Only patients at risk were included! **Additional outcomes:** / **Notes:** Braden scale scores were also

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
at risk or until PU development, discharge, transfer or death. Reference standard: **PU development; no further information.** Imputation: **no imputation, no exclusion** Number of events: **8 patients developed ulcers** Addressing missing data: **patient stayed for a minimum of 6 days.** Statistical analysis: **Sensitivity was defied as the proportion of individuals with a positive test who develop a disease, and specificity as the proportion of individuals with a negative test who do not develop a disease.** **The ROC curve is a graphic plot of true**	first assessment; a total Braden Scale score equal to 18 or less; informed consent. **Exclusion criteria:** Additional criteria (data from another study): patients with chronic renal failure; patients on dialyse for more than 1 month; patients with liver insufficiency accompanied with ascites.				collected, but no results of these scores were reported.

		Reference standard		
		Yes	No	
Index test	Yes	7	23	30
	No	1	41	42
		8	64	72

Outcome 6:
Sensitivity and specificity Braden scale cut-off 13 // 4 days

Sensitivity: 75.0%
Specificity: 81.3%
Raw data

		Reference standard		
		Yes	No	
Index test	Yes	6	12	18
	No	2	52	54
		8	64	72

Outcome 7:
Sensitivity and specificity Braden scale cut-off 13 // 6 days

Sensitivity: 75.0%
Specificity: 82.8%
Raw data

		Reference standard		
		Yes	No	
Index test	Yes	6	11	17
	No	2	53	55

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
positive values (sensitivity) on the ordinate and false positive values (1 – specificity) on the abscissa as a function of each cut-off point. There is an approximately linear quantitative-qualitative relationship between the area under the curve (AUC) and accuracy, which can be classified as follows: excellent (0.80-0.90), very good (0.70-0.79), good (0.60-0.69), and poor (0.50-0.59) Setting: **four ICUs of a large, non-profit charitable general hospital, Brazil.** Blinding: **not reported.**				<table><tr><td></td><td></td><td>8</td><td>64</td><td>72</td></tr></table>	

Table 74 – Suriadi 2006

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Intervention
Comparison</th><th>Outcome measures</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>Author and year: Suriadi (2006)
Title: A new instrument for predicting pressure ulcer risk in an intensive care unit.
Journal: Journal of Tissue Viability, 16(3); 21-26.
Study type: prospective cohort study
Selection patient:
Patients admitted to an ICU.
Recruitment strategy not reported.
Index test: The Braden scale was used to assess PU risk after 24 hours. This assessment was repeated three times a week (stay: 3-22 days). Patients were screened by a research assistant.
Reference standard: Skin condition was assessed daily (stay:</td>
<td>Patient group: ICU patients of all age.

All patients
Included N: 105
Completed N: 105
Drop-outs: 0

Group PU+
Age (mean years (SD); range): 50.9 (17.0); 17-77
Gender (m/f): 24/11
Number of patients with a PU:
Stage I: 21
Stage II: 14
PU location:
Sacrum: 28
Heel: 4
Trochanter: 1
Elbow: 2
Vertebrae: 1
Scapula: 1
More than one PU: 3

Group PU-</td>
<td>Index test 1: the Braden scale
Reference standard: development of pressure ulcer according to the criteria of the NPUAP classification (Burd et al., 1992).

Preventive methods:
Not reported</td>
<td>Outcome 1:
Incidence of PU
(> 1 week; 22 days)

Outcome 2:
Area under the ROC

Outcome 3:
Sensitivity and specificity Braden scale cut-off 14</td>
<td>Value: 33.3%

Value: 0.770
95% CI: 0.70-0.89

Sensitivity: 80.0%
Specificity: 54.3%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>28</td><td>32</td><td>60</td></tr>
<tr><td>No</td><td>7</td><td>38</td><td>45</td></tr>
<tr><td></td><td>35</td><td>70</td><td>105</td></tr>
</table>
</td>
<td>Funding: /

Limitations: no imputation, no exclusion; low event rate; not reported when patients dropped from the study; no report on preventive measures; no sub-analyses according to preventive measures.

Additional outcomes: /

Notes: /</td>
</tr>
</table>

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
3-22 days) by the primary researcher. Imputation: **no imputation, no exclusion** Number of events: **35 patients developed ulcers** Addressing missing data: **not reported when patients dropped from the study** Statistical analysis: **In the statistical methods, diagnostic probabilities (sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV)) were calculated.** **In this study we also evaluated the likelihood ratio (LR) for this tools.** **A receiver-operating characteristic (ROC) curve plot of the sensitivity versus 1-**	**Age PU- (mean years (SD); range):** 47.5 (17.6); 17-82 **Gender (m/f):** 48/22 **Number of patients without a PU:** 70 **Inclusion criteria:** Free of pressure ulcer; bedfast; could not walk. **Exclusion criteria:** Physically incapable of participating; refusal				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
specificity over the range of the Braden scale scores confirmed the cut-off value of the instrument Setting: **an intensive care unit within Pontianak Public Hospital, Sei Jawi in West Kalimantan, Indonesia** Blinding: **The Braden scale was used by a research assistant and the skin condition was assessed by the primary researcher.**					

Table 75 – Suriadi 2008

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments
Author and year: **Suriadi (2008)** Title: **Development of a new risk assessment scale for predicting pressure ulcers in an intensive care unit.**	**Patient group:** ICU patients older than 18 yrs. **All patients** **Included N:** 253 **Completed N:** 253	**Index test 1:** the Suriadi and Sanada scale **Reference standard:** development of pressure ulcer according to the criteria of the NPUAP classification (Ayello et al. 2003).	**Outcome 1:** Cumulative incidence of PU **Outcome 2:** Incidence density of PU	**Unit 1:** 27% **Unit 2:** 31.6% **Total:** 28.5% **Unit 1:** 0.060/100 person days **Unit 2:** 0.059/100 person days	**Funding:** / **Limitations:** only part index test repeated; end of observation PU development not

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Intervention
Comparison</th><th>Outcome measures</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>Journal: British Association of Critical Care Nurses, 13(1); 34-43.

Study type: prospective cohort study
Selection patient:
Patients admitted to an ICU.
Patients were selected by the researcher.
Index test: The SS (Suriadi and Sanada) scale was used to assess PU risk within 24 hours. Body temperature was repeated once a day. Patients were screened by a research assistant.
Reference standard: Skin condition was assessed daily by a researcher.
Imputation: no imputation, no exclusion</td>
<td>Drop-outs: 0

ICU 1
Included N: 174
Completed N: 174
Drop-outs: 0
Age (mean years (SD)): 55.2 (18.4)
Gender (m/f): 104/70
Number of patients with a PU:
Stage I: 20
Stage II: 22
Stage III: 5
Stage IV: 1
One patient had more than one PU
PU location:
Sacrum: 44
Heel: 2
Trochanter: 1
Malleolus: 1

ICU 2
Included N: 79
Completed N: 79
Drop-outs: 0</td>
<td>Preventive methods:
Not reported</td>
<td>Outcome 3:
Area under the ROC

Outcome 4:
Sensitivity and specificity SS scale cut-off 0

Outcome 5:
Sensitivity and specificity SS scale cut-off 2</td>
<td>Value: 0.888
95% CI: 0.84-0.93

Sensitivity: 100.0%
Specificity: 0.0%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>72</td><td>181</td><td>253</td></tr>
<tr><td>No</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td></td><td>72</td><td>181</td><td>253</td></tr>
</table>
Sensitivity: 97.2%
Specificity: 42.0%
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>70</td><td>105</td><td>175</td></tr>
<tr><td>No</td><td>2</td><td>76</td><td>78</td></tr>
<tr><td></td><td>72</td><td>181</td><td>253</td></tr>
</table>
</td>
<td>reported; no imputation, no exclusion; low event rate; not reported when patients dropped from the study; no report on preventive measures; no sub-analyses according to preventive measures; no report on withdrawal.

Additional outcomes: /

Notes: /</td>
</tr>
</table>

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Intervention
Comparison</th><th>Outcome measures</th><th>Results</th><th>Comments</th></tr>
<tr><td>Number of events: 72 patients developed ulcers
Addressing missing data: not reported when patients dropped from the study
Statistical analysis:
To evaluate the accuracy of the S.S. scale, diagnostic
probabilities [sensitivity, specificity, positive predictive
value (PPV), negative predictive value (NPV) and the likelihood ratio (LR)] were calculated for the range of the S.S. score. Area under the curve (AUC) of the ROC was calculated to assess the overall validity of the scale
Incidence density is computed as the number of persons developing new</td><td>Age (mean years (SD)): 42.6 (18.8)
Gender (m/f): 54/25
Number of patients with a PU:
Stage I: 12
Stage II: 13
PU location:
Sacrum: 25

Inclusion criteria:
Aged 18 yrs or more; admitted to the ICU at least 24h before enrolment; bedfast; no existing PU at time of enrolment; ability to give informed consent; Indonesian origin.
Exclusion criteria:
Active skin disease; previous enrolment in the study; physically incapable of participating; length of stay < 72 h after initial data collection.</td><td></td><td>Outcome 6:
Sensitivity and specificity SS scale cut-off 3

Outcome 7:
Sensitivity and specificity SS scale cut-off 4

Outcome 8:
Sensitivity and specificity SS scale cut-off 5</td><td>Sensitivity: 97.2%
Specificity: 53.0%
Raw data<table><tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Index test</td><td>Yes</td><td>70</td><td>85</td><td>155</td></tr><tr><td>No</td><td>2</td><td>96</td><td>98</td></tr><tr><td></td><td>72</td><td>181</td><td>253</td></tr></table>Sensitivity: 80.6%
Specificity: 82.9%
Raw data<table><tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Index test</td><td>Yes</td><td>58</td><td>31</td><td>89</td></tr><tr><td>No</td><td>14</td><td>150</td><td>164</td></tr><tr><td></td><td>72</td><td>181</td><td>253</td></tr></table>Sensitivity: 72.2%
Specificity: 86.7%
Raw data<table><tr><td></td><td></td><td>Reference</td><td></td></tr></table></td><td></td></tr>
</table>

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments

pressure ulcers (numerator) divided by the total person-days [sum of all the days over which each patient participated in the study (denominator)]

Setting: **two intensive care units of two hospitals in Pontianak, Indonesia**

Blinding: **two nurses being assessors used their assigned scale to independently assess the patients.**

		standard		
		Yes	No	
Index test	Yes	52	24	76
	No	20	157	177
		72	181	253

Outcome 9:

Sensitivity and specificity SS scale cut-off 6

Sensitivity: 61.1%

Specificity: 92.3%

Raw data

		Reference standard		
		Yes	No	
Index test	Yes	44	14	58
	No	28	167	195
		72	181	253

Outcome 10:

Sensitivity and specificity SS scale cut-off 7

Sensitivity: 58.3%

Specificity: 95.0%

Raw data

		Reference standard		
		Yes	No	
Index	Yes	42	9	51

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Results	Comments

test	No	30	172	202
		72	181	253

Outcome 11:

Sensitivity and specificity SS scale cut-off 9

Sensitivity: 6.9%

Specificity: 100.0%

Raw data

		Reference standard		
		Yes	No	
Index test	Yes	5	0	5
	No	67	181	248
		72	181	253

3. SKIN ASSESSMENT – CLINICAL EFFECTIVENESS

3.1. Review protocol

Table 1 – Protocol review question

Protocol	Skin assessment
Review question	What is the clinical effectiveness of skin assessment methods in the prevention of pressure ulcers?
Population	Individuals of all in all settings
Intervention	• Diascopy: finger method and transparent disk • Measuring of skin temperature
Comparison	• Each other • No skin assessment • Other
Outcomes	**Critical outcome for decision-making** • Proportion of participants developing new pressure ulcers (dichotomous outcome) (describe different categories of ulcer) **Important outcomes** • Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital (continuous data) • Patient acceptability • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised) o Short-form health survey (SF36) o Manchester Short Assessment of Quality of Life o EQ-5D o WHOQOL-BREF o Cardiff HRQoL tool o HUI o Pressure ulcer quality of life (Gorecki)
Study design	• High quality systematic reviews of RCTs or RCTs only

Protocol	Skin assessment
	• Cochrane reviews will be included if they match the inclusion criteria and have appropriate assumptions for missing data such as available case analysis or Intention to treat (with the appropriate assumptions). • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies with another population, intervention, comparison or outcome. • Non-English, non-French, non-Dutch language papers
Search strategy	**The electronic databases to be searched are:** • Medline (OVID interface), Cinahl (EBSCO-interface), Embase, Library of the Cochrane Collaboration (All years)
Review strategy	**How will individual PICO characteristics be combined across studies)** • Population: any population will be combined except those specified in the strata • Intervention – any intervention will be combined • Comparison – any comparison will be combined • Outcomes – same outcomes will be combined • Blinding – Blinded and not-blinded studies will be meta-analysed together • Minimum follow up = no minimum • Minimum total size = no minimum • Use available case analysis for dealing with missing data if there is a 10% differential or higher between the groups or if the missing data is higher than the event rate, if cannot work out the available case analysis will take the author's data.
Analysis	**Strata:** The following groups will be considered separately if data are present: • Children (neonates, infants and children) • ICU patients; • Patients with a spinal cord injury; • Palliative patients. **Subgroups:** The following groups will be considered separately as subgroups if data are present and there is inconsistency: • Different categories of pressure ulcer (from category 2 upwards where outcomes are reported separately • Different ulcer locations: sacral, heel and others

3.2. Search Strategy

3.2.1. Search filters

Table 2 – Search filters Medline (OVID)

Date	**30/08/2012**	
Database	Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present	
Search Strategy	1. Pressure ulcer.sh	9118
	2. decubit*.ti,ab.	3948
	3. (pressure adj (sore* or ulcer* or damage)).ti,ab.	6254
	4. (bedsore* or bed-sore*).ti,ab.	506
	5. ((moist* or friction or shear) adj2 (sore* or ulcer* or damage or wound* or injur* or lesion*)).ti,ab.	654
	6. OR/1 – 5	
	7. finger method.tw	13818
	8. transparent disk*.tw	13
	9. diascopy.tw	7
	10. ultrasonograph*.tw	29
	11. ultrasonography.sh	69872
	12. ultrasonics.sh	60511
	13. ultrasound.tw	19248
	14. durometer.tw	134401
	15. durometry.tw	95
	16. elastometer.tw	9
	17. haptic finger.tw	24
	18. digital imag*.tw	1
	19. digital colo?r imag*.tw	9221
	20. spectrometer.tw	47
	21. multispectral imag*.tw	18194
	22. multiwavelength imag*.tw	375
	23. clinical assessment.tw	8
	24. transcutaneous oximetry.tw	14292
	25. Blood Gas Monitoring, Transcutaneous.sh	137
	26. tympanic thermometer*.tw	2012
	27. Doppler blood flowmetry.tw	144
	28. laser Doppler imag*.tw	41
	29. Minimum Data Set.tw or MDS.tw or RAI.tw	484

Date	30/08/2012	
	30. skin assess*.tw	11620
	31. skin inspect*.tw	153
	32. skin exam*.tw	46
	33. skin eval*.tw	595
	34. skin observ*.tw	61
	35. skin risk assess*.tw	56
	36. skin status.tw	5
	37. skin condition.tw	68
	38. judgment.sh	1221
	39. clinical judgment.tw	11538
	40. skin temperature.tw	2889
	41. skin temperature.sh	5344
	42. OR/7 – 42	8195
	43. AND/6, 43	313866
	44. Limit language: ‘English, Dutch, Flemish, French’	665
		619

Table 3 – Search filters Embase

Date	**30/08/2012**	
Database	Embase	
Search Strategy (attention, for PubMed, check « Details »)	1. ‘decubitus’/exp	13355
	2. decubit*:ti,ab	5459
	3. (pressure NEAR/1 (sore* OR ulcer* OR damage)):ab,ti	7477
	4. (bed NEAR/2 sore*):ab,ti OR bedsore*:ti,ab	741
	5. ((moist* or friction or shear) near/2 (sore* or ulcer* or damage or wound* or injur* or lesion*)):ti,ab	812
	6. OR/1 – 5	
	7. ‘finger method’:ti,ab	18263
	8. ‘transparent disk’:ti,ab	20
	9. ‘diascopy’:ti,ab	6
	10. ultrasonograph*:ti,ab	40
	11. ‘echography’/exp	88906
	12. ‘Doppler echography’/exp	447225
	13. ‘color ultrasound flowmetry’/exp	26680
	14. ‘ultrasound’/exp	19948
	15. ‘ultrasound’:ti,ab	85221
	16. ‘durometer’:ti,ab	179253
	17. ‘durometry’:ti,ab	110
	18. ‘elastometer’:ti,ab	9
	19. ‘haptic finger’:ti,ab	32
	20. (digital NEXT/1 imag*):ti,ab	1
	21. (‘digital colo?r’ NEXT/1 imag*):ti,ab	10513
	22. ‘spectrometer’:ti,ab	14
	23. ‘mass spectrometer’/exp	19687
	24. (multispectral NEXT/1 imag*):ti,ab	3983
	25. (multiwavelength NEXT/1 imag*):ti,ab	379
	26. ‘clinical assessment’:ti,ab	7
	27. ‘clinical assessment’/exp	18659
	28. ‘transcutaneous oximetry’:ti,ab	49109
	29. ‘transcutaneous oxygen monitoring’/exp	164
	30. ‘thermographic scanner’:ti,ab	2268
	31. (tympanic NEXT/1 thermometer*):ti,ab	7
	32. ‘tympanic thermometer’/exp	168
	33. ‘Doppler blood flowmetry’:ti,ab	63

Date	30/08/2012	
	34. ‘Doppler flowmetry’/exp	61
	35. ‘blood flowmetry’/exp	23546
	36. (‘laser Doppler’ NEXT/1 imag*):ti,ab	2867
	37. ‘laser Doppler flowmetry’/exp	604
	38. ‘Minimum Data Set’:ti,ab or ‘MDS’:ti,ab or ‘RAI’:ti,ab	7831
	39. (skin NEXT/1 assess*):ti,ab	16943
	40. (skin NEXT/1 inspect*):ti,ab	213
	41. (skin NEXT/1 exam*):ti,ab	49
	42. (skin NEXT/1 eval*):ti,ab	875
	43. (skin NEXT/1 observ*):ti,ab	87
	44. (‘skin risk’ NEXT/1 assess*):ti,ab	85
	45. ‘skin status’:ti,ab	9
	46. ‘skin condition’:ti,ab	96
	47. ‘clinical judgment’:ti,ab	1768
	48. ‘clinical observation’/exp	3472
	49. ‘skin temperature’:ti,ab	16035
	50. ‘skin temperature’/exp	6524
	51. OR/7 – 50	9393
	52. AND/6, 51	743775
	53. Limit language: ’English, Dutch, French’ and limited to embase	1195
		794

Table 4 – Search filters Cochrane Library

Date	30/08/2012	
Database	The Library of the Cochrane Collaboration	
Search Strategy (attention, for PubMed, check « Details »):ti,ab,kw	1. MeSH descriptor “Pressure ulcer” explode all trees	490
	2. Decubit*:ti,ab,kw	349
	3. (pressure near/2 (sore* or ulcer* or damage)):ti,ab,kw	834
	4. (bedsore* or bed-sore*):ti,ab,kw	33
	5. ((moist* or friction or shear) near/2 (sore* or ulcer* or damage or wound* or injur*or lesion*)):ti,ab,kw	63
	6. OR/1 – 5	1168
	7. (finger method):ti,ab,kw	940
	8. (transparent disk*):ti,ab,kw	2
	9. (diascopy):ti,ab,kw	0
	10. (ultrasonograph*):ti,ab,kw	9365
	11. MeSH descriptor “ultrasonography” explode all trees	6678
	12. MeSH descriptor “ultrasonics” explode all trees	230
	13. (ultrasound):ti,ab,kw	6626
	14. (durometer) :ti,ab,kw	6
	15. (durometry) :ti,ab,kw	1
	16. (elastometer) :ti,ab,kw	0
	17. (haptic finger) :ti,ab,kw	9
	18. (digital imag*):ti,ab,kw	706
	19. (digital colo?r imag*):ti,ab,kw	24
	20. (spectrometer):ti,ab,kw	114
	21. (multispectral imag*):ti,ab,kw	4
	22. (multiwavelength imag*):ti,ab,kw	0
	23. (clinical assessment):ti,ab,kw	18722
	24. (transcutaneous oximetry):ti,ab,kw	49
	25. MeSH descriptor “Blood Gas Monitoring, Transcutaneous” explode all trees	173
	26. (thermographic scanner):ti,ab,kw	
	27. (tympanic thermometer*):ti,ab,kw	1
	28. (Doppler blood flowmetry):ti,ab,kw	36
	29. (laser Doppler imag*):ti,ab,kw	808
	30. (Minimum Data Set):ti,ab,kw or (MDS) :ti,ab,kw or (RAI):ti,ab,kw	150
	31. (skin assess*):ti,ab,kw	655
	32. (skin inspect*):ti,ab,kw	

Date	30/08/2012	
	33. (skin exam*):ti,ab,kw	4602
	34. (skin eval*):ti,ab,kw	57
	35. (skin observ*):ti,ab,kw	1886
	36. (skin risk assess*):ti,ab,kw	5109
	37. (skin status):ti,ab,kw	3358
	38. (skin condition*):ti,ab,kw	675
	39. Mesh descriptor “Judgment” explode all trees	637
	40. (clinical judgement):ti,ab,kw	1635
	41. (Skin temperature):ti,ab,kw	430
	42. Mesh descriptor “skin temperature” explode all trees	405
	43. OR/7 – 42	1837
	44. AND/6, 43	708
		46802
		203

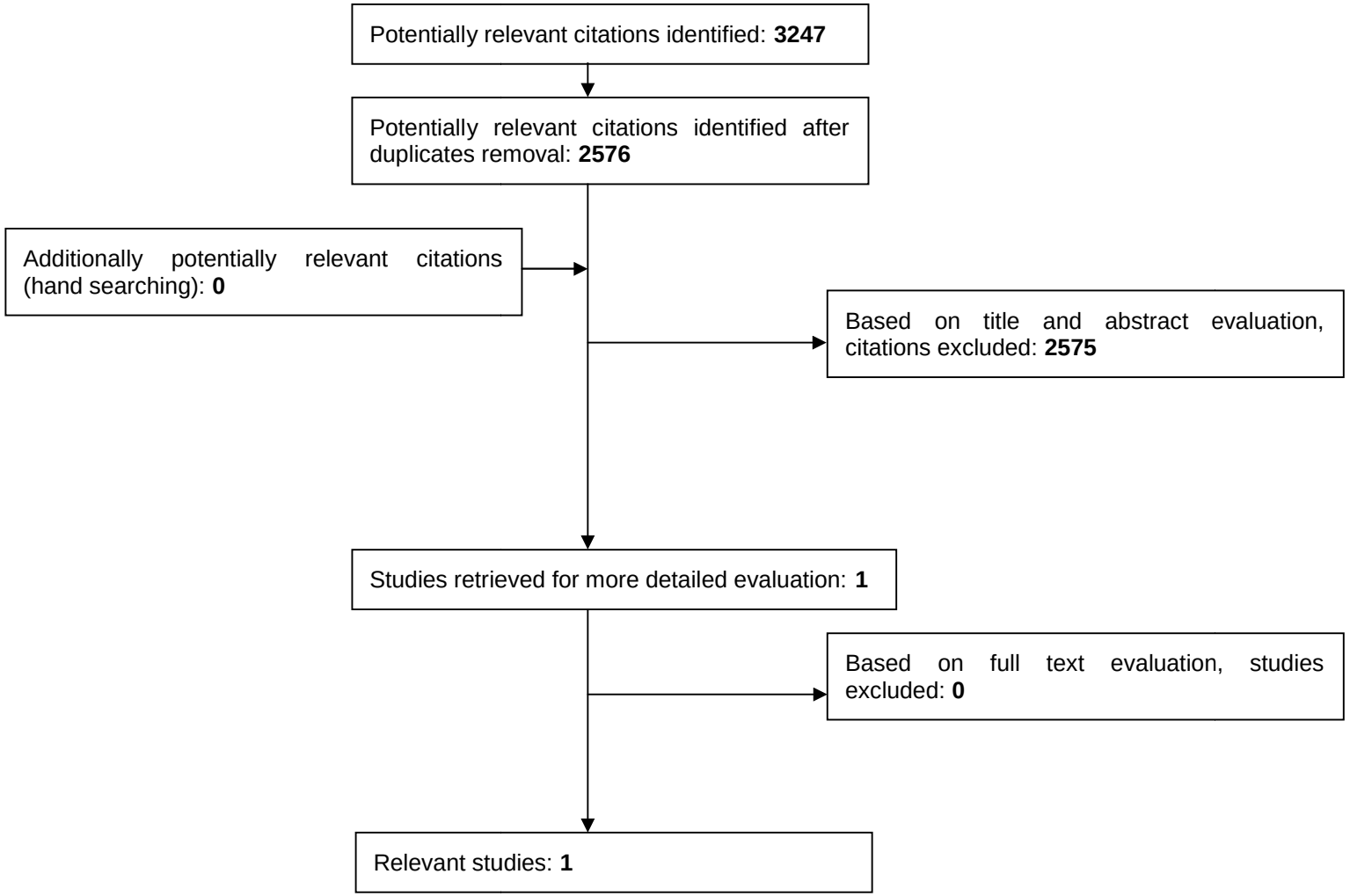
Table 5 – Search filters CINAHL

Date	30/08/2012	
Database	CINAHL	
Search Strategy (attention, for PubMed, check « Details »)	1. MH “Pressure Ulcer”	7748
	2. Decubit*	487
	3. Pressure n1 sore* OR pressure n1 ulcer* OR pressure n1 damage*	8540
	4. Bedsore* OR bed-sore*	157
	5. ((moist* or friction or shear) and (sore* or ulcer* or damage or wound* or injur* or lesion*))	1424
	6. OR/1 – 5	
	7. finger method	9876
	8. transparent disk*	30
	9. diascopy	4
	10. ultrasonograph*	2
	11. MH ultrasonography	27983
	12. MH ultrasonics	7546
	13. Ultrasound	669
	14. durometer	11286
	15. durometry	17
	16. elastometer	2

Date	30/08/2012	
	17. haptic finger	0
	18. digital imag*	1
	19. digital color imag* or digital colour imag*	2301
	20. spectrometer	26
	21. multispectral imag*	114
	22. multiwavelength imag*	9
	23. clinical assessment	0
	24. transcutaneous oximetry	59006
	25. MH Blood Gas Monitoring, Transcutaneous	43
	26. thermographic scanner	296
	27. tympanic thermometer*	3
	28. Doppler blood flowmetry	139
	29. laser Doppler imag*	62
	30. “Minimum Data Set” or MDS or RAI	97
	31. skin assess*	2908
	32. skin inspect*	770
	33. skin exam*	57
	34. skin eval*	510
	35. skin observ*	760
	36. skin risk assess*	286
	37. skin status	80
	38. skin condition	127
	39. MH judgment	350
	40. clinical judgment	1889
	41. skin temperature	875
	42. MH skin temperature	1041
	43. OR/7 – 42	703
	44. AND/6, 43	101023
	45. Limit language=’English, Dutch, French’	1778
		1631

3.2.2. Selection of articles

Figure 1 – Flow chart search strategy



3.3. Clinical evidence

3.3.1. Search strategy

The systematic search through multiple electronic databases resulted in 3 247 records: 619 in Medline (Ovid), 1 631 in Cinahl (EBSCO interface), 794 in Embase, and 203 in the Library of the Cochrane Collaboration. Duplicate records were excluded, which resulted in 2 576 records. Based on the screening of title and abstract 2 575 records were excluded. Reasons for exclusion were listed. The full text of the remaining record was reviewed in detail and included in this review.

3.3.2. Clinical evidence

One randomized controlled trial of Vanderwee (2007) was included in this review[59] Evidence from this study is summarised in the clinical GRADE evidence profiles. The forest plot and the study evidence table are presented in respectively Appendix 3.3.5. and Appendix 3.3.6. In case that data were reported as medians and interquartile ranges, medians were used as a surrogate for means and standard deviations were estimated as 80% of the interquartile range.

3.3.3. Summary table

Table 6 – Summary of included studies

Study	Intervention/comparator	Population	Outcome	Study length
Vanderwee 2007[59]	(1) Daily skin assessment with transparent disk. Preventive measures were started when non-blanchable erythema (NBE) appeared. (2) Braden score and daily skin assessment with transparent disk. Preventive measures were started if the Braden score was <17 or NBE appeared. Patients received preventive measures according to the same pressure redistribution protocol. The patients were randomized to either the Polyéthylène-uréthane mattress (Tempur-World Inc, Lexington, Kentucky USA), or to the Alternating pressure air mattress (Alpha-XCell, Huntleigh	Patients with an expected hospitalization of at least three days admitted between May 2000 and March 2002 in 14 surgery, internal medicine and geriatric wards of six Belgian hospitals	Incidence of PU (grades 2-4) per 1 000 days (95% CI) Time (days) to development of PU (grades 2-4)	The study was carried out between May 2000 and March 2002. Each nursing unit took part in the study for the duration of five months.

Study	Intervention/comparator	Population	Outcome	Study length
	Healthcare, UK). On the Polyéthylène-uréthane mattress, patients were turned every four hours, as proved to be indicated in an earlier study (Defloor et al. 2005). On the Alternating pressure air mattress, no standardized position changes were carried out.			

3.3.4. Clinical evidence GRADE tables

Table 7 – Skin assessment with transparent disk versus skin assessment with transparent disk and Braden scale for the prevention of pressure ulcers development

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	**Skin assessment with transparent disk for non-blanchable erythema (NBE)**	**skin assessment with transparent disk combined with the Braden scale**	**Relative (95% CI)**	**Absolute**		
Incidence of pressure ulcers (grades 2-4) per 1000 days												
1 (Vanderwee 2007)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	56/826 (6.8%)	53/791 (6.7%)	RR 1.01 (0.7 to 1.45)	1 more per 1000 (from 20 fewer to 30 more)	⊕⊕OO MODERATE	CRITICAL

									6.7%	1 more per 1000 (from 20 fewer to 30 more)		

[1] *No blinding, randomisation tables used, concealment of allocation sequence, no drop-outs*

Table 8 – Time to development of pressure ulcers (grade 2-4) for skin assessment with transparent disk versus skin assessment with transparent disk and Braden scale

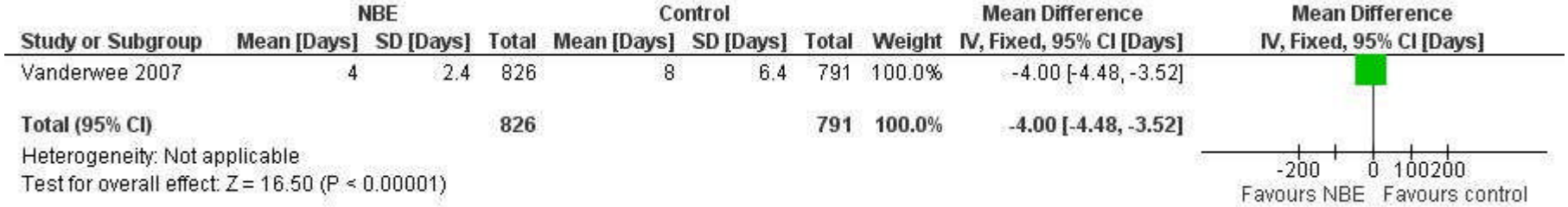
Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Skin assessment with transparent disk for non-blanchable erythema (NBE)**	**skin assessment with transparent disk combined with the Braden scale**	**Relative (95% CI)**	**Absolute**		
Time (days) to develop pressure ulcers (grade 2-4) (Better indicated by higher values)												
1 (Vanderwee 2007)	randomised trials	Serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	4 (SD 2.4)	8 (SD 6.4)	-	MD 4 lower (4.48 to 3.52 lower)	⊕⊕⊕O MODERATE	IMPORTANT

[1] *No blinding, randomisation tables used, concealment of allocation sequence, no drop-outs*

3.3.5. Forest plots

Figure 2 – Skin assessment with transparent disk (NBE) versus skin assessment with transparent disk and Braden scale (control) – for pressure ulcer (grades 2-4) development

Figure 3 – Skin assessment with transparent disk (NBE) versus skin assessment with transparent disk and Braden scale (control) – time to develop PU (grades 2-4)



3.3.6. Evidence tables

Table 9 – Vanderwee 2007

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Vanderwee, 2007 **Title:** Non-blanchable erythema as an indicator for the need for PU prevention: a randomized-controlled trial **Journal:** Journal of Clinical Nursing, 2007;16: 325–335 **Study type:** RCT **Sequence generation:** based on randomization tables generated with the software package SPSS 10 **Allocation:** Serially numbered, closed envelopes were made available for each participating nursing unit. Each time a patient was admitted the envelope with the	**Patient group:** Patients with an expected hospitalization of at least three days admitted between May 2000 and March 2002 in 14 surgery, internal medicine and geriatric wards of six Belgian hospitals **All patients** **Randomized N:** 1 617 **Completed N:** 1 617 **Drop-outs:** 0 **Group 1** **Randomized N:** 826 **Completed N:** 826 **Dropouts:** 0 **Age:** (median and interquartile range) 78 (70-86) **Gender (m/f):** 332/494 **Other relevant patient characteristics:** Braden score on admission (median and interquartile range): 19 (16-21)	**Group 1 (NBE):** Daily skin assessment with transparent disk. Preventive measures were started when NBE appeared. The patient continued to be observed daily. When the NBE disappeared, the measures were discontinued and restarted only if the NBE reappeared. **Group 2 (Control):** Braden score and daily skin assessment with transparent disk. Preventive measures were started if the Braden score was <17 or NBE appeared. If the Braden score was 17 or higher, the patient was scored again on the Braden scale three days later.	**Outcome 1:** Incidence of PU (grades 2-4) per 1 000 days (95% CI) **Outcome 2:** Time (days) to develop PU (grades 2-4) Mean (IQR)	**Group 1:** 4.5 (3.3-5.7%) **Group 2:** 4.2 (3.0-5.3%) **Risk Ratio:** 1.01 **95% CI:** 0.7-1.45 **P value:** Fisher exact test, p>0.99 **Group 1:** 4 (2-5) **Group 2:** 8 (4-16) **Mean difference (95% CI):** - 4 (- 4.48;- 3.52) **P value:** Mann-Whitney U test, p=0.001	**Funding:** This study was supported by a grant from the Ghent University and from Huntleigh Healthcare **Limitations:** No blinding **Additional outcomes:** In the group using Alternating pressure air mattress, the incidence of pressure ulcers (grades 2–4) was lower, but not significantly different in the NBE group (14.5%) compared with the control group (20.5%) (Fisher's exact test, P=0.42). In the group using Polyéthylène-uréthane mattress, the difference in the incidence of pressure

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
lowest number was opened. The envelope contained the patient's admission form on which the assignment of the patient was indicated, by means of a flow chart. The flow chart indicated whether the patient belonged to the control group or the NBE group, and whether to use a Polyéthylène-uréthane mattress or an Alternating pressure air mattress if pressure redistribution was needed. **Blinding:** No blinding (for practical and ethical reasons) **Addressing incomplete outcome data:** No incomplete outcome data **Statistical analysis:** The Mann–Whitney U-test was used for continuous variables that were not distributed normally. The Fisher's	**Group 2** **Randomized N:** 791 **Completed N:** 791 **Dropouts:** 0 **Age:** (median and interquartile range) 79 (71-85) **Gender (m/f):** 289/502 Braden score on admission (median and interquartile range): 19 (17-21) **Inclusion criteria:** Hospitalization of at least 3 days **Exclusion criteria:** -grade 2 pressure ulcer (abrasion or blister), grades 3 (superficial ulcer) and 4 (deep ulcer) on admission -age younger than 18 -bodyweight of over 140 kg -contra-indication for turning because of medical reasons	Pressure points were observed daily **Both groups:** Patients received preventive measures according to the same pressure redistribution protocol. It consisted of pressure redistribution while sitting up and while in bed. During sitting in an (arm)chair, an air cushion (Airtech_, Huntleigh Healthcare, UK) was used for all patients and they had to stand up every two hours, alone or with some help. If the back of the armchair could be tilted backwards, the patient's legs were put on a footrest. If the back of the armchair could not be tilted backwards, the patient's feet were placed on the floor. The patients were			ulcers (grades 2–4) approached significance (Fisher's exact test, P =0.052), the incidence being lower in the control group (14.2%) than in the NBE group (25.8%). In the intervention group, 16% of patients received preventive measures, in the control group 32% (Fisher's exact test, P < 0.001). The sensitivity of the risk assessment method used in the control group was 81.1% and the specificity 71.8%. The sensitivity of NBE as a method for assigning preventive measures was 46.6% and the specificity 86.8%. The time when prevention started was not significantly different in the two groups (Mann–Whitney U = 479, P =

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
exact test was used for categorical variables. A Kaplan–Meier survival analysis was performed to evaluate the effect of the risk assessment method on the incidence of PU (grade 2 or higher). All analyses were carried out with the software package SPSS 10. A value of P < 0.05 was considered statistically significant. **Baseline differences:** The random assignment produced comparable intervention and control groups with regard to age, gender, Braden score on admission, medical specialty and primary diagnosis. **Study power/sample size:** Based on a PU (grade 2 or higher) incidence of 6%, a sample size was calculated of 1 624 patients (812 in each group) to detect a difference of 3% in the		randomized to either the Polyéthylène-uréthane mattress (Tempur_-World Inc, Lexington, Kentucky USA), or to the Alternating pressure air mattress (Alpha-XCell, Huntleigh Healthcare, UK). On the Polyéthylène-uréthane mattress, patients were turned every four hours, as proved to be indicated in an earlier study (Defloor et al. 2005). On the Alternating pressure air mattress, no standardized position changes were carried out. In the intervention group 66 patients received pressure redistribution by Polyéthylène-uréthane mattress and 62 by Alternating pressure air mattress.			0.28). The separate analyses for the Polyéthylène-uréthane mattress group and the Alternating pressure air mattress group did not reveal a significant difference either. Adjusted for the prevention protocols, the Kaplan–Meier survival analysis revealed a significant difference between control and NBE groups (Log-rank test=7.18, d.f.=1, p=0.007). **Notes:** any note the reviewer thinks may be important

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
incidence of PU between the NBE and control group (α= 0.05; power = 80%). **Setting:** 14 surgery, internal medicine and geriatric wards of six Belgian hospitals **Length of study:** The study was carried out between May 2000 and March 2002. Each nursing unit took part in the study for the duration of five months. **Assessment of PUs:** In the NBE group and in the control group, the skin was examined at all pressure points, by nursing staff on admission and then daily during the morning shift. The observed pressure points were the sacrum, heels, hips, ankles, shoulder, elbows, ears and knees. PU were classified according to the four grades of the European Pressure Ulcer Advisory		In the control group 134 patients received pressure redistribution by Polyéthylène-uréthane mattress and 117 by Alternating pressure air mattress.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Panel. A patient was considered to have a pressure ulcer when a pressure ulcer grades 2–4 were observed. A transparent pressure disk with a size of 5 cm by 5 cm, was used to distinguish between blanchable (BE) and nonblanchable erythema (NBE). The nurse pressed the transparent disk on the erythema. If the erythema blanched, it was defined as BE. If the erythema remained while pressing, it was defined as NBE **Multiple ulcers:** Unit of analysis was number of patients developing PU					

4. SKIN ASSESSMENT – PROGNOSTIC

4.1. Review protocol

Table 1 – Protocol review question

Protocol	Skin assessment
Review question	What is the predictive ability of skin assessment methods for pressure ulcer risk?
Population	Individuals of all ages in all settings
Skin assessment method	Structured, systematic skin assessment methods/tools: • Ultrasonography • Ultrasound • Durometer/durometry • Diascopy: finger method and transparent disk • Elastometer • Haptic finger • Multispectral imaging device • Multiwavelength imaging • Multispectral images • Digital color images • Clinical assessment • Transcutaneous oximetry • Termographic scanner • Tympanic thermometers (to measure skin temperature) • Doppler blood flowmetry • Laser • Doppler imaging
Outcomes	**Patient outcomes**

Protocol	Skin assessment
Statistical measures	• Incidence of pressure ulcers (all grades and grades 2-4) – up to one week • Incidence of pressure ulcers (all grades and grades 2-4) – up to three months **Statistical measures** • Sensitivity • Specificity • Area under the ROC (AUC) (for skin temperature) • Diagnostic Odds Ratio
Study design	• High quality systematic reviews of prospective cohort studies. • Prospective cohort studies in which the patients considered had not developed pressure ulcers at the beginning of the study and with a follow-up in a systematic way during an established period
Exclusion	• Non-English, non-French, non-Dutch language papers
Search strategy	**The electronic databases to be searched are:** • Medline (OVID interface), Cinahl (EBSCO-interface), Embase, Library of the Cochrane Collaboration • All years
Review strategy	**How will individual PICO characteristics be combined across studies)** • Population – any population will be combined except those specified in the strata • Skin assessment method – only same methods will be combined • Outcomes – same outcomes will be combined • Minimum follow up = no minimum. • Minimum total size = no minimum
Analysis	**The following groups will be considered separately if data are present:** • ICU patients • Spinal cord injury patients • Palliative care patients • Paediatric patients • Adults (if not in other previous subgroup) **Following analyses will be performed** • Sensitivity and specificity analyses • Diagnostic odds ratios will be meta-analysed

4.2. Search strategy

4.2.1. Search filters

Table 2 – Search filters Medline (OVID)

Date	30/08/2012	
Database	**Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present**	
Search Strategy	1. Pressure ulcer.sh	9118
	2. decubit*.ti,ab.	3948
	3. (pressure adj (sore* or ulcer* or damage)).ti,ab.	6254
	4. (bedsore* or bed-sore*).ti,ab.	506
	5. ((moist* or friction or shear) adj2 (sore* or ulcer* or damage or wound* or injur* or lesion*)).ti,ab.	654
	6. OR/1 – 5	
	7. finger method.tw	13818
	8. transparent disk*.tw	13
	9. diascopy.tw	7
	10. ultrasonograph*.tw	29
	11. ultrasonography.sh	69872
	12. ultrasonics.sh	60511
	13. ultrasound.tw	19248
	14. durometer.tw	134401
	15. durometry.tw	95
	16. elastometer.tw	9
	17. haptic finger.tw	24
	18. digital imag*.tw	1
	19. digital colo?r imag*.tw	9221
	20. spectrometer.tw	47
	21. multispectral imag*.tw	18194
	22. multiwavelength imag*.tw	375
	23. clinical assessment.tw	8
	24. transcutaneous oximetry.tw	14292
	25. Blood Gas Monitoring, Transcutaneous.sh	137
	26. tympanic thermometer*.tw	2012
	27. Doppler blood flowmetry.tw	144
	28. laser Doppler imag*.tw	41

Date	30/08/2012	
	29. Minimum Data Set.tw or MDS.tw or RAI.tw	484
	30. skin assess*.tw	11620
	31. skin inspect*.tw	153
	32. skin exam*.tw	46
	33. skin eval*.tw	595
	34. skin observ*.tw	61
	35. skin risk assess*.tw	56
	36. skin status.tw	5
	37. skin condition.tw	68
	38. judgment.sh	1221
	39. clinical judgment.tw	11538
	40. skin temperature.tw	2889
	41. skin temperature.sh	5344
	42. OR/7 – 41	8195
	43. AND/6, 42	313866
	44. Limit language: 'English, Dutch, Flemish, French'	665
		619

Table 3 – Search filters Embase

Date	30/08/2012	
Database	Embase	
Search Strategy (attention, for PubMed, check « Details »)	1. 'decubitus'/exp	13355
	2. decubit*:ti,ab	5459
	3. (pressure NEAR/1 (sore* OR ulcer* OR damage)):ab,ti	7477
	4. (bed NEAR/2 sore*):ab,ti OR bedsore*:ti,ab	741
	5. ((moist* or friction or shear) near/2 (sore* or ulcer* or damage or wound* or injur* or lesion*)):ti,ab	812
	6. OR/1 – 5	
	7. 'finger method':ti,ab	18263
	8. 'transparent disk':ti,ab	20
	9. 'diascopy':ti,ab	6
	10. ultrasonograph*:ti,ab	40
	11. 'echography'/exp	88906
	12. 'Doppler echography'/exp	447225

Date	30/08/2012	
	13. ‘color ultrasound flowmetry’/exp	26680
	14. ‘ultrasound’/exp	19948
	15. ‘ultrasound’:ti,ab	85221
	16. ‘durometer’:ti,ab	179253
	17. ‘durometry’:ti,ab	110
	18. ‘elastometer’:ti,ab	9
	19. ‘haptic finger’:ti,ab	32
	20. (digital NEXT/1 imag*):ti,ab	1
	21. (‘digital colo?r’ NEXT/1 imag*):ti,ab	10513
	22. ‘spectrometer’:ti,ab	14
	23. ‘mass spectrometer’/exp	19687
	24. (multispectral NEXT/1 imag*):ti,ab	3983
	25. (multiwavelength NEXT/1 imag*):ti,ab	379
	26. ‘clinical assessment’:ti,ab	7
	27. ‘clinical assessment’/exp	18659
	28. ‘transcutaneous oximetry’:ti,ab	49109
	29. ‘transcutaneous oxygen monitoring’/exp	164
	30. ‘thermographic scanner’:ti,ab	2268
	31. (tympanic NEXT/1 thermometer*):ti,ab	7
	32. ‘tympanic thermometer’/exp	168
	33. ‘Doppler blood flowmetry’:ti,ab	63
	34. ‘Doppler flowmetry’/exp	61
	35. ‘blood flowmetry’/exp	23546
	36. (‘laser Doppler’ NEXT/1 imag*):ti,ab	2867
	37. ‘laser Doppler flowmetry’/exp	604
	38. ‘Minimum Data Set’:ti,ab or ‘MDS’:ti,ab or ‘RAI’:ti,ab	7831
	39. (skin NEXT/1 assess*):ti,ab	16943
	40. (skin NEXT/1 inspect*):ti,ab	213
	41. (skin NEXT/1 exam*):ti,ab	49
	42. (skin NEXT/1 eval*):ti,ab	875
	43. (skin NEXT/1 observ*):ti,ab	87
	44. (‘skin risk’ NEXT/1 assess*):ti,ab	85
	45. ‘skin status’:ti,ab	9
	46. ‘skin condition’:ti,ab	96
	47. ‘clinical judgment’:ti,ab	1768
	48. ‘clinical observation’/exp	3472

Date	30/08/2012	
	49. 'skin temperature':ti,ab	16035
	50. 'skin temperature'/exp	6524
	51. OR/7 – 50	9393
	52. AND/6, 51	743775
	53. Limit language: 'English, Dutch, French' and limited to embase	1195
		794

Table 4 – Search filters Cochrane Library

Date	30/08/2012	
Database	The Library of the Cochrane Collaboration	
Search Strategy (attention, for PubMed, check « Details »):ti,ab,kw	1. MeSH descriptor "Pressure ulcer" explode all trees	490
	2. Decubit*:ti,ab,kw	349
	3. (pressure near/2 (sore* or ulcer* or damage)):ti,ab,kw	834
	4. (bedsore* or bed-sore*):ti,ab,kw	33
	5. ((moist* or friction or shear) near/2 (sore* or ulcer* or damage or wound* or injur*or lesion*)):ti,ab,kw	63
	6. OR/1 – 5	1168
	7. (finger method):ti,ab,kw	940
	8. (transparent disk*):ti,ab,kw	2
	9. (diascopy):ti,ab,kw	0
	10. (ultrasonograph*):ti,ab,kw	9365
	11. MeSH descriptor "ultrasonography" explode all trees	6678
	12. MeSH descriptor "ultrasonics" explode all trees	230
	13. (ultrasound):ti,ab,kw	6626
	14. (durometer) :ti,ab,kw	6
	15. (durometry) :ti,ab,kw	1
	16. (elastometer) :ti,ab,kw	0
	17. (haptic finger) :ti,ab,kw	9
	18. (digital imag*):ti,ab,kw	706
	19. (digital colo?r imag*):ti,ab,kw	24
	20. (spectrometer):ti,ab,kw	114
	21. (multispectral imag*):ti,ab,kw	4
	22. (multiwavelength imag*):ti,ab,kw	0

Date	30/08/2012	
	23. (clinical assessment):ti,ab,kw	18722
	24. (transcutaneous oximetry):ti,ab,kw	49
	25. MeSH descriptor “Blood Gas Monitoring, Transcutaneous” explode all trees	173
	26. (thermographic scanner):ti,ab,kw	
	27. (tympanic thermometer*):ti,ab,kw	1
	28. (Doppler blood flowmetry):ti,ab,kw	36
	29. (laser Doppler imag*):ti,ab,kw	808
	30. (Minimum Data Set):ti,ab,kw or (MDS) :ti,ab,kw or (RAI):ti,ab,kw	150
	31. (skin assess*):ti,ab,kw	655
	32. (skin inspect*):ti,ab,kw	
	33. (skin exam*):ti,ab,kw	4602
	34. (skin eval*):ti,ab,kw	57
	35. (skin observ*):ti,ab,kw	1886
	36. (skin risk assess*):ti,ab,kw	5109
	37. (skin status):ti,ab,kw	3358
	38. (skin condition*):ti,ab,kw	675
	39. Mesh descriptor “Judgment” explode all trees	637
	40. (clinical judgement):ti,ab,kw	1635
	41. (Skin temperature):ti,ab,kw	430
	42. Mesh descriptor “skin temperature” explode all trees	405
	43. OR/7 – 42	1837
	44. AND/6, 43	708
		46802
		203

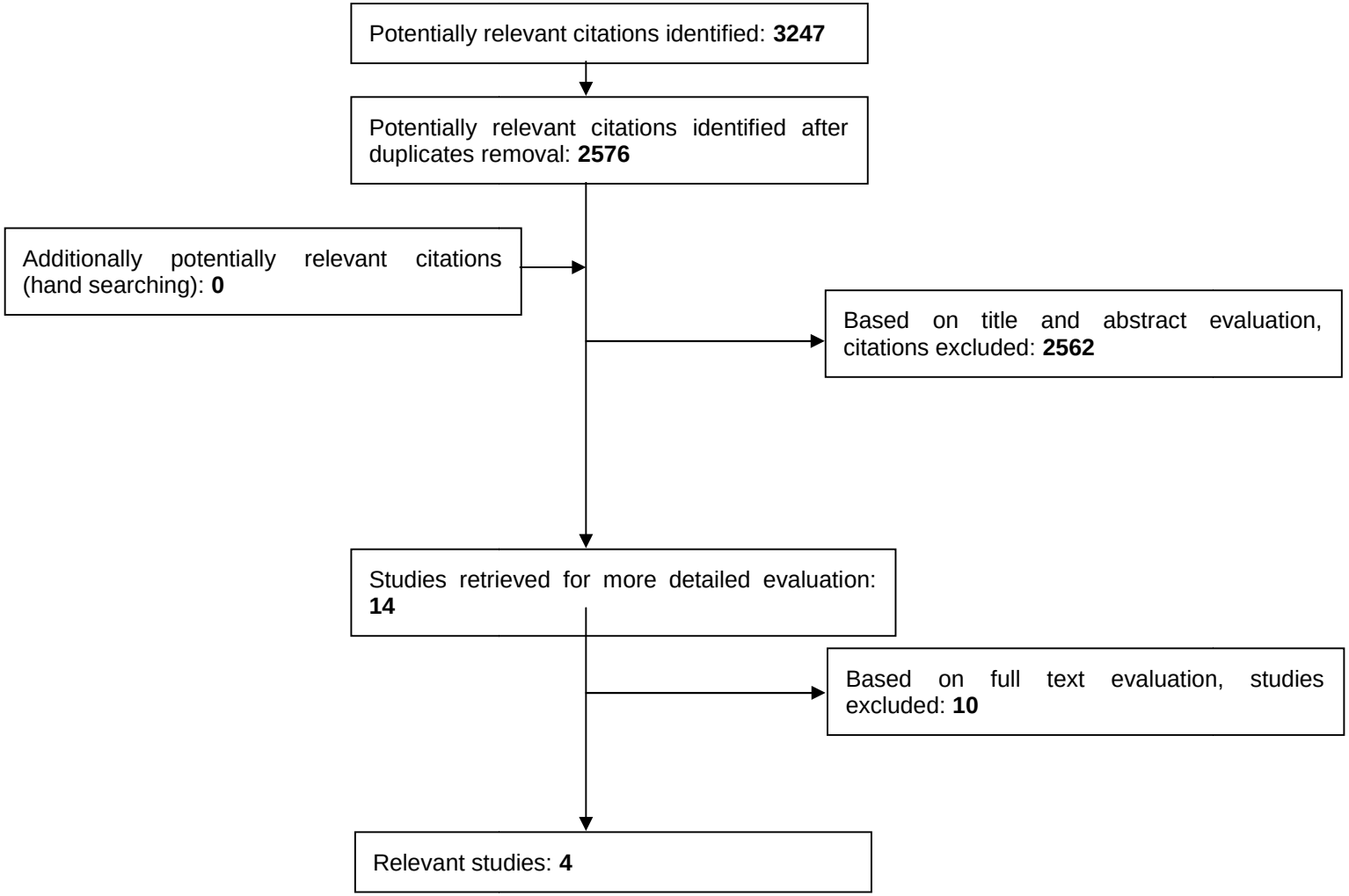
Table 5 – Search filters CINAHL

Date	30/08/2012	
Database	CINAHL	
Search Strategy (attention, for PubMed, check « Details »)	1. MH “Pressure Ulcer”	7748
	2. Decubit*	487
	3. Pressure n1 sore* OR pressure n1 ulcer* OR pressure n1 damage*	8540
	4. Bedsore* OR bed-sore*	157
	5. ((moist* or friction or shear) and (sore* or ulcer* or damage or wound* or injur* or lesion*))	1424
	6. OR/1 – 5	
	7. finger method	9876
	8. transparent disk*	30
	9. diascopy	4
	10. ultrasonograph*	2
	11. MH ultrasonography	27983
	12. MH ultrasonics	7546
	13. Ultrasound	669
	14. durometer	11286
	15. durometry	17
	16. elastometer	2
	17. haptic finger	0
	18. digital imag*	1
	19. digital color imag* or digital colour imag*	2301
	20. spectrometer	26
	21. multispectral imag*	114
	22. multiwavelength imag*	9
	23. clinical assessment	0
	24. transcutaneous oximetry	59006
	25. MH Blood Gas Monitoring, Transcutaneous	43
	26. thermographic scanner	296
	27. tympanic thermometer*	3
	28. Doppler blood flowmetry	139
	29. laser Doppler imag*	62
	30. “Minimum Data Set” or MDS or RAI	97
	31. skin assess*	2908
	32. skin inspect*	770
	33. skin exam*	57

Date	30/08/2012	
	34. skin eval*	510
	35. skin observ*	760
	36. skin risk assess*	286
	37. skin status	80
	38. skin condition	127
	39. MH judgment	350
	40. clinical judgment	1889
	41. skin temperature	875
	42. MH skin temperature	1041
	43. OR/7 – 42	703
	44. AND/6, 43	101023
	45. Limit language='English, Dutch, French'	1778
		1631

4.2.2. Selection of articles

Figure 1 – Flow chart search strategy



4.2.3. List of excluded studies

Reference	Reason of exclusion
Bates-jensen 2007	Outcome: no sensitivity and specificity reported and impossible to calculate from the available data
Bates-jensen 2009	Outcome: no sensitivity and specificity reported and impossible to calculate from the available data
Bates-jensen 2010	Design: Abstract describing study protocol
Judy 2011	Outcome: no sensitivity and specificity reported and impossible to calculate from the available data
Guihan 2012	Population – all had pressure ulcers and were hospitalized for care of the PUs
Rapp 2006	Dissertation: same data as in article “Rapp, M. P., Bergstrom, N., & Padhye, N. S. (2009). Contribution of skin temperature regularity to the risk of developing pressure ulcers in nursing facility residents. 22, 506-513.”
Rapp 2009	Outcome; no sensitivity and specificity reported and impossible to calculate from the available data
Stordeur 1998	Intervention: risk assessment scales
Vanderwee 2006	Intervention: assessment of interrater reliability
Vanderwee 2007	Included in the clinical effectiveness review

4.3. Clinical evidence

4.3.1. Search strategy

The systematic search through multiple electronic databases resulted in 3 247 records: 619 in Medline (Ovid), 1 631 in Cinahl (EBSCO interface), 794 in Embase, and 203 in the Library of the Cochrane Collaboration. Duplicate records were excluded, which resulted in 2 576 records. Based on the screening of title and abstract 2 562 records were excluded. Reasons for exclusion were listed. The full text of the remaining 14 studies was reviewed in detail. Based on this review, 10 studies were excluded. Four studies were included in this review.

4.3.2. Clinical evidence

Four studies[24, 60, 61, 62] were included in this review. Sensitivity and specificity were re-calculated by using the raw data as presented in the individual studies.

4.3.3. Summary table

Table 6 – Summary of included studies

Study	Skin assessment test Outcome	Population	Length of follow-up
Compton 2008[24]	Subjective nursing skin assessment on admission Occurrence of PU development (grades 2-4) according to the European Pressure Ulcer Advisory Panel classification system in the course of ICU treatment	ICU patients	Not reported
Konishi 2008[60]	Presence of blanchable erythema assessed by finger test Occurrence of PU development according to the National Pressure Ulcer Advisory Panel classification	Hospitalized patients	Not reported
Newman 1981[61]	Thermography: presence of thermal anomaly (an area of the skin at least 1°C warmer than the surrounding	Hospitalized patients	Not reported

Study	Skin assessment test Outcome	Population	Length of follow-up
	skin). Development of skin breakdown in the buttock region within 10 days of admission was reported by the nursing staff and photographed. Redness alone, however marked or persistent, was not categorized as a pressure sore.		
Nixon 2007[62]	Skin assessment according to the classification scale adapted from international classification scales (AHCPR (Agency for Health Care Policy and Research) 1992; EPUAP, 1999) Occurrence PU development (grades 2-4) according the classification scale adapted from international classification scales (AHCPR (Agency for Health Care Policy and Research) 1992; EPUAP, 1999)	Surgical in-patients	Not reported

4.3.4. Predictive ability

Table 7 – Subjective nursing assessment of moist skin as a predictor for the development of pressure ulcers (grades 2-4) development according to the European Pressure Ulcer Advisory Panel classification system

Study	Incidence	Sensitivity	Specificity	DOR	PPV	NPV
1 (Compton 2008)	/	76% (67-83%)	65% (61-69%)	5.9 (3.84-9.03)	31%	93%

Table 8 – Subjective nursing assessment of oedematous skin as a predictor for the development of pressure ulcers (grades 2-4) development according to the European Pressure Ulcer Advisory Panel classification system

Study	Incidence	Sensitivity	Specificity	DOR	PPV	NPV
1 (Compton 2008)	/	64% (54-72%)	77% (73-80%)	5.7 (4.05-8.11)	36%	91%

Table 9 – Subjective nursing assessment of mottled skin as a predictor for the development of pressure ulcers (grades 2-4) development according to the European Pressure Ulcer Advisory Panel classification system

Study	Incidence	Sensitivity	Specificity	DOR	PPV	NPV
1 (Compton 2008)	/	33% (25-42%)	92% (89-94%)	5.4 (4.21-7.03)	45%	87%

Table 10 – Subjective nursing assessment of livid skin as a predictor for the development of pressure ulcers (grades 2-4) development according to the European Pressure Ulcer Advisory Panel classification system

Study	Incidence	Sensitivity	Specificity	DOR	PPV	NPV
1 (Compton 2008)	/	31% (23-40%)	92% (89-94%)	5.0 (3.92-6.5)	44%	86%

Table 11 – Subjective nursing assessment of centralised circulation as a predictor for the development of pressure ulcers (grades 2-4) development according to the European Pressure Ulcer Advisory Panel classification system

Study	Incidence	Sensitivity	Specificity	DOR	PPV	NPV
1 (Compton 2008)	/	71% (62-79%)	70% (66-74%)	5.8 (3.95-8.61)	33%	92%

Table 12 – Subjective nursing assessment of cyanosis as a predictor for the development of pressure ulcers (grades 2-4) development according to the European Pressure Ulcer Advisory Panel classification system

Study	Incidence	Sensitivity	Specificity	DOR	PPV	NPV
1 (Compton 2008)	/	45% (36-55%)	81% (77-84%)	3.5 (2.63-4.64)	33%	88%

Table 13 – Subjective nursing assessment of reddened skin as a predictor for the development of pressure ulcers (grades 2-4) development according to the European Pressure Ulcer Advisory Panel classification system

Study	Incidence	Sensitivity	Specificity	DOR	PPV	NPV
1 (Compton 2008)	/	69% (60-77%)	70% (66-74%)	5.1 (3.54-7.47)	33%	91%

Table 14 – Subjective nursing assessment of hyperaemic skin as a predictor for the development of pressure ulcers (grades 2-4) development according to the European Pressure Ulcer Advisory Panel classification system

Study	Incidence	Sensitivity	Specificity	DOR	PPV	NPV
1 (Compton 2008)	/	21% (15-30%)	91% (89-93%)	2.9 (2.28-3.65)	34%	85%

Table 15 – Presence of blanchable erythema assessed by the finger test as a predictor for the development of pressure ulcers development according to the European Pressure Ulcer Advisory Panel classification system

Study	Incidence	Sensitivity	Specificity	DOR	PPV	NPV
1 (Konishi 2008)	/	75% (35-97%)	77% (71-82%)	9.9 (1.94-50.49)	10%	99%

Table 16 – Presence of blanchable erythema assessed by the finger test as a predictor for the development of pressure ulcers (grades 2-4) development according to the European Pressure Ulcer Advisory Panel classification system

Study	Incidence	Sensitivity	Specificity	DOR	PPV	NPV
1 (Konishi 2008)	/	75% (19-99%)	76% (70-81%)	9.4 (0.94-94.58)	5%	99%
1 (Nixon 2007)	/	75% (19-99%)	10% (4-20%)	0.33 (0.03-3.27)	5%	86%

Table 17 – Thermography (presence of thermal anomaly – an area of the skin at least 1°C warmer than the surrounding skin) as a predictor for the development of skin breakdown

Study	Incidence	Sensitivity	Specificity	DOR	PPV	NPV
1 (Newman 1981)	/	100% (54-100%)	74% (63-83%)	36.7 (1.41-952.24)	21%	100%

Table 18 – Presence of non-blanchable erythema assessed by the finger test as a predictor for the development of pressure ulcers (grades 2-4) development according to the European Pressure Ulcer Advisory Panel classification system

Study	Incidence	Sensitivity	Specificity	DOR	PPV	NPV
1 (Nixon 2007)	/	73% (45-92%)	74% (64-83%)	8.0 (2.53-25.26)	34%	94%

4.3.5. Quality of the studies

Table 19 – Quality of the studies

Study	Selection bias	Risk tool bias	Outcome bias	Analysis bias
Compton 2008	Very high[1]	High[4]	Low	High[7]
Konishi 2008	High[2]	Low	High[5]	High[8]
Newman 1981	High[2]	Low	Low	High[8]
Nixon 2007	Very high[2]	Low	High[6]	High[8]

[1] *Consecutive patient enrolment, database cohort but participants followed prospectively, unclear validation method*
[2] *Consecutive patient enrolment, prospective cohort study, unclear validation method*
[3] *selected patient enrolment, prospective cohort study, unclear validation method*
[4] *Unclear definition and measurement of prognostic factors, prognostic factors were dichotomised, use of imputation technique or clear description of exclusion, adequate threshold*
[5] *Duration was unclear*
[6] *Uncertain if duration was appropriate*
[7] *incidence data only*
[8] *Incidence data only, inadequate number of events (<100 events)*
[9] *incidence data only, inadequate number of events (<100 events), unclear how they dealt with missing data*

4.3.6. Forest plots sensitivity and specificity

Figure 2 – Subjective nursing assessment of moist skin – ICU- grades 2-4

Study	TP	FP	FN	TN	Sensitivity	Specificity
Compton 2008	92	202	29	375	0.76 [0.67, 0.83]	0.65 [0.61, 0.69]

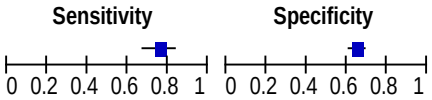


Figure 3 – Subjective nursing assessment of oedematous skin – ICU- grades 2-4

Study	TP	FP	FN	TN	Sensitivity	Specificity
Compton 2008	77	135	44	442	0.64 [0.54, 0.72]	0.77 [0.73, 0.80]

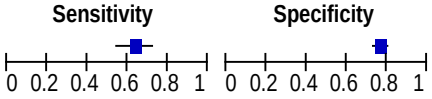


Figure 4 – Subjective nursing assessment of mottled skin – ICU- grades 2-4

Study	TP	FP	FN	TN	Sensitivity	Specificity
Compton 2008	40	48	81	529	0.33 [0.25, 0.42]	0.92 [0.89, 0.94]

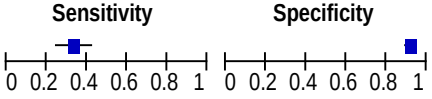


Figure 5 – Subjective nursing assessment of centralised circulation – ICU- grades 2-4

Study	TP	FP	FN	TN	Sensitivity	Specificity
Compton 2008	86	171	35	406	0.71 [0.62, 0.79]	0.70 [0.66, 0.74]

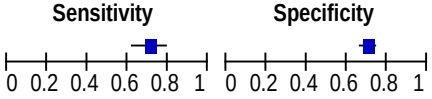


Figure 6 – Subjective nursing assessment of livid skin – ICU- grades 2-4

Study	TP	FP	FN	TN	Sensitivity	Specificity
Compton 2008	38	48	83	529	0.31 [0.23, 0.40]	0.92 [0.89, 0.94]

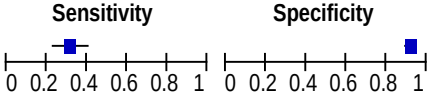


Figure 7 – Subjective nursing assessment of cyanosis – ICU- grades 2-4

Study	TP	FP	FN	TN	Sensitivity	Specificity
Compton 2008	77	135	44	442	0.64 [0.54, 0.72]	0.77 [0.73, 0.80]

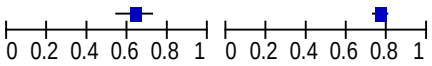


Figure 8 – Subjective nursing assessment of reddened skin – ICU- grades 2-4

Study	TP	FP	FN	TN	Sensitivity	Specificity
Compton 2008	83	172	38	405	0.69 [0.60, 0.77]	0.70 [0.66, 0.74]

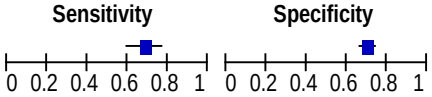


Figure 9 – Subjective nursing assessment of hyperaemic skin – ICU- grades 2-4

Study	TP	FP	FN	TN	Sensitivity	Specificity
Compton 2008	26	50	95	527	0.21 [0.15, 0.30]	0.91 [0.89, 0.93]

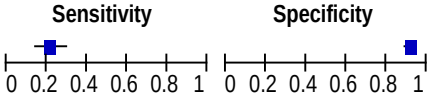


Figure 10 – Presence of blanchable erythema assessed by finger test – hospitalized patients- all grades

Study	TP	FP	FN	TN	Sensitivity	Specificity
Konishi 2008	6	56	2	185	0.75 [0.35, 0.97]	0.77 [0.71, 0.82]

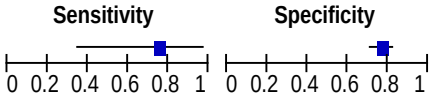


Figure 11 – Presence of thermal anomaly (an area of the skin at least 1°C warmer than the surrounding skin) – follow-up 10 days- geriatric inpatients- all grades

Study	TP	FP	FN	TN	Sensitivity	Specificity
Newman 1981	6	22	0	63	1.00 [0.54, 1.00]	0.74 [0.63, 0.83]

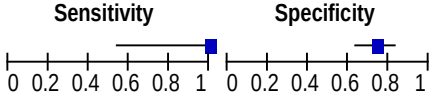


Figure 12 – Presence of blanchable erythema assessed by finger test – hospitalized patients – grades 2-4

Study	TP	FP	FN	TN	Sensitivity	Specificity
Konishi 2008	3	59	1	186	0.75 [0.19, 0.99]	0.76 [0.70, 0.81]
Nixon 2006	3	55	1	6	0.75 [0.19, 0.99]	0.10 [0.04, 0.20]

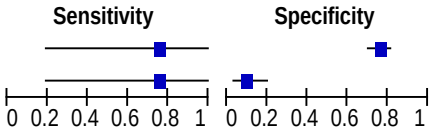
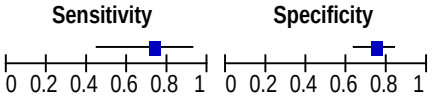


Figure 13 – Presence of non-blanchable erythema assessed by finger test – surgical inpatients – grades 2-4

Study	TP	FP	FN	TN	Sensitivity	Specificity
Nixon 2006	11	21	4	61	0.73 [0.45, 0.92]	0.74 [0.64, 0.83]



4.3.7. Clinical evidence tables

Table 20 – Compton 2008

Reference	Patient Characteristics	Predictive test Outcome	Outcome measures	Effect sizes	Comments
Author and year: **Compton, 2008** Title: **Pressure ulcer predictors in ICU patients: nursing skin assessment versus objective parameters** Journal: **Journal of Wound**	**Patient group:** ICU patients **All patients:** 713 **Included N:** 698 **Completed N:** 698	**Index test 1:** Nursing skin assessment on admission **Predictive test 2:** **Outcome:** Occurrence of PU (grades 2-4) development according to the European Pressure Ulcer Advisory Panel classification system in the course of ICU treatment	**Outcome 1:** Sensitivity and specificity (95% CI) moist skin	**Sensitivity:** 76% (67-83%) **Specificity**: 65% (61-69%) **Raw data** 5.9 (3.84-9.03)	**Funding:** Supported by a research grant of the Robert-Bosch-Stiftung, Stuttgart, Germany **Limitations:** index test measured only at admission; no report on blinding of

		Reference standard		
		Yes	No	
Index test	Yes	92	202	294
	No	29	375	404
		121	577	698

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Predictive test
Outcome</th><th>Outcome measures</th><th>Effect sizes</th><th>Comments</th></tr>
<tr>
<td>Care, 2008; 17 (10): 417-24

Study type:
Prospective cohort study

Selection patient:
All patients admitted at ICU between April 2001 and December 2004 without a PU at admission and remaining at least 72 h were eligible for the study

Index test:
Subjective nursing assessment of the skin condition on admission including the presence of moist skin, oedematous skin, mottled skin, livid skin, centralised circulation, cyanosis, reddened skin and hyperaemic skin.</td>
<td>Drop-outs:
0

Age (median years, quartiles):
66 ((56, 75, 25)

Gender (m/f):
392/306

Number of patients with a PU:
121

Number of patients without a PU:
577

Inclusion criteria:
ICU patient
No PU on admission

Exclusion criteria:
Stay in the ICU less than 72 h</td>
<td>Preventive methods:
Not reported</td>
<td>DOR 95%CI

Outcome 2:

Sensitivity and specificity (95% CI)

oedematous skin

DOR 95%CI

Outcome 3:

Sensitivity and specificity (95% CI)

mottled skin</td>
<td>Sensitivity: 64% (54-72%)
Specificity: 77% (73-80%)
Raw data
<table><tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Index test</td><td>Yes</td><td>77</td><td>135</td><td>212</td></tr><tr><td>No</td><td>44</td><td>442</td><td>486</td></tr><tr><td></td><td>121</td><td>577</td><td>698</td></tr></table>5.7 (4.05-8.11)

Sensitivity: 33% (25-42%)
Specificity: 92% (89-94%)
Raw data
<table><tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td>Index</td><td>Yes</td><td>40</td><td>48</td><td>88</td></tr></table></td>
<td>researcher toward index test and reference standard; unclear if uninterpretable results were found; no information about preventive measures;
no sub-analyses according to preventive measures.

Additional outcomes:
With univariate analysis measures relating to organ dysfunction, circulatory impairment and sepsis showed significant association with the occurrence of PU. Multiple</td>
</tr>
</table>

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Predictive test
Outcome</th><th>Outcome measures</th><th>Effect sizes</th><th>Comments</th></tr>
<tr><td>Reference standard:
Occurrence of PU (grades 2-4) during course of ICU treatment.
PU were defined and graded according to the European Pressure Ulcer Advisory Panel classification system.

Addressing missing data:
To control for missing data, values of the continuous monitoring and laboratory variables were recorded into the point score used in the acute physiology score (APS) of the APACHE II severity-of-disease scoring system, where 0 to 4 points are assigned</td><td></td><td></td><td>DOR 95%CI

Outcome 4:

Sensitivity and specificity (95% CI)

livid skin</td><td>
<table>
<tr><td rowspan="2">test</td><td>No</td><td>81</td><td>529</td><td>610</td></tr>
<tr><td></td><td>121</td><td>577</td><td>698</td></tr>
</table>
5.4 (4.21-7.03)

Sensitivity: 31% (23-40%)
Specificity: 92% (89-94%)
Raw data
<table>
<tr><td rowspan="2"></td><td rowspan="2"></td><td colspan="2">Reference standard</td><td rowspan="2"></td></tr>
<tr><td>Yes</td><td>No</td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>38</td><td>48</td><td>86</td></tr>
<tr><td>No</td><td>83</td><td>529</td><td>612</td></tr>
<tr><td></td><td>121</td><td>577</td><td>698</td></tr>
</table>
</td><td>regression analysis showed subjective nursing skin assessment to outweigh these parameters as PU predictors.

A risk function comprised of 5 skin-related and gender yielded an overall correct PU prediction proportion of 84.6%. ROC analysis showed an AUC of 0.82 (0.79-0.86) compared with an AUC of 0.59 (0.54-0.65) obtained with the Waterlow scale on admission. Results were validated in 392 patients treated in the same ICU between</td></tr>
</table>

Reference	Patient Characteristics	Predictive test Outcome	Outcome measures	Effect sizes	Comments
according to the extent of deviation from the physiological range. Therefore, only monitoring and laboratory variables used in the APS score were entered in the logistic regression model. Statistical analysis: **Continuous data are displayed as median and quartiles and were compared between groups using Mann-Whitney U testing.** **Dichotomous parameters are displayed as absolute numbers and percentages and were compared between groups using the chi-square test or the Fisher's exact test. A two-sided p value < 0.05**			DOR 95%CI **Outcome 5:** Sensitivity and specificity (95% CI) centralised circulation	5.0 (3.92-6.5) **Sensitivity:** 71% (62-79%) **Specificity**: 70% (66-74%) **Raw data** Reference standard / Yes / No Index test – Yes: 86 / 171 / 257 Index test – No: 35 / 406 / 441 121 / 577 / 698	January 2005 and May 2006, yielding an AUC of 0.8 (0.73-0.86) compared with 0.58 (0.50-0.66) with the Waterlow scale. **Notes:**

Reference	Patient Characteristics	Predictive test Outcome	Outcome measures	Effect sizes	Comments
was considered significant. **Multiple stepwise regression analysis was used to analyze which of the examined parameters predict PU risk in critically ill patients.** **The predictive capacity of the logistic regression function was assessed and compared with the Waterlow scale by calculating the area under the curve (AUC) of a receiver-operator characteristic (ROC) curve. AUCs, sensitivities and specificities are displayed with 95% confidence intervals.** Setting: **Intensive Care Unit, Charité Campus**			DOR 95%CI **Outcome 6:** Sensitivity and specificity (95% CI) Cyanosis DOR 95%CI **Outcome 7:** Sensitivity and Specificity (95% CI) reddened skin	5.8 (3.95-8.61) **Sensitivity:** 45% (36-55%) **Specificity**: 81% (77-84%) **Raw data** 3.5 (2.63-4.64) **Sensitivity:** 69% (60-77%) **Specificity**: 70% (66-74%) **Raw data**	

		Reference standard		
		Yes	No	
Index test	Yes	55	111	166
	No	66	466	532
		121	577	698

		Reference standard		
		Yes	No	
Index test	Yes	83	172	255
	No	38	405	443

Reference	Patient Characteristics	Predictive test Outcome	Outcome measures	Effect sizes	Comments
Benjamin Franklin, Berlin, Germany Blinding: **no details**				<table><tr><td></td><td></td><td>121</td><td>577</td><td>698</td></tr></table> 5.1 (3.54-7.47) **Sensitivity:** 21% (15-30%) **Specificity**: 91% (89-93%) **Raw data** <table><tr><td></td><td></td><td>Reference standard</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td>Index test</td><td>Yes</td><td>26</td><td>50</td><td>76</td></tr><tr><td></td><td>No</td><td>95</td><td>527</td><td>622</td></tr><tr><td></td><td></td><td>121</td><td>577</td><td>698</td></tr></table> 2.9 (2.28-3.65)	
			DOR 95%CI **Outcome 8:** Sensitivity and specificity (95% CI) Hyperaemic skin DOR 95%CI		

Table 21 – Konishi 2008

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Predictive test
Outcome</th><th>Outcome measures</th><th>Effect sizes</th><th>Comments</th></tr>
<tr>
<td>Author and year:
Konishi, 2008

Title:
A prospective study of blanchable erythema among university hospital patients

Journal:
International Wound Journal, 2008; 5(3): 470-5.

Study type:
Prospective cohort study

Selection patient:
Subjects consisted of patients who were admitted to 6 wards in a university hospital with 832 beds between February and April</td>
<td>Patient group:
Patients admitted in a university hospital free of PU and spending most of the day in bed.

All patients:
493

Included N:
249

Completed N:
249

Drop-outs:
0

Age (mean years (SD); range):
not reported

Gender (m/f):
not reported</td>
<td>Index test 1:
Presence of blanchable erythema assessed by pressing firmly on the skin with a finger and by looking for blanching followed by prompt return of color to the area after lifting the finger

Reference standard:
Occurrence of PU development according to the National Pressure Ulcer Advisory Panel classification

Preventive methods:
Not reported</td>
<td>Outcome 1:
Sensitivity and specificity
of blanchable erythema as a predictor for PU development

DOR 95%CI

Outcome 2:
Sensitivity and specificity
of blanchable erythema as a predictor for PU (grades 2-4) development</td>
<td>Sensitivity: 75% (35-97%)
Specificity: 77% (71-82%)
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>6</td><td>56</td><td>62</td></tr>
<tr><td>No</td><td>2</td><td>185</td><td>187</td></tr>
<tr><td></td><td>8</td><td>241</td><td>249</td></tr>
</table>
9.9 (1.94-50.49)

Sensitivity: 75% (19-99%)
Specificity: 76% (70-81%)
Raw data
<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>3</td><td>59</td><td>62</td></tr>
<tr><td>No</td><td>1</td><td>186</td><td>187</td></tr>
<tr><td></td><td>4</td><td>245</td><td>249</td></tr>
</table>
</td>
<td>Funding:
None reported

Limitations:
No information about time of follow-up; no report on blinding of researcher toward index test and reference standard; unclear if uninterpretable results were found; no information about preventive measures;
no sub-analyses according to preventive measures.

Additional</td>
</tr>
</table>

Reference	Patient Characteristics	Predictive test Outcome	Outcome measures	Effect sizes	Comments
2005. Six wards were ICU, surgical recovery room, gastroenterological surgery and medicine, internal medicine and cardiovascular and respiratory surgery. These were selected, as three had the highest percentages of bedridden patients, and the other three had the lowest percentages. All subjects were required to be free of pressure ulcers at the beginning of the study and spent most of the day in bed. Index test: **Daily assessment of the presence of blanchable erythema.** **To assess for blanchability, researchers pressed**	**Number of patients with a PU:** 8 (for all stages of PU development) 4 (for PU (grades 2-4) development) **Number of patients without a PU:** 241 **Inclusion criteria:** Admission in one of the 6 participating wards Free of PU Bedridden **Exclusion criteria:** none		DOR 95%CI	9.4 (0.94-94.58)	**outcomes:** Identification of factors associated with the deterioration of blanchable erythema. The number of patients who had a risk under the item 'pressure', which is one of the triggering factors in the scale for predicting pressure ulcer development, was significantly higher in the deteriorated group (chi-squared=4.277, p= 0.039). Inadequate maintenance of support surfaces was observed in all six patients in the deteriorated

Reference	Patient Characteristics	Predictive test Outcome	Outcome measures	Effect sizes	Comments
firmly on the skin with a finger and lifted the finger and looked for blanching (sudden whitening of the skin), followed by prompt return of color to the area. Reference standard: **Occurrence of PU assessed by daily inspection.** **Pressure ulcers were defined by using the National Pressure Ulcer Advisory Panel classification** Addressing missing data: **No details** Statistical analysis: **To compare each parameter between the healed and the deteriorated groups, the chi-squared test**					Group (chi-squared =0.228, p= 0.015). **Notes:**

Reference	Patient Characteristics	Predictive test Outcome	Outcome measures	Effect sizes	Comments
and Mann-Whitney U test were performed using SPSS II for Windows for statistical analysis. P < 0.05 was considered statistically significant. **The probability of blanchable erythema resulting in pressure ulcer development was calculated in terms of sensitivity, specificity and positive likelihood ratio and diagnostic accuracy was examined. In the statistical methods, diagnostic probabilities (sensitivity, specificity and positive likelihood ratio) were calculated.** Setting: **Six wards in a**					

Reference	Patient Characteristics	Predictive test Outcome	Outcome measures	Effect sizes	Comments
university hospital with **832 beds, Ishikawa, Japan.** Blinding: **No details**					

Table 22 – Newman 1981

Reference	Patient Characteristics	Predictive test Outcome	Outcome measures	Effect sizes	Comments
Author and year: **Newman 1981** Title: **Thermography as a predictor of sacral pressure sores** Journal: **Age and Ageing, 1981; 10: 14-8.** Study type: **Prospective cohort study**	**Patient group:** 155 newly admitted in a 12-week period without pressure lesions 64 patients were not included because: - could not be screened within 24 h (N=29) - too ill to participate (N=11) - refusal (N=11) - miscellaneous (N=13)	**Index test 1:** Thermography: presence of thermal anomaly (an area of the skin at least 1°C warmer than the surrounding skin). **Reference standard:** Visual inspection **Preventive methods:** No details	**Outcome 1:** Proportion of patients developing pressure sores in the sacral region within 10 days after admission **Outcome 2:** Sensitivity and specificity (95% CI) Thermal anomaly	**Value:** 6/85 (7%) **Sensitivity:** 100% (54-100%) **Specificity**: 74% (63-83%) **Raw data**	**Funding:** None reported **Limitations:** index test measured only at admission; no report on blinding of researcher toward index test and reference standard; unclear if uninterpretable

Reference	Patient Characteristics	Predictive test Outcome	Outcome measures	Effect sizes	Comments
Selection patient: **New admissions to the geriatric assessment unit at the Southern General Hospital, Glasgow, over a 12-week period with unmarked skin were invited to participate in the study** Index test: **Thermography with a prototype, low cost, portable, heat- sensitive thermograph was performed within 24 h after admission.** **Patients lay on one side for 10 to 15 minutes with the buttocks exposed to allow skin temperature to stabilize. The ward temperature was maintained between 21 and 26°C; relative humidity was seldom below 40% or above 60%. The camera**	**All patients** **Included N:** 91 **Completed N:** 91 **Drop-outs:** 0 **Age (mean years (SD); range):** No details **Gender (m/f):** No details **Number of patients with a PU:** 6 **Number of patients without a PU:** 85		DOR (95% CI)	<table><tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr><tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr><tr><td rowspan="3">Index test</td><td>Yes</td><td>6</td><td>22</td><td>28</td></tr><tr><td>No</td><td>0</td><td>63</td><td>63</td></tr><tr><td></td><td>6</td><td>85</td><td>91</td></tr></table> 36.7 (1.41-952.24)	results were found; no information about preventive measures; no sub-analyses according to preventive measures. **Additional outcomes:** Patients with low Norton scores on admission developed more frequently skin breaks within the subsequent 10 days than those with high scores. Two of the 58 control patients (4%) developed sores within a week of admission. **Notes:**

Reference	Patient Characteristics	Predictive test Outcome	Outcome measures	Effect sizes	Comments
was positioned as square as possible to the sacrum, ischium and hip. A small reflective marker stuck on to the patient simplified focusing. Thermal images (thermograms) were recorded on video-tape; the patient was then turned, and the procedure, including stabilization, was repeated for the other buttock. During the subsequent 4 weeks, patients admitted were similarly examined, but thermography was not carried out. This control was established to determine whether the thermographic examination by itself had led to any change in the reported incidence of pressure sores. Reference	**Inclusion criteria:** New admission Unmarked skin **Exclusion criteria:** Pressure lesion on admission				

Reference	Patient Characteristics	Predictive test Outcome	Outcome measures	Effect sizes	Comments
standard: **Development of skin breakdown in the buttock region within 10 days of admission was reported by the nursing staff and photographed. Redness alone, however marked or persistent, was not categorized as a pressure sore.** Addressing missing data: **No details** Statistical analysis: **Only descriptive data** Setting: **Geriatric assessment unit at the Southern general Hospital, Glasgow, Scotland** Blinding: **No details**					

Table 23 – Nixon 2006

<table>
<tr><th>Reference</th><th>Patient Characteristics</th><th>Predictive test
Outcome</th><th>Outcome measures</th><th>Effect sizes</th><th>Comments</th></tr>
<tr>
<td>Author and year:
Nixon 2006

Title:
Skin alterations of intact skin and risk factors associated with pressure ulcer development in surgical patients: a cohort study

Journal:
International Journal of Nursing Studies, 2006; 44: 655-663

Study type:
Prospective cohort study

Selection patient:
Surgical in-patients admitted to St. James's University Hospital, Leeds between September 1998 and May 1999.</td>
<td>Patient group:
Surgical in-patients

All patients:
109

Included N:
109
Completed N:
97

Drop-outs:
12
Incomplete follow-up resulted from cancelled elective surgery and early discharge (N=4), patient request to discontinue (N=4) and
presence of pressure ulcer at baseline assessment (N=4)

Age (median years,</td>
<td>Index test 1:
skin assessment according the classification scale adapted from international classification scales (AHCPR (Agency for Health Care Policy and Research) 1992; EPUAP, 1999)

Index test 2:
Reference standard:
Occurrence of stage 2+ PU development according the classification scale adapted from international classification scales (AHCPR (Agency for Health Care Policy and Research) 1992; EPUAP, 1999)

Preventive methods:
Not reported</td>
<td>Outcome 1:

Sensitivity and specificity (95% CI)
of blanchable erythma as a predictor for PU development (grades 2-4)

DOR 95%CI

Outcome 2:

Sensitivity and specificity (95% CI)
of non-blanchable erythma as a predictor for PU</td>
<td>Sensitivity: 75% (19-99%)
Specificity: 10% (4-20%)
Raw data (Grade 1a vs Grade 0 erythema)

<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>3</td><td>55</td><td>58</td></tr>
<tr><td>No</td><td>1</td><td>6</td><td>7</td></tr>
<tr><td></td><td>4</td><td>61</td><td>65</td></tr>
</table>
0.33 (0.03-3.27)

Sensitivity: 73% (45-92%)
Specificity: 74% (64-83%)
Raw data (Grade 1b and 1b+ vs Grade 1a and Grade 0)

<table>
<tr><td></td><td></td><td colspan="2">Reference standard</td><td></td></tr>
<tr><td></td><td></td><td>Yes</td><td>No</td><td></td></tr>
</table>
</td>
<td>Funding:
Jane Nixon has been reimbursed for attending conferences, has been paid speakers fees and received research funding from Huntleigh Healthcare Ltd.
Funding awards from the Tissue Viability Society
Training Fellowship (UK) and the Smith and Nephew Foundation Nursing Research Fellowship were made to Jane Nixon. These organizations peer reviewed the grant
application and</td>
</tr>
</table>

<table>
<tr><th>Reference</th><th>Patient Characteristics
Outcome</th><th>Predictive test</th><th>Outcome measures</th><th>Effect sizes</th><th>Comments</th></tr>
<tr>
<td>Index test:
The classification scale used was adapted from international classification scales, (AHCPR (Agency for Health Care Policy and Research) 1992; EPUAP, 1999) in order to meet practical data collection requirements for the purpose of research. Specifically, Grade 0 (no skin changes) was included to clearly distinguish skin assessment of normal skin from missing data.
In addition, alterations to intact skin were classified as blanching (1a), non-blanching (1b) and non-blanching with other skin changes including, local induration, oedema, pain, warmth or discoloration (1b+).</td>
<td>quartiles):
75 (55-95)

Gender (m/f):
38/59

Number of patients with a PU:
15

Number of patients without a PU:
82

Inclusion criteria:
(a) Scheduled for elective major general or vascular surgery OR acute orthopaedic, vascular and general surgical admission.
(b) Aged 55 years or over on day of surgery.
(c) Expected length of stay of 5 or more days.</td>
<td></td>
<td>development (grades 2-4)

DOR 95%CI

I</td>
<td>
<table>
<tr><td rowspan="3">Index test</td><td>Yes</td><td>11</td><td>21</td><td>32</td></tr>
<tr><td>No</td><td>4</td><td>61</td><td>65</td></tr>
<tr><td></td><td>15</td><td>82</td><td>97</td></tr>
</table>
8.00 (2.53-25.26)
</td>
<td>received a report of the findings.

Limitations:
no report on blinding of researcher toward index test and reference standard; unclear if uninterpretable results were found; no information about preventive measures;
no sub-analyses according to preventive measures.

Additional outcomes:
There was significantly increased odds of pressure</td>
</tr>
</table>

Reference	Patient Characteristics	Predictive test Outcome	Outcome measures	Effect sizes	Comments
Reference standard: **The classification scale used was adapted from international classification scales, (AHCPR (Agency for Health Care Policy and Research) 1992; EPUAP, 1999) in order to meet practical data collection requirements for the purpose of research. The dependent outcome variable 'pressure ulcer' was defined as a skin area assessed as >=Grade 2, that is, a superficial skin break/blister or worse.** **Grade 5 (black eschar) was included as a separate grade until wound debridement enabled classification by tissue layer.** Addressing missing data: **Variables were excluded from further analysis if the p value**	**Exclusion criteria:** (a) General surgery sub-specialties including liver, urology and breast surgery. (b) Dark skin pigmentation which precluded reliable identification of skin erythema. (c) Skin conditions over the sacrum, buttocks or heels which precluded reliable identification of pressure induced skin erythema.				ulcer development associated with non-blanching erythema (7.98, p = 0.002) and non-blanching erythema with other skin changes (9.17, p = 0.035). Logistic regression modeling identified non-blanching erythema, pre-operative albumin, weight loss, and intra-operative minimum diastolic blood pressure, as independent predictors of Grade>=2 pressure ulcer development. **Notes:**

Reference	Patient Characteristics	Predictive test Outcome	Outcome measures	Effect sizes	Comments
was >=0.2 (Altman, 1991) or >=25% of data was missing. **Missing values were replaced by imputed data.** Statistical analysis: **A chi-square test was used to compare the proportions of patients classified as having Grade 0, Grade 1a, Grade 1b and Grade 1b+ on any skin site preceding pressure ulcer development. Skin changes preceding pressure ulcer development were also classified by Grade, independently for each site, and the difference in frequency of pressure ulcers between Grades examined using Fisher's exact test.** **To identify which clinical signs of erythema were**					

Reference	Patient Characteristics	Predictive test Outcome	Outcome measures	Effect sizes	Comments
predictive of skin loss, the odds of pressure ulcer development for Grade 0, Grade 1a, 1b and 1b+ were examined using single factor logistic regression. **To identify variables which independently are predictive of >=Grade 2 pressure ulcer development, the relationship between risk factors and pressure ulcer development was explored using a three stage process for patients who were pressure ulcer free at baseline. The 'worst' skin grade recorded at any time and on any site during hospital stay or preceding pressure ulcer development was used to categorise skin alteration as a risk factor. Univariate analysis used single factor logistic regression with a binary**					

Reference	Patient Characteristics	Predictive test Outcome	Outcome measures	Effect sizes	Comments
response of pressure ulcer or no pressure ulcer. **Correlations between variables were then examined using Pearson's correlation coefficient for continuous data or Spearman's rank correlation for ordered categorical data. Where variables were correlated with a correlation coefficient of 40.7 and an associated p-value of 0.01 (Fielding et al., 1992), one was eliminated from further consideration.** **The final candidate variables were entered into a logistic regression model using forward stepwise selection. The p value determined entry (<0.25) and removal (40.9). The variables identified by the**					

Reference	Patient Characteristics	Predictive test Outcome	Outcome measures	Effect sizes	Comments
forward stepwise selection were then used as the basic model for further logistic regression analysis. Correlated variables were dropped and added systematically in order to determine the final model in which each variable independently predicted subsequent pressure ulcer development as assessed by the size of the p value. **The model was determined only from patients with complete data for all candidate variables. Therefore, when the final set of variables was obtained the model was refitted with only those final variables in the model statement.** **Analyses were carried out using the Stata Statistical Software**					

Reference	Patient Characteristics	Predictive test Outcome	Outcome measures	Effect sizes	Comments
package. Setting: **St. James University Hospital Leeds** Blinding: **no blinding**					

5. SKIN MASSAGE

5.1. Review Protocol

Table 1 – Protocol review question

Review question: What is the clinical effectiveness of skin massage in the prevention of pressure ulcers?	
Population	Individuals of all ages
Intervention	Skin massage (method, frequency)
Comparison	• No skin massage • Other preventive methods
Outcomes	**Critical outcomes for decision-making:** • Proportion of participants developing new pressure ulcers (dichotomous outcome) • Skin damage **Important outcomes:** • Patient acceptability • Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital or other healthcare settings (continuous data) • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised) o Short-form health survey (SF36) o Manchester Short Assessment of Quality of Life o EQ-5D o WHO-Quality of life BREF o Cardiff HRQoL tool o HUI

Review question: What is the clinical effectiveness of skin massage in the prevention of pressure ulcers?	
	o Pressure ulcer quality of life (Gorecki)
Study design	• High quality systematic reviews of RCTs and/or RCTs only. • Cochrane reviews will be included if they match our inclusion criteria and have appropriate assumptions for missing data such as available case analysis or ITT (with the appropriate assumptions) • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies with another population, intervention, comparison or outcome. • Non-English, non-French, non-Dutch language papers
Search strategy	**The electronic databases to be searched are:** • Medline (OVID interface), Cinahl (EBSCO-interface), Embase, Library of the Cochrane Collaboration • All years
Review strategy	**How will individual PICO characteristics be combined across studies in a meta-analysis (for intervention reviews)** • Population – any population will be combined for meta-analysis except combination of children and adults. • Intervention – different types of methods will be combined for meta-analysis; different products will be combined for meta-analysis; different types of frequency will be combined for meta-analysis. • Comparison – any comparison which fits the inclusion criteria will be meta-analysed • Outcomes – same outcomes will be combined for meta-analysis; single side effects will be meta-analysed separately from other side effects • Blinding – Blinded and unblinded studies will be meta-analysed together. • Unit of analysis – patients, individual pressure ulcers • Minimum duration of treatment = no minimum. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use available case analysis for dealing with missing data if there is a 10% differential or higher between the groups or if the missing data is higher than the event rate, if cannot work out the available case analysis will take the author's data.
Analysis	**The following groups will be considered separately if data are present:** • Children and adults (neonates, infants, children).

Review question: What is the clinical effectiveness of skin massage in the prevention of pressure ulcers?

The following groups will be considered separately as subgroups if data are present:

- Different categories of pressure ulcers(from category 2 upwards where outcomes are reported separately);
- Different locations of pressure ulcers: sacral, heel and others.

5.2. Search strategy

5.2.1. Search filters

Table 2 – Search filters Medline (OVID)

Date	**05/06/2012**	
Database	**Ovid MEDLINE® In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R)** 1946 to **present**	
Search Strategy	1. Pressure ulcer.sh	**9012**
	2. decubit*.ti,ab.	**3784**
	3. (pressure adj (sore* or ulcer* or damage*)).ti,ab.	**5916**
	4. (bedsore* or bed-sore*).ti,ab.	**479**
	5. ((moist* or friction or shear) adj2 (sore* or ulcer* or damage or wound* or injur* or lesion*)).ti,ab.	**601**
	6. OR/1 – 5	
	7. Massage.sh	**13233**
	8. Massage*.tw	**4303**
	9. Rub*.tw	**6112**
	10. Emollients.sh	**45509**
	11. Emollient*.tw	**1201**
	12. Moistur*.tw	**868**
	13. skin care.sh	**11252**
	14. skin care.tw or care skin.tw	**3996**
	15. OR/7 – 14	**1547**
	16. randomized controlled trial.pt.	**70561**
	17. controlled clinical trial.pt.	**327649**
	18. randomi#ed.ab.	**84127**
	19. placebo.ab.	**277597**
	20. randomly.ab.	**131376**
	21. exp Clinical Trials as topic/	**167239**

Date	05/06/2012	
	22. trial.ti	**255547**
	23. OR/16 – 22	**100097**
	24. AND/6, 15, 23	**825108**
	25. Limit language: 'English, Dutch, Flemish, French'	**100**
		98
Note		

Table 3 – Search filters Embase

Date	28/06/2012	
Database	Embase	
Search Strategy (attention, for PubMed, check « Details »)	1. 'decubitus'/exp	**13168**
	2. decubit*:ti,ab	**5405**
	3. (pressure NEAR/1 (score* OR ulcer* OR damage)):ab,ti	**4764**
	4. (bed NEAR/2 sore*):ab,ti OR bedsore*:ti,ab	**736**
	5. ((moist* or friction or shear) near/2 (sore* or ulcer* or damage or wound* or injur* or lesion*)):ti,ab	**797**
	6. OR/1 – 5	
	7. 'massage'/exp	**17616**
	8. massage*:ti,ab	**8552**
	9. rub*:ti,ab	**8558**
	10. 'emollient agent'/exp	**60494**
	11. emollient*:ti,ab	**3174**
	12. moistur*:ti,ab	**1510**
	13. 'skin care'/exp	**17833**
	14. 'skin care':ti,ab or 'care skin':ti,ab	**6427**
	15. OR/7– 14	**2473**
	16. 'clinical trial'/exp	**100941**
	17. 'clinical trial (topic)'/exp	**912587**
	18. random*:ti,ab	**38567**
	19. factorial*:ti,ab	**736201**
	20. crossover*:ti,ab OR (cross NEXT/1 over*):ti,ab	**19421**
	21. ((doubl* or singl*) NEAR/2 blind*):ti,ab	**62987**

Date	28/06/2012	
	22. (assign* or allocat* or volunteer* or placebo*):ti,ab	**144221**
	23. ‘crossover procedure’/exp	**572555**
	24. ‘single blind procedure’/exp	**33225**
	25. ‘double blind procedure’/exp	**15382**
	26. OR/16 – 25	**108418**
	27. AND/6, 15, 26	**1736560**
	28. Limit language: ’English, Dutch, French’ AND exclude medline	**146**
		40

Note

Table 4 – Search filters Cochrane

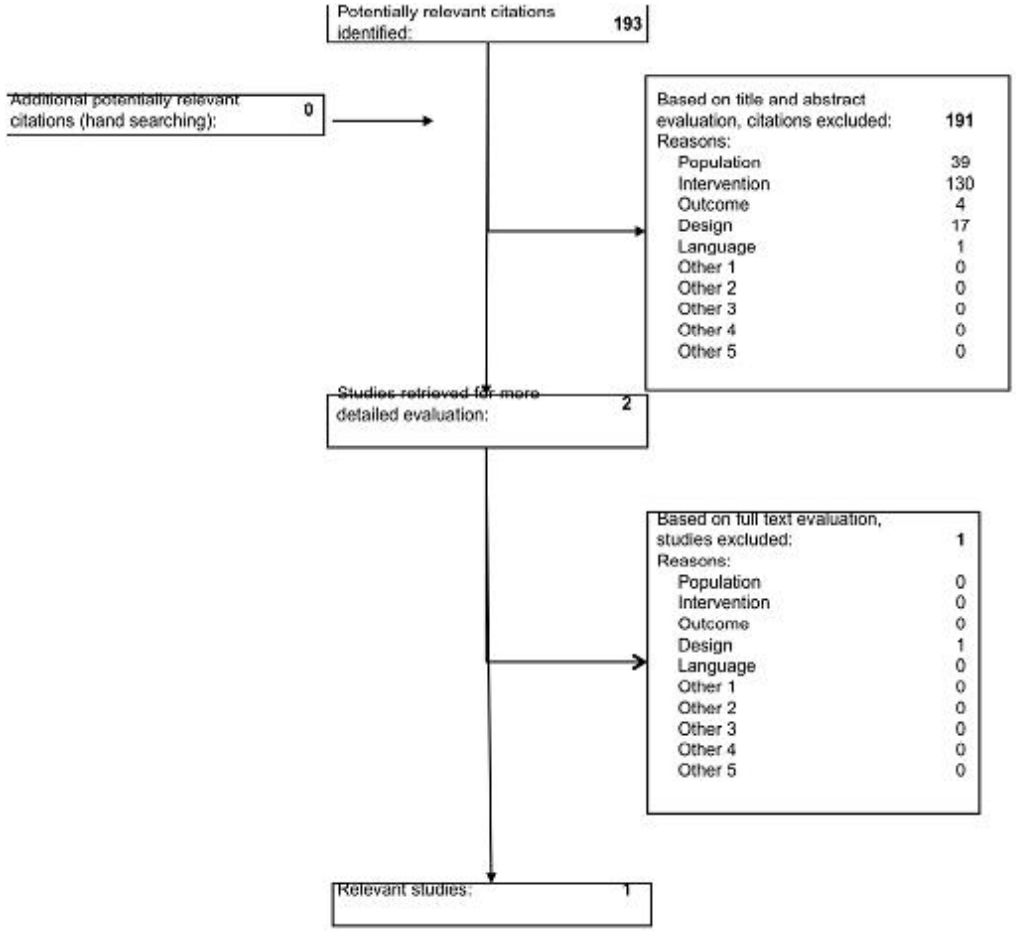
Date	**5/06/2012**	
Database	The Library of the Cochrane Collaboration	
Search Strategy **(attention, for PubMed, check « Details »):ti,ab,kw**	1. MeSH descriptor “Pressure ulcer” explode all trees 2. Decubit*:ti,ab,kw 3. (pressure near/2 (sore* or ulcer* or damage*)):ti,ab,kw 4. (bedsore* or bed-sore*):ti,ab,kw 5. ((moist* or friction or shear) near/2 (sore* or ulcer* or damage or wound* or injur*or lesion*)):ti,ab,kw 6. OR/1 – 5 7. MeSH descriptor “massage” explode all trees 8. (massage*):ti,ab,kw 9. (rub*):ti,ab,kw 10. (emollient*):ti,ab,kw 11. MeSH descriptor “emollients” explode all trees 12. (moistur*):ti,ab,kw 13. (skin care):ti,ab,kw 14. MeSH descriptor “skin care” explode all trees 15. OR/7 – 14 16. “Clinical Trial”:pt 17. “Randomized Controlled Trial”:pt 18. MeSH descriptor “clinical trial as topic” explode all trees 19. (trial*):ti,ab,kw 20. (randomized or randomised):ti,ab,kw 21. (randomly):ti,ab,kw 22. (group*):ti,ab,kw 23. OR/16 – 22 24. AND/6, 15, 23	**487** **349** **829** **33** **63** **1163** **590** **1355** **1322** **437** **258** **636** **1566** **265** **5054** **294493** **313107** **50972** **247198** **263851** **85743** **273083** **532112** **109**
Note		

Table 5 – Search filters CINAHL

Date	05/06/2012	
Database	CINAHL (EBSCO-interface)	
Search Strategy (attention, for PubMed, check « Details »)	34. MH “Pressure Ulcer”	**7641**
	35. Decubit*	**480**
	36. Pressure n1 sore* OR pressure n1 ulcer* OR pressure n1 damage*	**8402**
	37. Bedsore* OR bed-sore*	**156**
	38. ((moist* or friction or shear) and (sore* or ulcer* or damage or wound* or injur* or lesion*))	**1399**
	39. OR/1 – 5	
	40. MH "Massage"	**9715**
	41. “massage*”	**5537**
	42. “rub*”	**7354**
	43. MH "Emollients+"	**4095**
	44. "Emollient*”	**780**
	45. “moistur*”	**679**
	46. MH "Skin Care"	**750**
	47. “skin care” or “care skin”	**3773**
	48. OR/7 – 14	**4884**
	49. MH "Clinical Trials+"	**17265**
	50. “trial*”	**105365**
	51. “randomi#ed”	**134991**
	52. “randomly”	**64632**
	53. “randomized controlled trial”	**24832**
	54. PT “randomized controlled trial”	**8857**
	55. PT “clinical trial”	**9758**
	56. OR/16 – 22	**51022**
	57. AND/6, 15, 23	**165760**
	58. Limit language=’English, Dutch, French’ AND exclude medline records	**78**
		23
Note		

5.2.2. Selection of articles

Figure 1 – Flowchart search strategy



5.2.3. Excluded study

Study	Reason for exclusion
Arashi, M., Sugama, J., Sanada, H., Konya, C., Okuwa, M., Nakagami, G. et al. (2010). Vibration therapy accelerates healing of Stage I pressure ulcers in older adult patients. *Advances in Skin & Wound Care.23(7):321-7*.	Non-randomized trial

5.3. Clinical evidence

5.3.1. Search strategy

The systematic search through multiple electronic databases resulted in 270 records: 98 in Medline (Ovid), 23 in Cinahl (EBSCO interface), 40 in Embase, and 109 in the Library of the Cochrane Collaboration. Duplicate records were excluded, which resulted in 193 records. Based on the screening of titles and abstracts another 191 records were excluded. Reasons for exclusion are listed in figure 1. The full text of the remaining 2 records was reviewed in detail. Based on this review, 1 record was excluded. Reason for exclusion was listed. This resulted in retaining 1 clustered cross-over randomized trial performed in Dutch nursing homes. [63]

5.3.2. Summary tables

Table 6 – Summary table

Study ID	Intervention/ comparator	Population	Outcome	Length of study
Duimel-Peeters 2007[63]	Massage with indifferent cream versus massage with dimethyl sulfoxide (DMSO) cream versus no massage	Residents of 8 Dutch nursing homes	Incidence of pressure ulcers	4 weeks of treatment followed by a wash-out period of 2 weeks and another 4 weeks of treatment

5.3.3. Grade evidence profiles

Table 7 – Clinical GRADE evidence profile: Massage with indifferent cream (Vaseline) + position change versus position change only for the prevention of pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Massage with indifferent cream + position change	Position change only	Relative (95% CI)	Absolute		
Incidence of PU (follow-up 4 weeks; assessed with the four-grade system of the EPUAP using a transparent disk)												
1 Duimel-Peeters, 2007	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness[2]	very serious[2]	none	13/31 (41.9%)	7/18 (38.9%)	RR 1.22 (0.61 to 2.41)	86 more per 1000 (from 152 fewer to 548 more)	⊕OOO VERY LOW	CRITICAL
								38.9%		86 more per 1000 (from 152 fewer to 548 more)		

1 No details of allocation concealment.It was not clear whether the outcome assessors were blinded
2 Confidence interval crossed both MID points.

Table 8 – Clinical GRADE evidence profile: Massage with DMSO cream + position change versus position change only for the prevention of pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Massage with DMSO cream + position change**	**Position change only**	**Relative (95% CI)**	**Absolute**		
Incidence of PU (follow-up 4 weeks; assessed with the four-grade system of the EPUAP using a transparent disk)												
1 Duimel-Peeters, 2007	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	18/29 (62.1%)	7/18 (38.9%)	RR 1.85 (0.87 to 2.99)	331 more per 1000 (from 51 fewer to 774 more)	⊕OOO VERY LOW	CRITICAL
								38.9%		331 more per 1000 (from 51 fewer to 774 more)		

1 No details of allocation concealment. It was not clear whether the outcome assessors were blinded
2 Confidence interval crossed one MID point.

Table 9 – Clinical GRADE evidence profile: Massage with DMSO cream + position change versus massage with indifferent cream (Vaseline) + position change for the prevention of pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Massage with DMSO cream + position change	Massage with indifferent cream + Position change	Relative (95% CI)	Absolute		
Incidence of PU (follow-up 4 weeks; assessed with the four-grade system of the EPUAP using a transparent disk)												
1 Duimel-Peeters, 2007	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	18/29 (62.1%)	13/31 (41.9%)	RR 1.43(0.79 to 2.14)	180 more per 1000 (from 88 fewer to 478 more)	⊕OOO VERY LOW	CRITICAL
								38.9%		167 more per 1000 (from 82 fewer to 443 more)		

1 No details of allocation concealment. It was not clear whether the outcome assessors were blinded
2 The confidence interval crossed one MID point.

5.3.4. Clinical evidence tables

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Duimel-Peeters, 2007 **Title:** The effectiveness of massage with and without dimethyl sulfoxide in preventing pressure ulcers: A randomized double-blind cross-over clinical trial in patients prone to pressure ulcers. **Journal:** International Journal of Nursing Studies, 2007; 44: 1285-95. **Study type:** Multicentric randomized double-blinded cross-over trial **Sequence generation:** Throwing a dice **Allocation:**not reported **Blinding:** Not reported **Addressing incomplete outcome data:** Not reported	**Patient group:** Residents of 8 Dutch nursing homes **All patients** **Randomised N:** 79 **Completed N:** Period 1: 78 Period 2: 64 **Drop-outs:** Period 1: 1 Period 2: 15 Some participants decided not to participate any longer Some health care workers got tired of applying the treatment as accurately as possible **Gender:** 69.6% female **Age:** mean 81.3, SD 9.76, range 45-97 **Group 1 (period 1)** **Randomised N:** 31 **Completed N:** 31	**Group 1:** A 2–3-min massage of the coccyx, both heels and ankles with an indifferent cream (Cremor vaselini cetomacrogolis FNA; 'Vaseline'). This procedure was repeated every 6 h for 4 weeks **Group 2:** A 2–3-min massage of the coccyx, both heels and ankles with a dimethyl sulfoxide (DMSO) cream (5%), This procedure was repeated every 6 h for 4 weeks **Group 3:** position change only **All groups:** 30° position change	**Outcome 1:** Incidence of PU (%/period of 4 weeks) in period 1 Incidence of PU (%/period of 4 weeks) in period 2	**Group 1:** Period 1: 13/31 (41.9%) Period 2: 3/22 (13.6%) **Group 2:** Period 1: 18/29 (62.1%) Period 2: 3/25 (12.0%) **Group 3:** Period 1: 7/18 (38.9%) Period 2: 1/17 (5.9%) Period 1 P value=0.189 Period 2 P value=0.726 **Period 1:** Treatment 1 **OR:** 1.135 **95% CI:** **P value:** 0.834 Treatment 2: **OR:** 2.571 **95% CI:** **P value:** 0.126	**Funding:** none reported **Limitations:** Underpowered Randomization process by throwing a dice for 2 of the 3 interventions. Unclear allocation concealment Not clear whether outcome assessors were blinded Relatively high dropout rate in period 2 **Additional outcomes:** KM survival curves. Massaging with the indifferent cream or only changing of positions seemed to result in better pressure ulcer free prognosis than being massaged with the DMSO cream. As times goes on, the dashed and bold curves appear to grow further

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical analysis: Differences in characteristics between patients in the various treatment groups were tested for each period with Chi-square tests for categorical data and t-tests for continuous data. Mann–Whitney and Kruskal–Wallis tests were used because of non-normality of some variables. Frequency tables for the outcome variable were constructed for each treatment period. Logistic regression was used to examine the results of each treatment in terms of pressure ulcer prevention. To correct for possible confounding variables, the following covariates were added (together and separately): length,	**Dropouts:** 0 **Age:** not reported **Gender (m/f):** not reported **Other relevant patient characteristics:** none **Group 2 (period 1)** **Randomised N:** 29 **Completed N:** 29 **Dropouts:** 0 **Age:** not reported **Gender (m/f):** Not reported **Other relevant patient characteristics:** none **Group 3 (period 1)** **Randomised N:** 18 **Completed N:** 18 **Dropouts:** 0 **Age:** not reported **Gender (m/f):** Not reported **Other relevant patient characteristics:** none			**Period 2:** Treatment 1 **OR:** 2.526 **95% CI:** **P value:** 0.441 Treatment 2: **OR:** 2.182 **95% CI:** **P value:** 0.516	apart (until day 18), suggesting that the beneficial effects of only changing position relative to massaging with a DMSO-cream increase as treatment continued for a longer period. However, beyond day 18, the three treatments tended to have the same effects. **Notes:** none

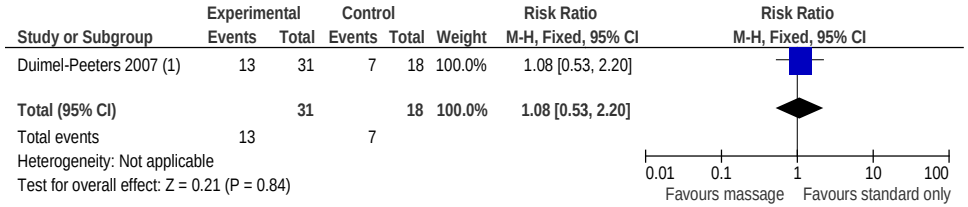
Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
weight, body mass index (BMI), length of stay on the ward (in months), age, sex, incontinence level, type of pressure-relieving cushions used and use of other preventive methods. Non-significant covariates were removed using backward deletion. Kaplan–Meier curves were constructed to obtain a clearer representation of the survival prognosis for each treatment. Baseline differences: Patients were not significantly different across periods with respect to age, sex, length, weight, BMI, length of stay on the ward, incontinence level, type of pressure-relieving cushions used and use of other preventive methods. **Study power/sample size:**	**Group 1 (period 2)** **Randomised N:** 28 **Completed N:** 22 **Dropouts:** 6 **Age:** not reported **Gender (m/f):** not reported **Other relevant patient characteristics:** none **Group 2 (period 2)** **Randomised N:** 27 **Completed N:** 25 **Dropouts:** 2 **Age:** not reported **Gender (m/f):** Not reported **Other relevant patient characteristics:** none **Group 3 (period 2)** **Randomised N:** 24 **Completed N:** 17 **Dropouts:** 7 **Age:** not reported **Gender (m/f):**				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
No a priori sample size calculation **Setting:** Dutch nursing homes **Length of study:** 4 weeks in period 1 4 weeks in period 2 2 weeks wash-out period between periods 1 and 2 **Assessment of PUs:** Braden scale to assess PU risk (cutoff point of 20) PU were graded according to the four-grade system of the European Pressure Ulcer Advisory Panel using a transparent disk. Because of the reversibility of grade I ulcers, these ulcers were only recorded as pressure ulcers if they were still present after 4 h and if two external observers confirmed the nurse's rating of grade I. A transparent disk	Not reported **Other relevant patient characteristics:** none **Inclusion criteria:** 1) have a light skin colour, 2) have resided in a long-stay ward of a nursing home for more than two months 3) rest on an anti-pressure ulcer mattress (i.e. poly urethane mattress or equivalent), 4) be willing to give informed consent or have this provided by their relative/legal representative 5) to be at high risk of developing pressure ulcers according to the Braden scale using a cut-off point of 20. **Exclusion criteria:** 1) already being treated with massage for another medical				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
with a diameter of 6.5 cm was used to assess local redness. This involved first releasing the pressure on the body part, for example by changing the patient's position. If the local redness persisted after 10min, when pushing the convex lens against the skin, the grade 1 pressure ulcer was confirmed. **Multiple ulcers:** The outcome variable development of PU or not regardless of the number of PU	indication (and it was not possible to end this treatment) 2) undergoing surgery in the near future or had undergone surgery less than two weeks previously 3) had pressure ulcers already present at the coccyx, heels or ankles (the only places that were massaged in this research 4) expected to have short length of stay 5) a short life expectancy (<10 months).				

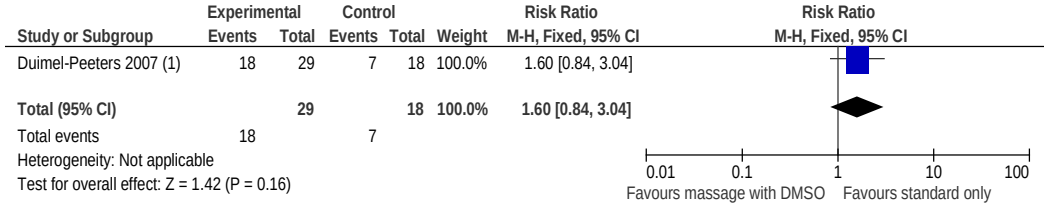
5.3.5. *Forest plots*

Figure 2 – Incidence of pressure ulcers for comparison: massage with indifferent cream + position change versus position change only



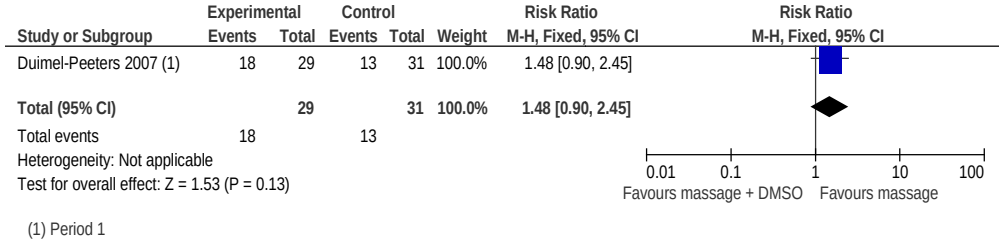
(1) Period 1

Figure 3 – Incidence of pressure ulcers for comparison: massage with DMSO cream + position change versus position change only



(1) Period 1

Figure 4 – Incidence of pressure ulcers for comparison: massage with DMSO cream + position change versus massage with indifferent cream + position change.



(1) Period 1

6. REPOSITIONING

6.1. Review protocol

Table 1 – Protocol review question

Protocol	Repositioning
Review question	How and at what frequency should repositioning be undertaken for the prevention of pressure ulcers?
Population	Individuals of all ages in all settings
Intervention	• Repositioning technique • Frequency of repositioning • Different positions (e.g. 90-degree lateral rotation, 30 degree tilt) Devices included for repositioning: • Profiling bed • Tilt in space chairs
Comparison	• No repositioning • Different frequencies of repositioning • Different positions for repositioning
Outcomes	**Critical outcomes for decision-making:**

Protocol	Repositioning
	• Proportion of participants developing new pressure ulcers (dichotomous outcome)(describe different categories of ulcer) **Important outcomes:** • Patient acceptability • Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital or other healthcare setting (continuous data) • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised o Short-form health survey (SF36) o Manchester Short Assessment of Quality of Life o EQ-5D o WHOQOL BREF o Cardiff HRQoL tool o HUI o Pressure ulcer quality of life (Gorecki)
Study design	• High quality systematic reviews of RCTs and/or RCTs only. • Cochrane reviews will be included if they match our inclusion criteria and have appropriate assumptions for missing data such as available case analysis or ITT (with the appropriate assumptions) • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies with outcomes that do not involve pressure ulcers • Abstracts unless no RCTs are found • Non-English language papers
Search strategy	**The databases to be searched are:** • Medline, Embase, Cinahl, the Cochrane Library. • All years. • Studies will be restricted to English language only

Protocol	Repositioning
The review strategy	**How will individual PICO characteristics be combined in a meta-analysis?:** • Population – any population will be combined for meta-analysis except for different strata. • Intervention – different types of frequency will be meta-analysed, different positions will be meta-analysed. • Outcomes – single side effects • Study design – randomised and quasi-randomised studies will be meta-analysed together. Blinded and unblinded studies will be meta-analysed together. Crossover trials will be meta-analysed together with parallel trials • Unit of analysis – patients, clusters (hospital wards), individual pressure ulcers – for those where patients are the unit of analysis and the patient has multiple ulcers it should be the first pressure ulcer occurring (describe different categories of ulcer). • Describe which support surfaces are used. • Minimum duration of treatment = no minimum, but would expect at least a fortnight before they show improvements. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use available case analysis for dealing with missing data if there is a 10% differential or higher between the groups or if the missing data is higher than the event rate, if cannot work out the available case analysis will take the author's data.. • MIDs: 0.75 to 1.25 for dichotomous variables and 0.5 x standard deviation for continuous variables.
Analysis	**Strata** – where included studies are split up at outset as separate reviews (dissimilar groups and we need to be confident that the intervention will work very differently in the two (or more) strata. The GDG will make separate recommendations on these. **The following groups will be considered separately as strata if data are present:** • Children (neonates, infants, children) and adults • People with neurological impairment or spinal cord damage or injury • Self repositioning versus manual repositioning versus repositioning by a device • People with sensory impairment

Protocol	Repositioning
	Subgroup analysis – combining all the studies together initially and then looking at any inconsistency between studies on the basis of pre-defined subgroups. **The following groups will be considered separately as subgroups (if there is heterogeneity):** • different risk stratification • different clinical populations
Notes	Where have said 'describe' or 'descriptive' this will be noted in the summary table.

6.2. search Strategy

6.2.1. Search filters

Table 2 – Search filters in OVID Medline

Search strategy	Repositioning		Results
Date	27th Mar 2012		
Database	Medline-Ovid		
Search strategy	1	pressure ulcer/	8802
	2	decubit*.ti,ab.	3830
	3	(pressure adj (sore* or ulcer* or damage)).ti,ab.	5969
	4	(bedsore* or bed-sore*).ti,ab.	494
	5	(incontinen* adj2 dermatitis).ti,ab.	49
	6	((moist* or friction or shear) adj2 (sore* or ulcer* or damage or wound* or injur* or lesion*)).ti,ab.	614
	7	or/1-6	13334
	8	limit 7 to english language	10621
	9	exp posture/	56402
	10	exp patient positioning/	689
	11	"moving and lifting patients"/	160
	12	(re-position* or reposition*).ti,ab.	9322
	13	(mobilis* or mobiliz*).ti,ab.	53398

Search strategy	Repositioning		Results
	14	(turn* adj5 (patient* or interval* or frequen*)).ti,ab.	6913
	15	or/9-14	125576
	16	8 and 15	1219
	17	randomized controlled trial.pt.	317876
	18	controlled clinical trial.pt.	83345
	19	randomi#ed.ab.	278870
	20	placebo.ab.	131961
	21	drug therapy.fs.	1492734
	22	randomly.ab.	171910
	23	trial.ab.	241007
	24	groups.ab.	1128651
	25	or/17-24	2856539
	26	Clinical Trials as topic.sh.	157206
	27	trial.ti.	99919
	28	or/17-20,22,26-27	777187
	29	Meta-Analysis/	31028
	30	Meta-Analysis as Topic/	11703
	31	(meta analy* or metanaly* or metaanaly*).ti,ab.	40322
	32	((systematic* or evidence*) adj2 (review* or overview*)).ti,ab.	48100
	33	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.	19344
	34	(search strategy or search criteria or systematic search or study selection or data extraction).ab.	20846
	35	(search* adj4 literature).ab.	18952
	36	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.	59408
	37	cochrane.jw.	7644
	38	or/29-37	140085
	39	28 or 38	877198
	40	16 and 39	154
	41	letter/	

Search strategy	Repositioning		Results
	42	editorial/	745026
	43	news/	297341
	44	exp historical article/	142441
	45	Anecdotes as Topic/	300400
	46	comment/	4103
	47	case report/	484718
	48	(letter or comment*).ti.	1546366
	49	or/41-48	82026
	50	randomized controlled trial/ or random*.ti,ab.	2995614
	51	49 not 50	661256
	52	animals/ not humans/	2980844
	53	exp Animals, Laboratory/	3553260
	54	exp Animal Experimentation/	655846
	55	exp Models, Animal/	5130
	56	exp Rodentia/	358217
	57	(rat or rats or mouse or mice).ti.	2423006
	58	or/51-57	1019659
	59	40 not 58	7043844
			154

Table 3 – Search filters in Embase

Search strategy	Repositioning		Results
Date	27th Mar 2012		
Database	Embase		
Search strategy	1	decubitus/	12141
	2	decubit*.ti,ab.	4617
	3	(pressure adj (sore* or ulcer* or damage)).ti,ab.	6831
	4	(bedsore* or bed-sore*).ti,ab.	631
	5	((moist* or friction or shear) adj2 (sore* or ulcer* or damage or wound* or injur* or lesion*)).ti,ab.	737
	6	(incontinen* adj2 dermatitis).ti,ab.	51
	7	or/1-6	16424
	8	limit 7 to english language	12654
	9	exp position/	83846
	10	patient positioning/	10602
	11	patient lifting/	92
	12	mobilization/	12892
	13	(re-position* or reposition*).ti,ab.	10628
	14	(mobilis* or mobiliz*).ti,ab.	61541
	15	(turn* adj5 (patient* or interval* or frequen*)).ti,ab.	8307
	16	or/9-15	178268
	17	8 and 16	1711
	18	random*.ti,ab.	677053
	19	factorial*.ti,ab.	17713
	20	(crossover* or cross over*).ti,ab.	57802
	21	((doubl$ or singl$) adj blind$).ti,ab.	130691
	22	(assign* or allocat* or volunteer* or placebo*).ti,ab.	526036
	23	crossover procedure/	31644
	24	double blind procedure/	102550
	25	single blind procedure/	14668

Search strategy	Repositioning		Results
	26	randomized controlled trial/	295607
	27	or/18-26	1123098
	28	systematic review/	46604
	29	meta-analysis/	58505
	30	(meta analy* or metanaly* or metaanaly*).ti,ab.	51361
	31	((systematic or evidence) adj2 (review* or overview*)).ti,ab.	54624
	32	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.	23210
	33	(search strategy or search criteria or systematic search or study selection or data extraction).ab.	24799
	34	(search* adj4 literature).ab.	22510
	35	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.	70467
	36	((pool* or combined) adj2 (data or trials or studies or results)).ab.	29479
	37	cochrane.jw.	11040
	38	or/28-37	210071
	39	letter.pt. or letter/	755399
	40	note.pt.	462400
	41	editorial.pt.	389343
	42	case report/ or case study/	1772519
	43	(letter or comment*).ti.	132536
	44	or/39-43	3256668
	45	randomized controlled trial/ or random*.ti,ab.	752555
	46	44 not 45	3232924
	47	animal/ not human/	1267429
	48	nonhuman/	3772499
	49	exp Animal Experiment/	1486602
	50	exp experimental animal/	366425
	51	animal model/	619749
	52	exp Rodent/	2423085
	53	(rat or rats or mouse or mice).ti.	

Search strategy	Repositioning		Results
	54	or/46-53	1073325
	55	27 or 38	8598716
	56	17 and 55	1271496
	57	56 not 54	298
			286

Table 4 – Search filters in CINAHL

Search strategy	Repositioning		Results
Date	27th Mar 2012		
Database	CINAHL		
Search strategy	S19	s17 not s18	156
	S18	PT anecdote or PT audiovisual or PT bibliography or PT biography or PT book or PT book review or PT brief item or PT cartoon or PT commentary or PT computer program or PT editorial or PT games or PT glossary or PT historical material or PT interview or PT letter or PT listservs or PT masters thesis or PT obituary or PT pamphlet or PT pamphlet chapter or PT pictorial or PT poetry or PT proceedings or PT "questions and answers" or PT response or PT software or PT teaching materials or PT website	979974
	S17	S7 and S15 Limiters – English Language; Exclude MEDLINE records	243
		Search modes – Boolean/Phrase	
	S16	S7 and S15	734
	S15	S8 or S9 or S10 or S11 or S12 or S13 or S14	20951
	S14	turn* N5 frequen*	112
	S13	turn* N5 interval*	29
	S12	turn* N5 patient*	1043
	S11	mobilis* or mobiliz*	4063
	S10	re-position* or reposition*	975
	S9	(MH "Posture+")	9597
	S8	(MH "Patient Positioning+")	5903
	S7	S1 or S2 or S3 or S4 or S5 or S6	9430

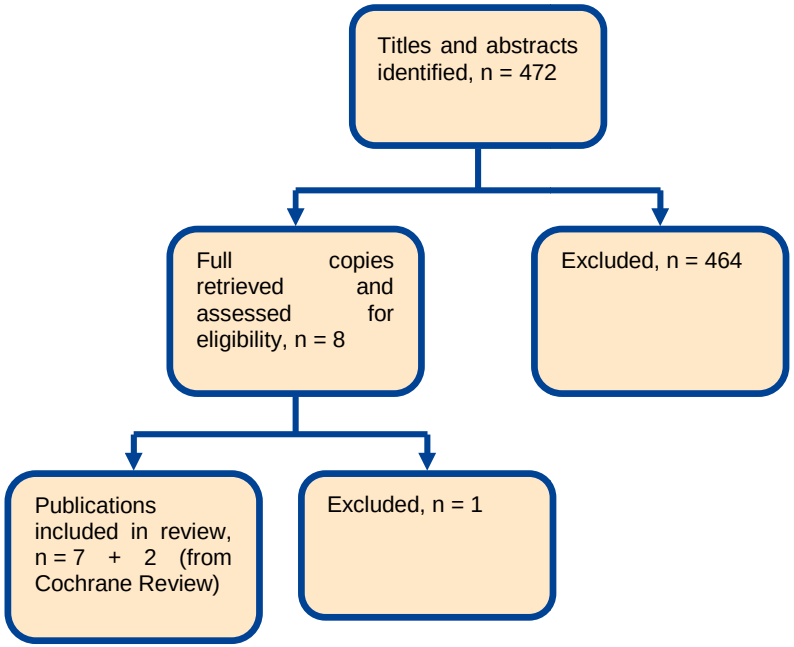
Search strategy	Repositioning		Results
	S6	((moist* or friction or shear) and (sore* or ulcer* or damage or wound* or injur* or lesion*))	1336
	S5	incontinen* n2 dermatitis	65
	S4	bedsore* OR bed-sore*	152
	S3	pressure n1 sore* OR pressure n1 ulcer* OR pressure n1 damage*	8135
	S2	decubit*	467
	S1	(MH "Pressure Ulcer")	7399

Table 5 – Search filters in Cochrane

Search strategy	Repositioning		Results
Date	27th Mar 2012		
Database	Cochrane		
Search strategy	#1	MeSH descriptor Pressure Ulcer explode all trees	480
	#2	decubit*:ti,ab,kw	341
	#3	(pressure near/2 (sore* or ulcer* or damage)):ti,ab,kw	818
	#4	(bedsore* or bed-sore*):ti,ab,kw	32
	#5	(incontinen* near/2 dermatitis):ti,ab,kw	10
	#6	((moist* or friction or shear) near/2 (sore* or ulcer* or damage or wound* or injur* or lesion*)):ti,ab,kw	62
	#7	(#1 OR #2 OR #3 OR #4 OR #5 OR #6)	1151
	#8	MeSH descriptor Posture explode all trees	3009
	#9	MeSH descriptor Patient Positioning explode all trees	39
	#10	MeSH descriptor Moving and Lifting Patients explode all trees	8
	#11	(mobilis* or mobiliz*):ti,ab,kw	2525
	#12	(re-position* or reposition*):ti,ab,kw	413
	#13	(turn* near/5 (patient* or interval* or frequen*)):ti,ab,kw	477
	#14	(#8 OR #9 OR #10 OR #11 OR #12 OR #13)	6328
	#15	(#7 AND #14)	138

6.2.2. Selection of articles

Figure 1 – Flow diagram of clinical article selection



6.2.3. Excluded clinical studies

Table 6 – Studies excluded from the clinical review

Reference	Reason for exclusion
Defloor 2005	Sub-population of included trial (Defloor 2005B)

6.3. Clinical evidence

6.3.1. Search strategy

Nine studies were included in the review.[64],[65],[66],[67,68,69,70],[71],[72]

6.3.2. Clinical evidence

Evidence from these are summarised in the clinical GRADE evidence profile. We searched for randomised trials assessing effectiveness of repositioning for the prevention of pressure ulcers in patients of all ages in any setting.

- Seven randomised trials (three cluster randomised trials [64],[65],[66] and six parallel RCTs [67,68,69,70],[71],[72] were identified.
- Included population varied from geriatric patients to critically ill infants and children, all assessed in different inpatient hospital settings. Four trials included geriatric patients with a mean age of 80 years, one trial included acute inpatient with a mean age of 70 years and the sixth trial included infants and children (Table 1). Two studies were of turning tables, were included in the Cochrane Review Support surfaces for the prevention of pressure ulcers[73], they were deemed more relevant to the repositioning review than the devices for prevention review.
- Studies looked at different reposition techniques applied at different time intervals. For this purpose of this review, the trials have been grouped and analysed in five different comparisons:
  - Repositioning (frequent turning with or without the use of pressure reducing mattress) versus no repositioning (standard care without turning). [64]
  - Different frequencies of repositioning – [64,66,68]
  - Different positions for repositioning – 30° tilt position versus 90° lateral and supine position [65,72] and semi recumbent position (i.e., 45° position of the head and back) versus standard care (supine position) [69]
  - Different positions for repositioning – prone/semi recumbent positioning versus control supine positioning [67]

    Turning tables for repositioning – [105,106]
- Trials reported the incidence of pressure ulcers (proportion of participants developing pressure ulcers, Grades I-IV)[65],[66],[72], the 'time to pressure ulcer development' and patient tolerability.

Included studies had varying time periods (ranging from one night to 5 weeks). Cluster randomised trials and trials including children[67] have been analysed separately.

6.3.3. Summary table

Table 7 – Summary of studies included in the review

Study	Intervention/comparator	Population	Outcomes	Study length
Defloor 2005 [64]	2, 3 hourly turning scheme on a standard institutional mattress and 4, 6-hourly turning scheme on a pressure reducing mattress. The turning schemes consisted in alternating a semi-recumbent position with a lateral position. Standard care involving preventive nursing care based on clinical judgement of the nurses. Preventive measures used were water mattresses, alternating mattresses, sheepskins and gel cushions. Preventive care did not include turning.	Geriatric nursing home patients. Mean age: 84.4 (SD 8.33) years, The mean Braden score was 13.2 (SD 2.36) and the mean Norton score was 10.0 (SD 1.96). Patients were considered to be at risk to develop pressure ulcers.	Development of Non-blanchable erythema: redness which cannot be pressed away with the thumb and which lasts longer than I day (GRADE I in the Agency of Health Care Policy and Research (AHCPR). Development of pressure ulcer lesion: blistering, superficial or deep pressure ulcer (grades II, III and IV in the AHCPR classification).	4 weeks.
Fineman 2006 [67]	Prone positioning: a 2-hr cyclic rotation from full prone to right lateral/prone to full prone to left lateral/prone and then to full prone. Supine positioning. All patients were maintained on standard hospital beds. Individually sized head, chest, pelvic, distal femoral and lower limb cushions were created using pressure-relieving material.	One hundred and two paediatric patients with acute lung injury.	Proportion of people that developed stage II or greater pressure ulcers.	28-days

Study	Intervention/comparator	Population	Outcomes	Study length
Gentilello 1988[70]	Kinetic treatment table (rotates through an arc of 124 degrees every 7 minutes) vs conventional beds (patients turned in conventional fashion every 2 hours)	Critically ill patients in surgical ICU immobilised because of head injury, spinal injuries or traction	Incidence of pulmonary complications; incidence of pressure ulcers	Duration of follow-up unclear
Moore 2011 [65]	Repositioning by using the 30° tilt (left side, back, right side, back) every three hours during the night. Repositioning every six hours at night, using 90° lateral rotation. Both groups were nursed during the day according to planned care. Pressure redistribution devices in current use on the bed and on the chair was continued. Patients' positions were altered every 2-3 hours.	Participants from 12 long-term care of the older person hospital settings. Seventy-nine percent were women. Eighty-seven per cent were chair-fast and 77% had very limited activity. Participants were at risk of developing pressure ulcers (using the Braden pressure ulcer risk assessment scale).	Proportion of people developing pressure ulcers (Grades I – IV). Time to pressure ulcer development.	4 weeks
Smith 1990 [68]	Small shift in body (adjusting the position of a limb or body part by placing a small rolled towel to designated areas). Shifts were completed in less than one minute. Sites for placement of rolled towel were under each arm, shoulder, hip, and leg. Both groups received normal, routine care and were turned every two hours.	Elderly patients. Participants ranged in age from 65 years to 91 years with a mean age of 80.55. Fourteen participants were women and five were men.	Proportion of people developing pressure ulcers (Grades II and higher)	2 weeks
Summer 1989[71]	Kinetic treatment table vs routine 2-hourly turning ICU conventional beds	Patients admitted to ICU	Incidence of pressure ulcers	Duration of follow-up unclear

Study	Intervention/comparator	Population	Outcomes	Study length
Vanderwee 2007 [66]	4 hours in a semi-recumbent 30° position and 2 hours in a lateral position 30°. Repositioning was the same as above but with equal time intervals of 4 hours in lateral 30° as in semi-recumbent 30° position. Patients in both groups were lying on a visco-elastic foam overlay mattress.	Geriatric nursing home patients. Mean age: 84.4 (SD 8.33) years, the mean Braden score was 13.2 (SD 2.36) and the mean Norton score was 10.0 (SD 1.96).	Proportion of people developing pressure ulcers (Grades II and higher). Time to developing pressure ulcers.	5 weeks
Van Nieuwenhoven 2006 [69]	Semi recumbent position. Aim was to achieve 45° position of the head and back. The 45° position was not achieved for 85% of the study time, and these patients more frequently changed position than supine positioned patients. Standard care (supine position)	221 adult patients admitted to four ICUs in three university hospitals in the Netherlands. 112 randomised to semi recumbent positioning and 109 to supine positioning. Mean age of 63.9 years	Proportion of patients developing ulcer (Grades I-IV)	7 days
Young 2004 [72]	30° tilt position during the night. 90° side-lying position during the night.	Acute inpatient in a district general hospital. Mean age of 70.3 years. Patients were at risk of developing pressure ulcers (confirmed by a Waterlow risk assessment score above ten).	Proportion of people developing pressure ulcers (Grade 1: non-blanching erythema). Patient tolerability.	One night

6.3.4. GRADE-tables

Frequencies of repositioning

Table 8 – Clinical evidence profile: Repositioning (Frequent turning or the use of pressure reducing mattress) versus no repositioning (standard care without turning).

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Repositioning	No repositioning	Relative (95% CI)	Absolute		
Proportion of people developing pressure ulcer (Grade I: Non-blanching Erythema) – 2-h turning scheme on a standard institutional mattress (follow-up 4 weeks)												
1 Deflor (2005)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	30/63 (47.6%)	220/511 (43.1%)	RR 1.11 (0.84 to 1.46)	47 more per 1000 (from 69 fewer to 198 more)	⊕⊕OO VERY LOW	CRITICAL
								43.1%		47 more per 1000 (from 69 fewer to 198 more)		
Proportion of people developing pressure ulcer (Grade I: Non-blanching Erythema) – 3-h turning scheme on a standard institutional mattress (follow-up 4 weeks)												
1 Deflor (2005)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	26/58 (44.8%)	220/511 (43.1%)	RR 1.04 (0.77 to 1.41)	17 more per 1000 (from 99 fewer to 177 more)	⊕⊕OO VERY LOW	CRITICAL
								43.1%		17 more per 1000 (from 99 fewer to 177 more)		
Proportion of people developing pressure ulcer (Grade I: Non-blanching Erythema) – 4-h turning + pressure reducing mattress (follow-up 4 weeks)												
1 Deflor (2005)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	Very serious[3]	none	28/66 (42.4%)	220/511 (43.1%)	RR 0.99 (0.73 to 1.33)	4 fewer per 1000 (from 116 fewer to 142 more)	⊕⊕OO VERY LOW	CRITICAL
								43.1%		4 fewer per 1000 (from 116 fewer to 142 more)		
Proportion of people developing pressure ulcer (Grade I: Non-blanching Erythema) – 6-h turning + pressure reducing mattress (follow-up 4 weeks)												
1 Deflo	randomised trials	Very seriou	no serious inconsistency	no serious indirectness	serious[2]	none	29/63 (46%)	220/511 (43.1%)	RR 1.07 (0.8 to	30 more per 1000 (from 86 fewer to 181	⊕⊕OO VERY	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Repositioning	No repositioning	Relative (95% CI)	Absolute		
or (2005)		s[1]							1.42)	more)	LOW	
								43.1%		30 more per 1000 (from 86 fewer to 181 more)		
Proportion of people developing pressure ulcer (Grade II and higher) – 2-h turning scheme on a standard institutional mattress (follow-up 4 weeks)												
1 Deflo or (2005)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	9/63 (14.3%)	220/511 (43.1%)	RR 0.33 (0.18 to 0.61)	288 fewer per 1000 (from 168 fewer to 353 fewer)	⊕⊕⊕O LOW	CRITICAL
								43.1%		289 fewer per 1000 (from 168 fewer to 353 fewer)		
Proportion of people developing pressure ulcer (Grade II and higher) – 3-h turning scheme on a standard institutional mattress (follow-up 4 weeks)												
1 Deflo or (2005)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	14/58 (24.1%)	220/511 (43.1%)	RR 0.56 (0.35 to 0.89)	189 fewer per 1000 (from 47 fewer to 280 fewer)	⊕⊕OO VERY LOW	CRITICAL
								43.1%		190 fewer per 1000 (from 47 fewer to 280 fewer)		
Proportion of people developing pressure ulcer (Grade II and higher) – 4-h turning + pressure reducing mattress (follow-up 4 weeks)												
1 Deflo or (2005)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	2/66 (3%)	220/511 (43.1%)	RR 0.07 (0.02 to 0.28)	400 fewer per 1000 (from 310 fewer to 422 fewer)	⊕⊕⊕O LOW	CRITICAL
								43.1%		401 fewer per 1000 (from 310 fewer to 422 fewer)		
Proportion of people developing pressure ulcer (Grade II and higher) – 6-h turning + pressure reducing mattress (follow-up 4 weeks)												
1 Deflo or (2005)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	10/63 (15.9%)	220/511 (43.1%)	RR 0.37 (0.21 to 0.66)	271 fewer per 1000 (from 146 fewer to 340 fewer)	⊕⊕⊕O LOW	CRITICAL
								43.1%		272 fewer per 1000 (from 147 fewer to 340 fewer)		

1 Incomplete data for 3 patients though authors claim that analysis including these patients did not change the result, uncle ar allocation concealment, mattress used was not the same for the experimental group.
2 Confidence interval crossed one MID point (0.75 to 1.25 for dichotomous outcomes)
3 Confidence interval crossed both ends of MID point (0.75 to 1.25 for dichotomous outcomes)

Table 9 – Clinical evidence profile: Different frequencies of repositioning: 2-h turning on a standard institutional mattress versus 3-h turning on a standard institutional mattress.

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	2-h turning	3-h turning	Relative (95% CI)	Absolute		
Proportion of people developing pressure ulcer (Grade I: Non-blanching Erythema) – 2-h turning on a standard institutional mattress versus 3-h turning on a standard institutional mattress (follow-up 4 weeks)												
1 Defloor (2005)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	30/63 (47.6%)	26/58 (44.8%) **44.8%**	RR 1.06 (0.72 to 1.56)	27 more per 1000 (from 126 fewer to 251 more) 27 more per 1000 (from 125 fewer to 251 more)	⊕OOO VERY LOW	CRITICAL

1 Incomplete data for 3 patients though authors claim that analysis including these patients did not change the result, uncle ar allocation concealment, mattress used was not the same for both groups.
2 Confidence interval crosses both ends of MID point (0.75 to 1.25 for dichotomous outcomes)

Table 10 – Different frequencies of repositioning: 2-h turning on a standard institutional mattress versus 4-h turning+ pressure reducing mattress

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	2-h turning	4-h turning+ pressure reducing mattress	Relative (95% CI)	Absolute		
Proportion of people developing pressure ulcer (Grade I: Non-blanching Erythema) – 2-h turning on a standard institutional mattress versus 4-h turning+ pressure reducing mattress (follow-up 4 weeks)												
1 Defloor (2005)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	Serious[2]	none	30/63 (47.6%)	28/66 (42.4%)	RR 1.12 (0.77 to 1.64)	51 more per 1000 (from 98 fewer to 272 more)	⊕⊕OO VERY LOW	CRITICAL
								42.4%		51 more per 1000 (from 98 fewer to 271 more)		

1 Incomplete data for 3 patients though authors claim that analysis including these patients did not change the result, unclear allocation concealment, mattress used was not the same for both groups.; 2 Confidence interval crosses one end of MID point (0.75 to 1.25 for dichotomous outcomes)

Table 11 – Different frequencies of repositioning: 2-h turning on a standard institutional mattress versus 6-h turning+ pressure reducing mattress

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	2-h turning	6-h turning+ pressure reducing mattress	Relative (95% CI)	Absolute		
Proportion of people developing pressure ulcer (Grade I: Non-blanching Erythema) – 2-h turning on a standard institutional mattress versus 6-h turning+ pressure reducing mattress (follow-up 4 weeks)												
1 Defloor (2005)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	30/63 (47.6%)	29/63 (46%)	RR 1.03 (0.71 to 1.5)	14 more per 1000 (from 133 fewer to 230 more) 46% 14 more per 1000 (from 133 fewer to 230 more)	⊕OOO VERY LOW	CRITICAL

1 Incomplete data for 3 patients though authors claim that analysis including these patients did not change the result, uncle ar allocation concealment, mattress used was not the same for both groups.
2 Confidence interval crosses both ends of MID point (0.75 to 1.25 for dichotomous outcomes)

Table 12 – Different frequencies of repositioning: 3-h turning on a standard institutional mattress versus 4-h turning+ pressure reducing mattress

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	3-h turning	4-h turning+ pressure reducing mattress	Relative (95% CI)	Absolute		
Proportion of people developing pressure ulcer (Grade I: Non-blanching Erythema) – 3-h turning on a standard institutional mattress versus 4-h turning+ pressure reducing mattress (follow-up 4 weeks)												
1 Defloor (2005)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	26/58 (44.8%)	28/66 (42.4%)	RR 1.06 (0.71 to 1.58)	25 more per 1000 (from 123 fewer to 246 more) 42.4% 25 more per 1000 (from 123 fewer to 246 more)	⊕OOO VERY LOW	CRITICAL

1 Incomplete data for 3 patients though authors claim that analysis including these patients did not change the result, uncle ar allocation concealment, mattress used was not the same for both groups.; 2 Confidence interval crosses both ends of MID point (0.75 to 1.25 for dichotomous outcomes)

Table 13 – Different frequencies of repositioning: 3-h turning on a standard institutional mattress versus 6-h turning+ pressure reducing mattress

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	3-h turning	6-h turning+ pressure reducing mattress	Relative (95% CI)	Absolute		
Proportion of people developing pressure ulcer (Grade I: Non-blanching Erythema) – 3-h turning on a standard institutional mattress versus 6-h turning+ pressure reducing mattress (follow-up 4 weeks)												
1 Defloor (2005)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	26/58 (44.8%)	29/63 (46%)	RR 0.97 (0.66 to 1.44)	14 fewer per 1000 (from 157 fewer to 203 more) 46% 14 fewer per 1000 (from 156 fewer to 202 more)	⊕OOO VERY LOW	CRITICAL

1 Incomplete data for 3 patients though authors claim that analysis including these patients did not change the result, unclear allocation concealment, mattress used was not the same for both groups.
2 Confidence interval crosses both ends of MID point (0.75 to 1.25 for dichotomous outcomes)

Table 14 – Different frequencies of repositioning: 4-h turning+ pressure reducing mattress versus 6-h turning+ pressure reducing mattress

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	4-h turning+ pressure reducing mattress	6-h turning+ pressure reducing mattress	Relative (95% CI)	Absolute		
Proportion of people developing pressure ulcer (Grade I: Non-blanching Erythema) – 4-h versus 6-h turning+ pressure reducing mattress (follow-up 4 weeks)												
1 Defloor (2005)	randomised trials	Serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	28/66 (42.4%)	29/63 (46%)	RR 0.92 (0.63 to 1.36)	37 fewer per 1000 (from 170 fewer to 166 more) 46% 37 fewer per 1000 (from 170 fewer to 166 more)	⊕OOO VERY LOW	CRITICAL

1 Incomplete data for 3 patients though authors claim that analysis including these patients did not change the result, unclear allocation concealment.
2 Confidence interval crosses both ends of MID point (0.75 to 1.25 for dichotomous outcomes);

Table 15 – Different frequencies of repositioning: turning 2-h in a lateral and 4-h in a supine position versus repositioning 4-hrly

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	2-h in a lateral and 4-h in a supine position	4-hrly turning	Relative (95% CI)	Absolute		
Proportion of people developing pressure ulcer (Grade II and higher) – Turning with unequal time intervals (follow-up 5 weeks)												
1 Vanderwee (2007)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	20/122 (16.4%)	24/113 (21.2%)	RR 0.77 (0.45 to 1.32)	49 fewer per 1000 (from 117 fewer to 68 more)	⊕OOO VERY LOW	CRITICAL
								21.2%		49 fewer per 1000 (from 117 fewer to 68 more)		
Time to develop a pressure ulcer												
1 Vanderwee (2007)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	N/A	Very serious[3]	-	-	-	Log rank test 1.18 (d.f 0.1), p=0.28	⊕OOO VERY LOW	IMPORTANT

1 Blinding, intention to treat analysis and allocation concealment not reported. Sample size lower than the desired (calculated) needed. ; 2 Confidence interval crosses both ends of MID point (0.75 to 1.25 for dichotomous outcomes); 3 No data could be analysed in Revman.

Table 16 – Different frequencies of repositioning: unscheduled small shifts in body position versus 2-hr turning

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	unscheduled small shifts	2-hrly turning	Relative (95% CI)	Absolute		
Proportion of people developing pressure ulcer (Grade II and higher) – Unscheduled (small) shifts in body positions (follow-up 2 weeks)												
1 Smith (1990)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	1/9 (11.1%)	1/10 (10%)	RR 1.11 (0.08 to 15.28)	11 more per 1000 (from 92 fewer to 1000 more)	⊕OOO VERY LOW	CRITICAL
								10%		11 more per 1000 (from 92 fewer to 1000 more)		

1 Blinding, intention to treat analysis and allocation concealment not reported. Sample size lower than the desired (calculated) needed, high rate of drop outs (difference between control and experimental greater than 10%)
2 Confidence interval crosses both ends of MID point (0.75 to 1.25 for dichotomous outcomes)

Table 17 – Different frequencies of repositioning: 2-h turning on a standard institutional mattress versus 3-h turning on a standard institutional mattress

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	2-h turning	3-h turning	Relative (95% CI)	Absolute		
Proportion of people developing pressure ulcer (Grade II and higher) – 2-h turning on a standard institutional mattress versus 3-h turning on a standard institutional mattress (follow-up 4 weeks)												
1 Defloor (2005)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	9/63 (14.3%)	14/58 (24.1%)	RR 0.59 (0.28 to 1.26)	99 fewer per 1000 (from 174 fewer to 63 more)	⊕OOO VERY LOW	CRITICAL
								24.1%		99 fewer per 1000 (from 174 fewer to 63 more)		

1 Incomplete data for 3 patients though authors claim that analysis including these patients did not change the result, unclear allocation concealment. Mattress used was not the same for both groups.
2 Confidence interval crosses both ends of MID point (0.75 to 1.25 for dichotomous outcomes)

Table 18 – Different frequencies of repositioning: 2-h turning on a standard institutional mattress versus 4-h turning+ pressure reducing mattress

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	2-h turning	4-h turning+ pressure reducing mattress	Relative (95% CI)	Absolute		
Proportion of people developing pressure ulcer (Grade II and higher) – 2-h turning on a standard institutional mattress versus 4-h turning+ pressure reducing mattress (follow-up 4 weeks)												
1 Defloor (2005)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	Serious[2]	none	9/63 (14.3%)	2/66 (3%)	RR 4.71 (1.06 to 20.98)	112 more per 1000 (from 2 more to 605 more)	⊕⊕OO VERY LOW	CRITICAL
								3%		111 more per 1000 (from 2 more to 599 more)		

1 Incomplete data for 3 patients though authors claim that analysis including these patients did not change the result, unclear allocation concealment, mattress used was not the same for both groups.; 2 Confidence interval crosses one end of MID point (0.75 to 1.25 for dichotomous outcomes)

Table 19 – Different frequencies of repositioning: 2-h turning on a standard institutional mattress versus 6-h turning + pressure reducing mattress

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	2-h turning	6-h turning+ pressure reducing mattress	Relative (95% CI)	Absolute		
Proportion of people developing pressure ulcer (Grade II and higher) – 2-h turning on a standard institutional mattress versus 6-h turning+ pressure reducing mattress (follow-up 4 weeks)												
1 Defloor (2005)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	9/63 (14.3%)	10/63 (15.9%)	RR 0.9 (0.39 to 2.06)	16 fewer per 1000 (from 97 fewer to 168 more)	⊕OOO VERY LOW	CRITICAL
								15.9%		16 fewer per 1000 (from 97 fewer to 169 more)		

1 Incomplete data for 3 patients though authors claim that analysis including these patients did not change the result, unclear allocation concealment, mattress used was not the same for both groups.; 2 Confidence interval crosses both ends of MID point (0.75 to 1.25 for dichotomous outcomes

Table 20 – Different frequencies of repositioning: 3-h turning on a standard institutional mattress versus 4-h turning+ pressure reducing mattress

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	3-h turning	4-h turning+ pressure reducing mattress	Relative (95% CI)	Absolute		
Proportion of people developing pressure ulcer (Grade II and higher) – 3-h turning on a standard institutional mattress versus 4-h turning+ pressure reducing mattress (follow-up 4 weeks)												
1 Defloor (2005)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	Serious[2]	none	14/58 (24.1%)	2/66 (3%)	RR 7.97 (1.89 to 33.59)	211 more per 1000 (from 27 more to 988 more)	⊕⊕OO VERY LOW	CRITICAL
								3%		209 more per 1000 (from 27 more to 978 more)		

1 Incomplete data for 3 patients though authors claim that analysis including these patients did not change the result, unclear allocation concealment, mattress used was not the same for both groups.
2 Confidence interval crosses one end of MID point (0.75 to 1.25 for dichotomous outcomes)

Table 21 – Different frequencies of repositioning: 3-h turning on a standard institutional mattress versus 6-h turning+ pressure reducing mattress

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	3-h turning	6-h turning+ pressure reducing mattress	Relative (95% CI)	Absolute		
Proportion of people developing pressure ulcer (Grade II and higher) – 3-h turning on a standard institutional mattress versus 6-h turning+ pressure reducing mattress (follow-up 4 weeks)												
1 Defloor (2005)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	14/58 (24.1%)	10/63 (15.9%)	RR 1.52 (0.73 to 3.15)	83 more per 1000 (from 43 fewer to 341 more)	⊕OOO VERY LOW	CRITICAL
								15.9%		83 more per 1000 (from 43 fewer to 342 more)		

1 Incomplete data for 3 patients though authors claim that analysis including these patients did not change the result, unclear allocation concealment, mattress used was not the same for both groups.
2 Confidence interval crosses both ends of MID point (0.75 to 1.25 for dichotomous outcomes)

Table 22 – Different frequencies of repositioning: 4-h turning+ pressure reducing mattress versus 6-h turning+ pressure reducing mattress

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	4-h turning+ pressure reducing mattress	6-h turning+ pressure reducing mattress	Relative (95% CI)	Absolute		
Proportion of people developing pressure ulcer (Grade II and higher) – 4-h versus 6-h turning+ pressure reducing mattress (follow-up 4 weeks)												
1 Defloor (2005)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	Serious[2]	none	2/66 (3%)	10/63 (15.9%)	RR 0.19 (0.04 to 0.84)	129 fewer per 1000 (from 25 fewer to 152 fewer)	⊕⊕OO LOW	CRITICAL
								15.9%		129 fewer per 1000 (from 25 fewer to 153 fewer)		

1 Incomplete data for 3 patients though authors claim that analysis including these patients did not change the result, uncle ar allocation concealment.
2 Confidence interval crosses one end of MID point (0.75 to 1.25 for dichotomous outcomes)

Table 23 – Clinical evidence profile: Different positions for repositioning – 30° tilt position versus 90° lateral and supine position (control)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	30° tilt position	90° lateral and supine position	Relative (95% CI)	Absolute		
Proportion of people developing pressure ulcer (Grades I – IV) – 30 degree tilt 3 hourly- (cluster) (follow-up 4 weeks)												
1 Moore (2011)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	3/99 (3%)	13/114 (11.4%)	RR 0.27 (0.08 to 0.91)	83 fewer per 1000 (from 10 fewer to 105 fewer)	⊕OOO VERY LOW	CRITICAL
								11.4%		83 fewer per 1000 (from 10 fewer to 105 fewer)		
Proportion of people developing pressure ulcer (Grade I: non-blanching erythema) – 30 degree tilt – (follow-up 1 night)												
1 Young (2004)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	very serious[4]	none	3/23 (13%)	2/23 (8.7%)	RR 1.5 (0.28 to 8.16)	43 more per 1000 (from 63 fewer to 623 more)	⊕OOO VERY LOW	CRITICAL
								8.7%		43 more per 1000 (from 63 fewer to 623 more)		
Mean time to pressure ulcer development												
1 Moore (2011)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	N/A	Very serious[5]	26 days (range 3 days)	17 days (range 24 days)	-	-	⊕OOO VERY LOW	IMPORTANT
Tolerability												
1 Young (2004)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	N/A	very serious[6]	5/23 (22%)	-	-	-	⊕OOO VERY LOW	IMPORTANT

1 Blinding not reported, sample size was lower than the desired (calculated) power needed.
2 Confidence interval crossed one MID point (0.75 to 1.25 for dichotomous outcomes)
3 Small sample size
4 Confidence interval crosses both ends of MID (0.75 to 1.25 for dichotomous outcomes)
5 Details could not be analysed in Revman.
6 Details only given for one arm of the trial.

Table 24 – Clinical evidence profile: Different positions for repositioning – semi recumbent position (45° position of the head and back) versus standard care (supine position)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Semi recumbent position (45 degree position of the head and back)	Supine position	Relative (95% CI)	Absolute		
Proportion of people developing pressure ulcers (Grade I-IV) – semi recumbent position (45° position of the head and back) (follow-up 7 days)												
1 Van Nieuwenhoven (2006)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[1]	none	31/112 (27.7%)	30/109 (27.5%)	RR 1.01 (0.66 to 1.54)	3 more per 1000 (from 94 fewer to 149 more)	⊕⊕OO LOW	CRITICAL
								27.5%		3 more per 1000 (from 93 fewer to 148 more)		

1 Confidence interval crossed both ends of MID points (0.75 to 1.25 for dichotomous outcomes).

Comparison between kinetic beds and conventional beds

Table 25 – Kinetic treatment table vs standard care for pressure ulcer prevention

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Kinetic treatment table	Standard care	Relative (95% CI)	Absolute		
Pressure ulcer incidence												
2 Gentilello(1988) Summer (1989)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	9/70 (12.9%)	10/81 (12.3%)	RR 1.23 (0.57 to 2.65)	28 more per 1000 (from 53 fewer to 204 more)	⊕OOO VERY LOW	Critical
Time in hospital (days)												
1 Summer (1989)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	none	very serious[3]	6.7 days	11.6 days	-	-	⊕OOO VERY LOW	Important

1 Unclear allocation concealment and blinding (Gentilello 1988, Summer 1989) and unclear addressing of incomplete outcome data. (Gentilello 1988). Unclear if similar at baseline (Summer 1989).; 2 Confidence interval crossed both MIDs.; 3 Not enough data for analysis in Revman.
4 Patients in Summer (1989) randomised only obtunded or unconscious patients (although this was not the initial intention) and Gentillello (1988) included patients immobilised from head injury, spinal injuries or traction. Most patients would not be able to reposition themselves so the two studies were meta-analysed together.

Table 26 – Critically ill infants and children: different positions for repositioning – prone positioning versus control supine positioning (control)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Prone positioning	Supine positioning	Relative (95% CI)	Absolute		
Proportion of people developing (Grade II and higher) – Prone positioning (2 hour cyclic rotation) (follow-up 28 days)												
1 Finem an (2006)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	10/51 (19.6%)	8/51 (15.7%) 15.7%	RR 1.25 (0.54 to 2.91)	39 more per 1000 (from 72 fewer to 300 more) 39 more per 1000 (from 72 fewer to 300 more)	⊕OOO VERY LOW	CRITICAL

1 Blinding of any kind not reported
2 Confidence interval crosses both ends of MID (0.75 to 1.25 for dichotomous outcomes)

6.3.5. Forest plots

Figure 2 – Repositioning (Frequent turning or the use of pressure reducing mattress) versus no repositioning (standard care without turn ing): Non-blanching erythema (Grade I pressure ulcer)

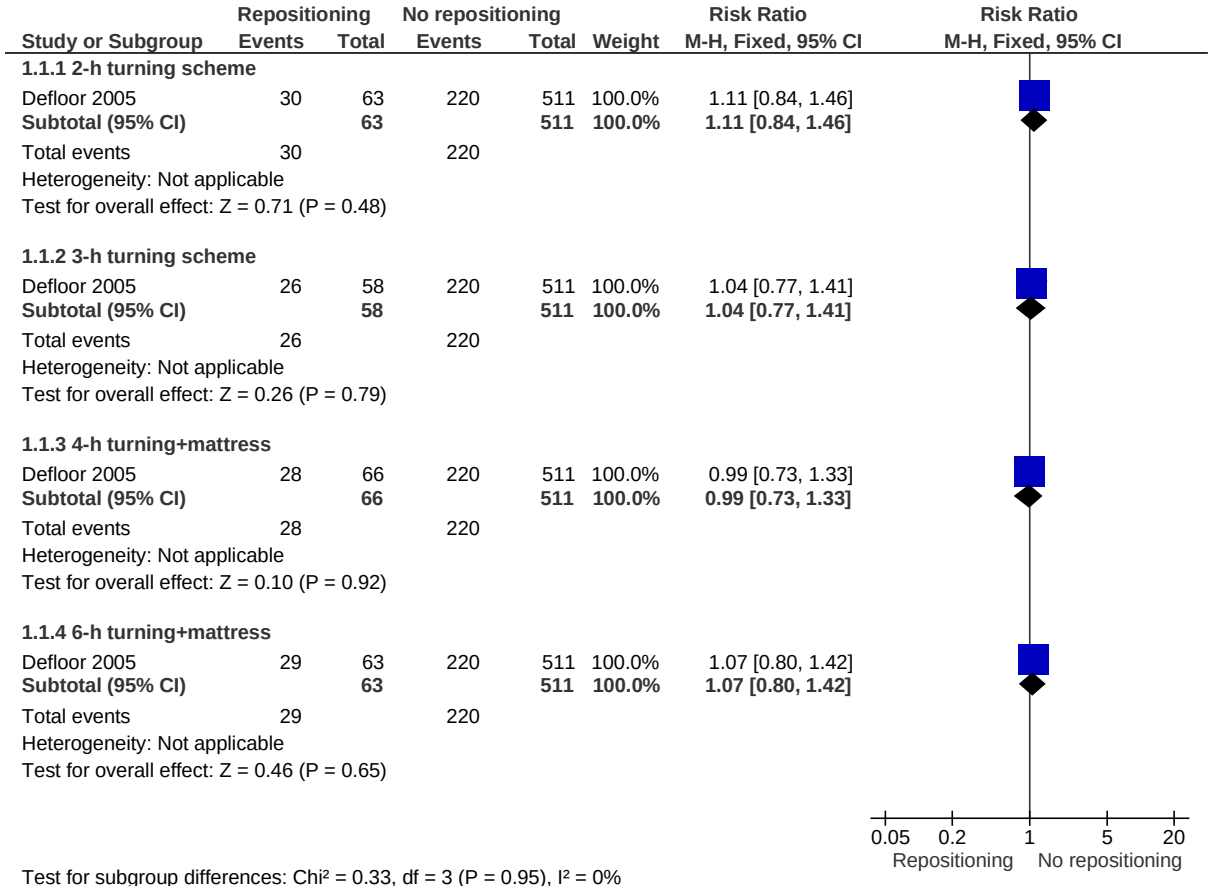


Figure 3 – Repositioning (Frequent turning or the use of pressure reducing mattress) versus no repositioning (standard care without turn ing): Pressure ulcers (Grades II – IV)

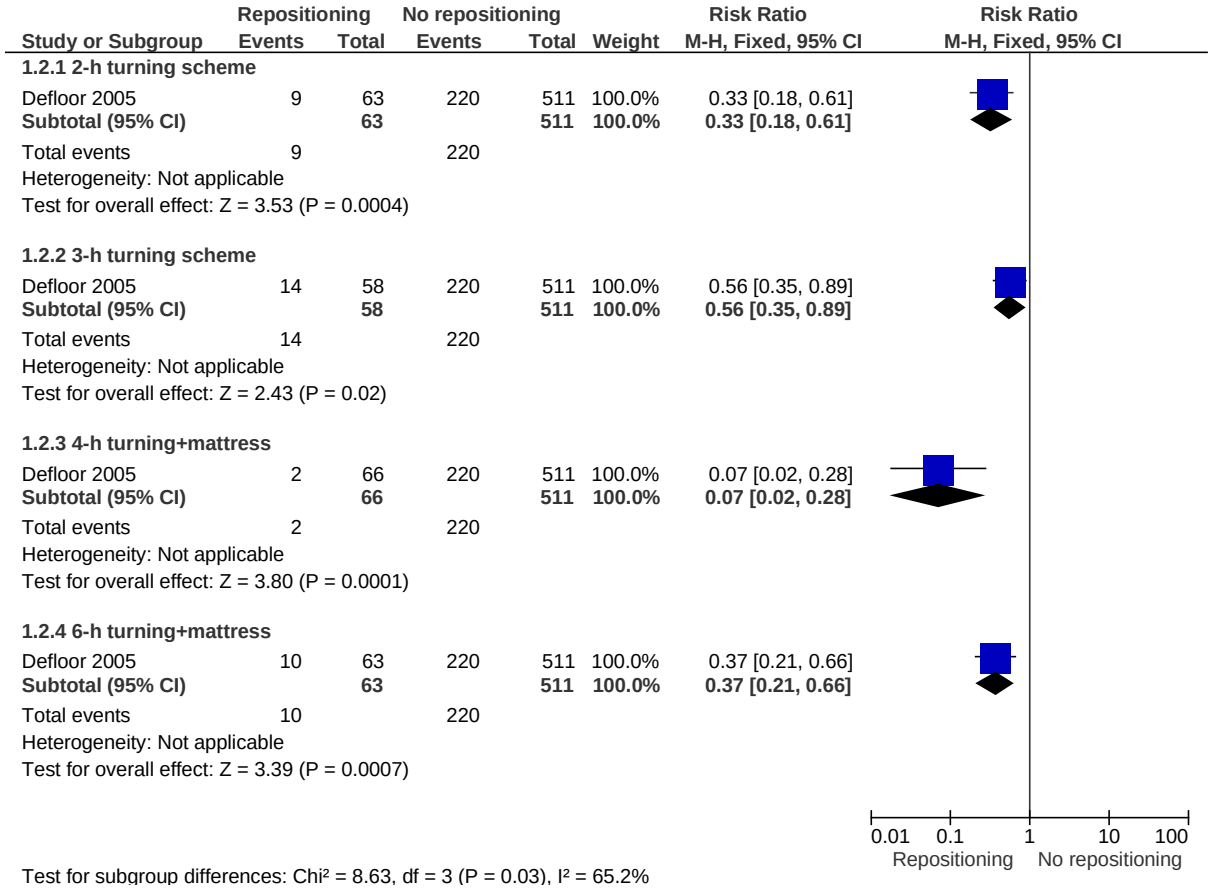
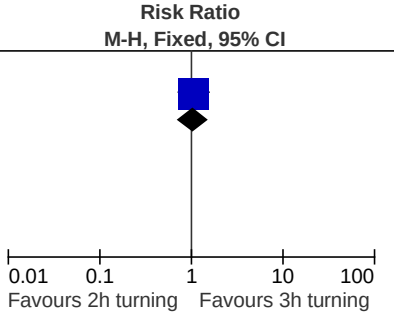


Figure 4 – Different frequencies of repositioning – 2-hour turning on a standard institutional mattress versus 3-hour turning on a standard institutional mattress: Non-blanching erythema (Grade I pressure ulcer)

Study or Subgroup	2h turning Events	Total	3h turning Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
3.8.1 2-h versus 3-h turning						
Defloor 2005	30	63	26	58	100.0%	1.06 [0.72, 1.56]
Subtotal (95% CI)		**63**		**58**	**100.0%**	**1.06 [0.72, 1.56]**
Total events	30		26			

Heterogeneity: Not applicable

Test for overall effect: Z = 0.31 (P = 0.76)



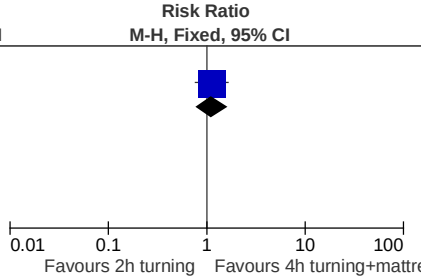
Test for subgroup differences: Not applicable

Figure 5 – Different frequencies of repositioning – 2-hour turning on a standard institutional mattress versus 4-hour turning scheme + pressure reducing mattress: non-blanching erythema (Grade I pressure ulcer)

Study or Subgroup	2h turning Events	Total	4h turning+mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
3.9.2 2-h versus 4-h turning+ pressure reducing mattress						
Defloor 2005	30	63	28	66	100.0%	1.12 [0.77, 1.64]
Subtotal (95% CI)		**63**		**66**	**100.0%**	**1.12 [0.77, 1.64]**
Total events	30		28			

Heterogeneity: Not applicable

Test for overall effect: Z = 0.59 (P = 0.55)



Test for subgroup differences: Not applicable

Figure 6 – Different frequencies of repositioning – 2-hour turning on a standard institutional mattress versus 6-hour turning scheme + pressure reducing mattress: non-blanching erythema (Grade I pressure ulcer)

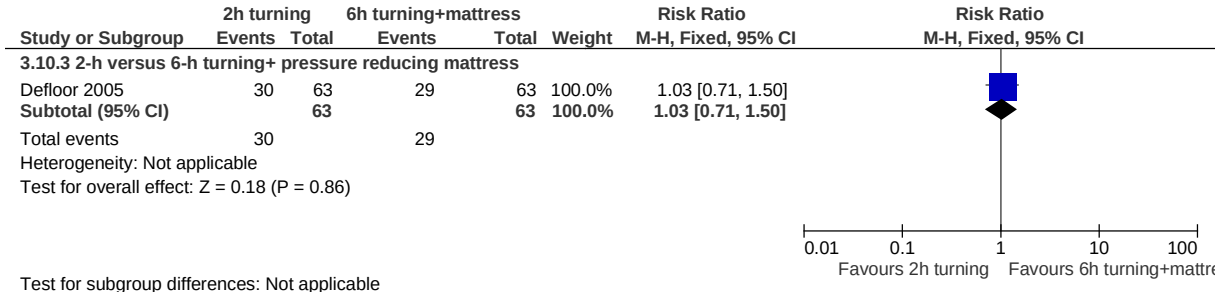


Figure 7 – Different frequencies of repositioning – 3-hour turning on a standard institutional mattress versus 4-hour turning scheme + pressure reducing mattress: Non-blanching erythema (Grade I pressure ulcer)

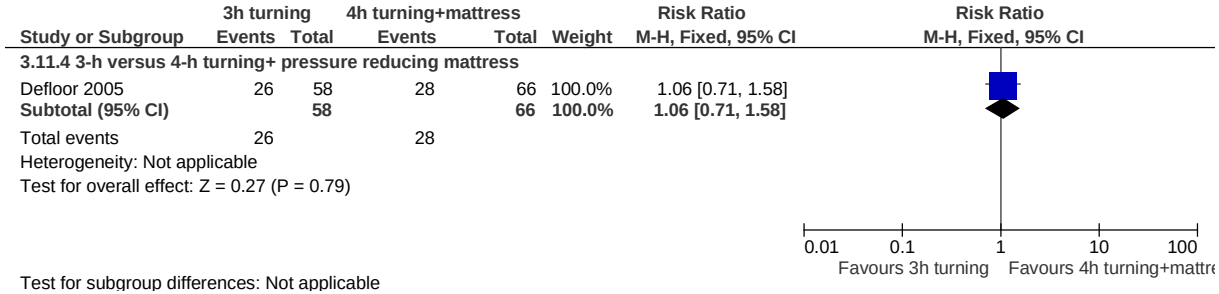


Figure 8 – Different frequencies of repositioning – 3-hour turning on a standard institutional mattress versus 6-hour turning scheme + pressure reducing mattress: Non-blanching erythema (Grade I pressure ulcer)

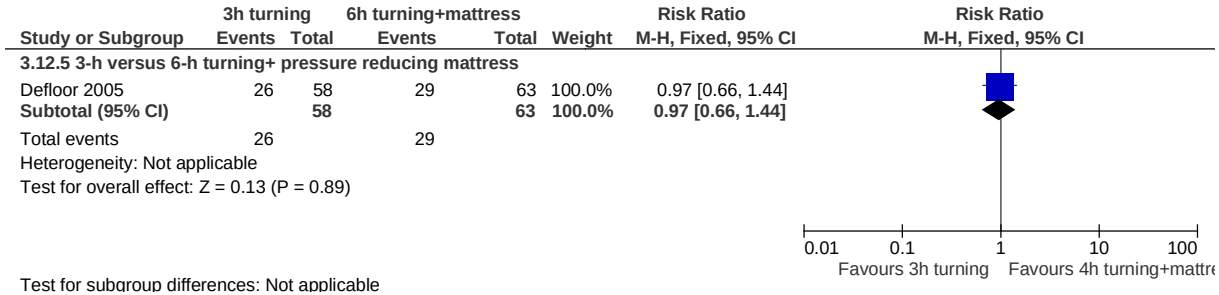
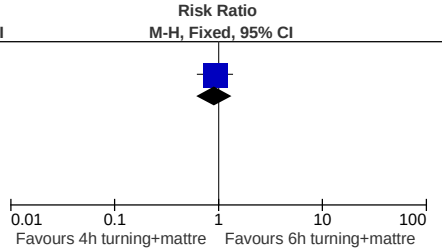


Figure 9 – Different frequencies of repositioning – 4-hour turning scheme + pressure reducing mattress versus 6-hour turning scheme + pressure reducing mattress: Non-blanching erythema (Grade I pressure ulcer).

Study or Subgroup	4h turning+mattress Events	Total	6h turning+mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
3.13.6 4-h versus 6-h turning+ pressure reducing mattress						
Defloor 2005	28	66	29	63	100.0%	0.92 [0.63, 1.36]
Subtotal (95% CI)		**66**		**63**	**100.0%**	**0.92 [0.63, 1.36]**
Total events	28		29			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.41 (P = 0.68)

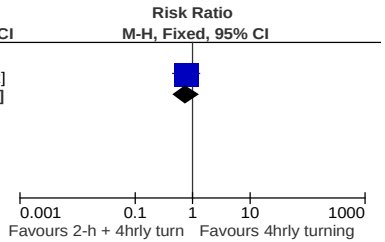


Test for subgroup differences: Not applicable

Figure 10 – Different frequencies of repositioning – turning 2-h in a lateral and 4-h in a supine position versus repositioning 4-hrly: incidence of pressure ulcers (Grade II and higher).

Study or Subgroup	2-h in a lateral and 4-h in a supine Events	Total	4-hrly turning Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
3.13.1 Turning with unequal time intervals						
Vanderwee 2007	20	122	24	113	100.0%	0.77 [0.45, 1.32]
Subtotal (95% CI)		**122**		**113**	**100.0%**	**0.77 [0.45, 1.32]**
Total events	20		24			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.95 (P = 0.34)

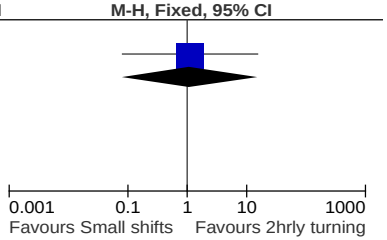


Test for subgroup differences: Not applicable

Figure 11 – Different frequencies of repositioning – unscheduled small shifts in body position versus 2-hrly turning: incidence of pressure ulcers (Grade II and higher).

Study or Subgroup	Small shifts in positions Events	Total	2hrly turn Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
3.14.2 Unscheduled (small) shifts in body positions						
Smith 1990	1	9	1	10	100.0%	1.11 [0.08, 15.28]
Subtotal (95% CI)		**9**		**10**	**100.0%**	**1.11 [0.08, 15.28]**
Total events	1		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.08 (P = 0.94)



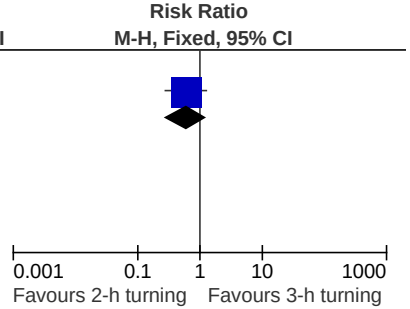
Test for subgroup differences: Not applicable

Figure 12 – Different frequencies of repositioning – 2-hour turning on a standard institutional mattress versus 3-hour turning scheme: incidence of pressure ulcers (Grade II and higher).

Study or Subgroup	2-h turning Events	Total	3-h turning Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
3.15.3 2-h versus 3-h turning						
Defloor 2005	9	63	14	58	100.0%	0.59 [0.28, 1.26]
Subtotal (95% CI)		**63**		**58**	**100.0%**	**0.59 [0.28, 1.26]**
Total events	9		14			

Heterogeneity: Not applicable

Test for overall effect: Z = 1.36 (P = 0.17)



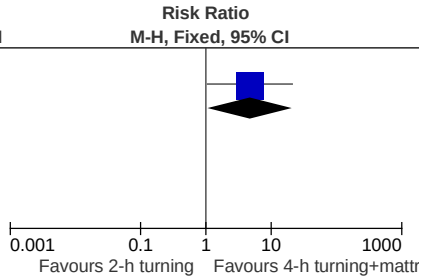
Test for subgroup differences: Not applicable

Figure 13 – Different frequencies of repositioning – 2-hour turning on a standard institutional mattress versus 4-hour turning scheme + pressure reducing mattress: incidence of pressure ulcers (Grade II and higher).

Study or Subgroup	2-h turning Events	Total	4-h turning+mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
3.16.4 2-h versus 4-h turning+ pressure reducing mattress						
Defloor 2005	9	63	2	66	100.0%	4.71 [1.06, 20.98]
Subtotal (95% CI)		**63**		**66**	**100.0%**	**4.71 [1.06, 20.98]**
Total events	9		2			

Heterogeneity: Not applicable

Test for overall effect: Z = 2.04 (P = 0.04)

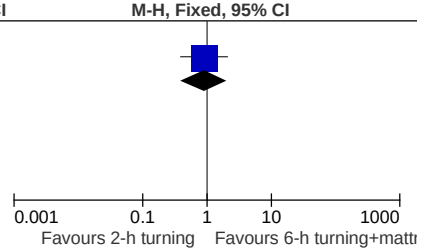


Test for subgroup differences: Not applicable

Figure 14 – Different frequencies of repositioning – 2-hour turning on a standard institutional mattress versus 6-hour turning scheme + pressure reducing mattress: incidence of pressure ulcers (Grade II and higher).

Study or Subgroup	2-h turning Events	Total	6-h turning + mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
3.17.5 2-h versus 6-h turning+ pressure reducing mattress						
Defloor 2005	9	63	10	63	100.0%	0.90 [0.39, 2.06]
Subtotal (95% CI)		**63**		**63**	**100.0%**	**0.90 [0.39, 2.06]**
Total events	9		10			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.25 (P = 0.80)

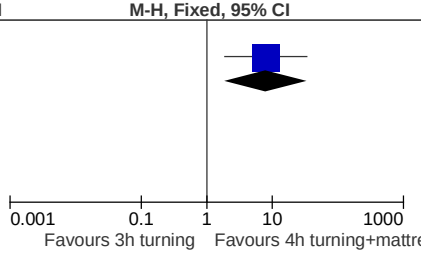


Test for subgroup differences: Not applicable

Figure 15 – Different frequencies of repositioning – 3-hour turning on a standard institutional mattress versus 4-hour turning scheme + pressure reducing mattress: incidence of pressure ulcers (Grade II and higher).

Study or Subgroup	3h turning Events	Total	4h turning+mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
3.18.6 3-h versus 4-h turning+ pressure reducing mattress						
Defloor 2005	14	58	2	66	100.0%	7.97 [1.89, 33.59]
Subtotal (95% CI)		**58**		**66**	**100.0%**	**7.97 [1.89, 33.59]**
Total events	14		2			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.83 (P = 0.005)

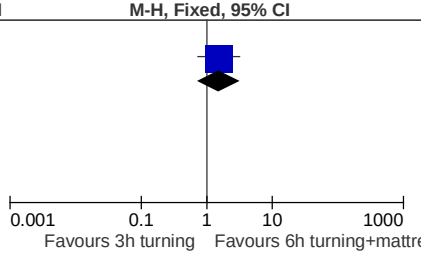


Test for subgroup differences: Not applicable

Figure 16 – Different frequencies of repositioning – 3-hour turning on a standard institutional mattress versus 6-hour turning scheme + pressure reducing mattress: incidence of pressure ulcers (Grade II and higher).

Study or Subgroup	3h turning Events	Total	6h turning+mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
3.19.7 3-h versus 6-h turning+ pressure reducing mattress						
Defloor 2005	14	58	10	63	100.0%	1.52 [0.73, 3.15]
Subtotal (95% CI)		**58**		**63**	**100.0%**	**1.52 [0.73, 3.15]**
Total events	14		10			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.13 (P = 0.26)



Test for subgroup differences: Not applicable

Figure 17 – Different frequencies of repositioning – 4-hour turning scheme + pressure reducing mattress versus 6-hour turning scheme + pressure reducing mattress: incidence of pressure ulcers (Grade II and higher).

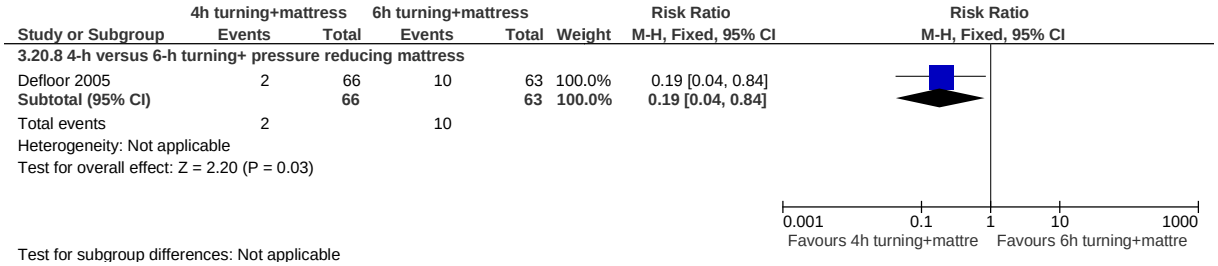


Figure 18 – Different positions for repositioning – 30° tilt position versus 90° lateral and supine position: incidence of pressure ulcer (Grade I – IV).

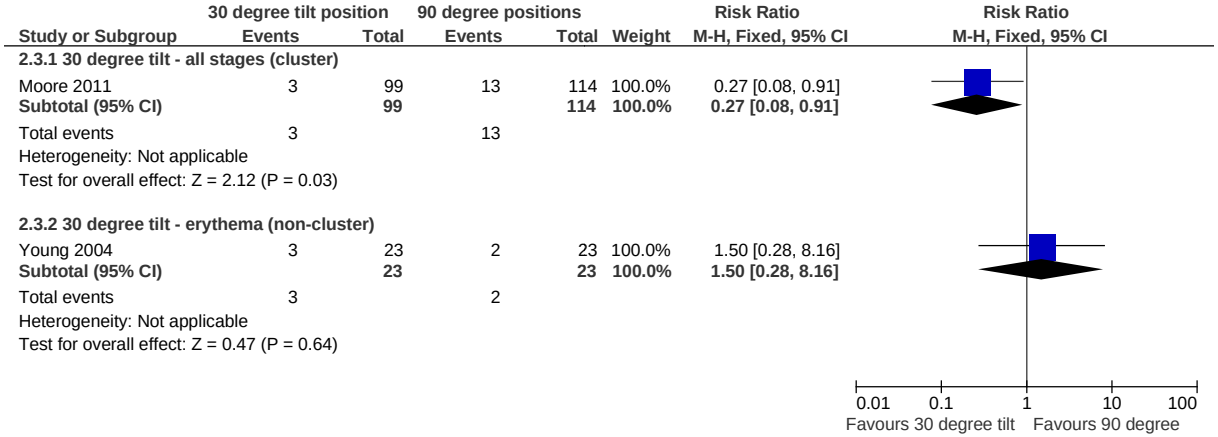


Figure 19 – Different positions for repositioning – semi recumbent position (45° position of the head and back) versus standard care (supine position): incidence of pressure ulcer (Grade I-IV).

Study or Subgroup	Semi recumbent position Events	Total	Supine position Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
van Nieuwenhoven 2006	31	112	30	109	100.0%	1.01 [0.66, 1.54]
Total (95% CI)		**112**		**109**	**100.0%**	**1.01 [0.66, 1.54]**
Total events	31		30			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.03 (P = 0.98)

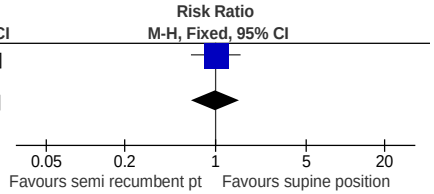


Figure 20 – Critically ill infants and children: different positions for repositioning – prone positioning versus control supine positioning. Pressure ulcer (Grade II and higher)

Study or Subgroup	Prone positioning Events	Total	Supine positioning Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Fineman 2006	10	51	8	51	100.0%	1.25 [0.54, 2.91]
Total (95% CI)		**51**		**51**	**100.0%**	**1.25 [0.54, 2.91]**
Total events	10		8			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.52 (P = 0.60)

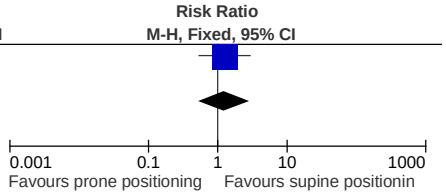
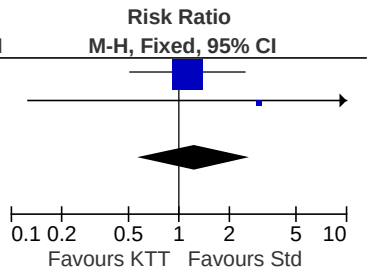


Figure 21 – Kinetic treatment table vs standard care

Study or Subgroup	KTT Events	Total	Standard Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Gentilello 1988	8	27	10	38	94.3%	1.13 [0.51, 2.48]
Summer 1989	1	43	0	43	5.7%	3.00 [0.13, 71.65]
Total (95% CI)		**70**		**81**	**100.0%**	**1.23 [0.57, 2.65]**
Total events	9		10			

Heterogeneity: Chi² = 0.35, df = 1 (P = 0.55); I² = 0%
Test for overall effect: Z = 0.54 (P = 0.59)



6.3.6. Clinical evidence tables

Table 27 – FINEMAN 2006

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Fineman 2006 **Title: Prone positioning can be safely performed in critically ill infants and children** **Journal: Paediatric Critical Care Medicine** **Sequence generation: Randomisation done using a permuted block sizes** **Allocation concealment: Each centre received serially numbered, opaque, sealed envelopes containing study assignments** **Blinding: not reported** **Addressing incomplete outcome data: not reported** **Analysis: Analysis were carried out on**	Patient group: One hundred and two paediatric patients with acute lung injury. All patients Randomised N: 102 Completed N: 98 Drop-outs: 4 Group 1 Randomised N: 51 Completed N: 47 Dropouts: 4 Group 2 Randomised N: 51 Completed N: 51 Dropouts: none Inclusion criteria: Paediatric patients (2 wks to 18 yrs) who were intubated and mechanically ventilated with a PaO2/FIO2 ratio	Group 1: Prone positioning: a 2-hr cyclic rotation from full prone to right lateral/prone to full prone to left lateral/prone and then to full prone. Prone positioning continued each day during the acute phase of their Acute Lung Injury illness for a maximum of 7 days of treatment. Infants/toddlers were lifted up, turned 45°, and turned prone on their cushions. School-aged and adolescent patients were turned using the mummy technique. During each turn, the patient's head was kept in alignment with the body, avoiding hyperextension. Group 2: Supine positioning All patients were maintained on standard hospital beds. Individually sized head, chest, pelvic, distal femoral and lower limb cushions were created using pressure-relieving material.	Outcome 1: Adverse event (proportion of participants that developed stage II or greater pressure ulcers)	Group 1: 10/51 (19.60%) Group 2: 8/51 (15.69%)	Funding: not reported. Limitations: Blinding for outcome assessors not reported Additional outcomes:

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
an intention-to-treat basis **Statistical analysis: Wilcoxon's rank-sum test or Fisher's exact test, as appropriate, to compare prone and supine groups in their baseline characteristics and outcomes that were calculated on a per patient basis.** **Baseline differences: There were no significant differences between the prone and supine groups** **Study power/sample size: Study power not reported.** **Setting: Seven paediatric intensive care units that participate in the Paediatric Acute Lung Injury and Sepsis Investigators (PALISI) Network in the United States** **Length of study: 28**	of ≤300, bilaterally pulmonary infiltrates, and no clinical evidence of left atrial hypertension Exclusion criteria: <2 wks of age (newborn physiology), <42 wks post conceptual age (considered preterm), were unable to tolerate a position change (persistent hypotension, cerebral hypertension), had respiratory failure from cardiac disease, had hypoxemia without bilateral infiltrates, had received a bone marrow or lung transplant, were supported on extracorporeal membrane oxygenation, had a nonpulmonary condition that could be exacerbated by the prone position, or had participated in other clinical trials within the preceding 30 days.				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
days **Assessment of PUs: Not reported** **Multiple ulcers: Not reported**					

Table 28 – DEFLOOR 2005B

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Defloor 2005B **Title: The effect of various combinations of turning and pressure reducing devices on the incidence of pressure ulcers** **Journal: International Journal of Nursing Studies** **Sequence generation: cluster randomisation done using a permuted block sizes. Cluster randomisation using computerised randomisation**	Patient group: 838 geriatric nursing home patients. Mean age: 84.4 (SD 8.33) years, The mean Braden score was 13.2 (SD 2.36) and the mean Norton score was 10.0 (SD 1.96). All patients Randomised N: 838 Completed N: 761 Drop-outs: 77 Group 1 Randomised N: 65 Completed N: 63 Dropouts: 2 (1 died and 1 transferred to hospital)	Group 1: 2-hour turning scheme on a standard institutional mattress Group 2: 3-hour turning scheme on a standard institutional mattress Group 3: 4-hour turning scheme + pressure reducing mattress Group 4: 6-hour turning scheme + pressure reducing mattress. The turning schemes consisted in alternating a semi-Fowler position with a lateral position. Group 5: Standard care involving preventive nursing care based on clinical judgement of the nurses.	Outcome 1: Development of Non-blanchable erythema: redness which cannot be pressed away with the thumb and which lasts longer than I day (GRADE I in the Agency of Health Care Policy and Research (AHCPR)	Group 1: 30/63 (47.6%) Group 2: 26/58 (44.8%) Group 3: 28/66 (42.4%) Group 4: 29/63 (46.0%) Group 5: 220/511 (43.0%)	Funding: not reported. Limitations: Intention-To-Treat analysis not reported. Additional outcomes:
			Outcome 2: Development of pressure ulcer lesion: blistering, superficial or deep pressure	Group 1: 9/63 (14.3%) Group 2: 14/58 (24.1%) Group 3: 2/66 (3%) Group 4: 10/63 (15.9%) Group 5: 102/511 (20%)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
tables. **Allocation concealment: Sealed envelope containing all room numbers in a random order.** **Blinding: Outcome assessors blinded** **Addressing incomplete outcome data: Gave details of what happened to drop outs and data of available patients** **Analysis: not reported** **Statistical analysis: The incidence of pressure ulcer lesions in relation to the different turning schemes was visualized using survival curves estimated according to the Kaplan-Meier method** **Baseline differences: No significant differences between the group** **Study power/sample**	Group 2 Randomised N: 65 Completed N: 58 Dropouts: 7 (5 transferred to hospital and 2 missing data) Group 3 Randomised N: 67 Completed N: 66 Dropouts: 1 (missing data) Group 4 Randomised N: 65 Completed N: 63 Dropouts: 2 (2 died) Group 5 Randomised N: 576 Completed N: 511 Dropouts: 65 (20 died, 24 transferred to hospital and 21 missing data)	Nurses did not use a pressure ulcer risk assessment scale and were not familiar with those scales. Preventive care did not include turning.	ulcer (grades II, III and IV in the AHCPR classification)		

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
size: Power analysis was performed using the national Belgian pressure ulcer prevalence figures. Desired power of 80% and a significance level of 0.05, a sample of 60 in each group was deemed sufficient. **Setting: Eleven geriatric nursing homes in Flanders (Belgium)** **Length of study: 4-week study period** **Assessment of PUs: not reported** **Multiple ulcers: N/A**	Inclusion criteria: A Braden score of less than 17 or a Norton score of less than 12; informed consent of patient/family Exclusion criteria: no reported				

Table 29 – SMITH 1990

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Smith 1990 **Title: Preventing pressure ulcers in institutionalized elders: assessing the effects of small, unscheduled shifts in body position** **Journal: Decubitus** **Sequence generation: Participants were randomly assigned to the treatment or control group by drawing names from a hat.** **Allocation concealment** **Blinding: Not reported** **Addressing incomplete outcome data: Provided details to missing data and used available patients** **Analysis: not reported**	Patient group: Participants ranged in age from 65 years to 91 years with a mean age of 80.55. Fourteen participants were women and five were men. Elderly patients: All patients Randomised N: 26 Completed N: 19 Drop-outs: 7 Group 1 Randomised N: 14 Completed N: 9 Dropouts: 5 (3 found to have pressure ulcer before study and 2 missing data) Group 2 Randomised N: 12 Completed N: 10 Dropouts: 2 (1 found to have pressure ulcer before study and	Group 1: Small shift in body (adjusting the position of a limb or body part by placing a small rolled towel to designated areas). A hand towel was used because it was efficient, convenient, and an existing resource. Shifts were completed in less than one minute. Sites for placement of rolled towel were under each arm, shoulder, hip, and leg. Group 2: Turning every two hours. Both groups received normal, routine care and were turned every two hours.	Outcome 1: Development of pressure ulcer.	Throughout the second week of the study, one subject in each of the two groups developed a pressure ulcer which healed by the end of the study. The mean post test Norton scores for the experimental group decreased to 9.44, while the control group increased to 12.5. There was no difference between post-test scores for the two groups.	Funding: not reported. Limitations: Allocation concealment not reported. Intention-To-Treat analysis not reported. Blinding not reported. High rate of drop outs (difference between control and experimental greater than 10%). Small sample size. Clinically experimental group were more at risk. Narrative report of effect sizes was given. Additional

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical analysis: **Baseline differences: No significant differences between the group** **Study power/sample size: not reported** **Setting: Participants were drawn from a single, skilled, 100-bed long –term care facility in a large Midwestern metropolitan city.** **Length of study: 2-week study period** **Assessment of PUs: When a pressure ulcer was found, it was measured using a Medirule. Information on the progression of pressure ulcer formation, chart information, and observations pertinent to the study were kept in a diary.** **Multiple ulcers: no details**	1missing data) Inclusion criteria: Patients who received a 14 or below on the Norton scale and were 65 years or older. Exclusion criteria: No details provided				outcomes:

Table 30 – VANDERWEE 2007

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Vanderwee 2007 **Title: Effectiveness of turning with unequal time intervals on the incidence of pressure ulcer lesions.** **Journal: JAN Original Research** **Sequence generation: Randomisation done at ward level using randomisation lists generated with the software package SPSS 12.** **Allocation concealment: Not reported** **Blinding: Not reported** **Addressing incomplete outcome data: None reported. No loss to follow up.** **Analysis: no details provided.**	Patient group: 838 geriatric nursing home patients. Mean age: 84.4 (SD 8.33) years, The mean Braden score was 13.2 (SD 2.36) and the mean Norton score was 10.0 (SD 1.96). All patients Randomised N: 235 Completed N: 235 Drop-outs: not reported Group 1 Randomised N: 122 Completed N: 122 Dropouts: not reported Group 2 Randomised N: 113 Completed N: 113 Dropouts: not reported	Group 1: 4 hours in a semi-Fowler 30° position and 2 hours in a lateral position 30°. The semi-Fowler position consisted of a 30° elevation of the head end and the foot end of the bed. In a lateral position, the position, the patient was rotated 30°, with their back supported with an ordinary pillow. Group 2: Repositioning was the same as above but with equal time intervals of 4 hours in lateral 30° as in semi-Fowler 30° position. Patients in both groups were lying on a visco-elastic foam overlay mattress	Outcome 1: Incidence of pressure ulcer (proportion of patients developing ulcer)	Group 1: 20/122 (16.4%) Group 2: 24/113 (21.2%)	Funding: not reported. Limitations: Intention-To-Treat analysis not reported. Blinding not reported. Allocation concealment not mentioned. Sample size was lower than the desired power needed. Results should be interpreted with caution. Additional outcomes:
			Outcome 2: The severity of pressure ulcer lesion	The majority of patients in the experimental group (17/122; 13.9%) and the control group (22/113; 19.5%) developed a grade 2 pressure ulcer. Three patients (2.5%) in the experimental group and two (1.8%) in the control group had a grade 3 or 4 pressure ulcer. No statistically significant difference in the severity of pressure ulcer.	
			Outcome 3: Location of pressure ulcer lesion	Group 1: 13 patients (10.7%) developed a pressure ulcer at the sacral area; 7 patients (5.7%) on the heels or ankles. Group 2: 20 patients (17.7%) had a pressure ulcer on the sacrum and four (3.5%) on the heels or ankles. Difference between the two groups was not statistically significant.	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical analysis: Data were analysed using the software package SPSS version 12.0. **Baseline differences: The two groups were comparable with respect to baseline and mobility characteristics.** **Study power/sample size: Sample size for the trial was calculated based on an incidence of pressure ulcer lesions (grade 2 or higher) in nursing homes of 17% (to detect a difference of 0.05; power = 80%). In order to detect a difference of 10% in the pressure ulcer incidence between the groups, 148 patients per group would have to be included in the trial.** **Setting: 84 wards of 16 Belgian elder care nursing homes**	Inclusion criteria: Patients were eligible for the study if they had no pressure ulcer lesion (grades 2, 3 or 4) (EPUAP 1999) at the start of the study, if they could be repositioned, and if they are expected to stay for >3 days in the nursing home. Exclusion criteria:		Outcome 4: Time to developing pressure ulcer (analysed using a Kaplan-Meier survival analysis)	No statistically significant difference between the two turning protocols (Log Rank test = 1.18, d.f. = .1, p = 0.28). To account for the delay in which a pressure ulcer becomes visible on the skin surface, the survival analysis was repeated starting from day 4. No statistically significant difference was found (Log Rank test = 1.04, d.f. = 1; P = 0.31)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Length of study: 5-week study period **Assessment of PUs: Occurrence of pressure ulcers was assessed daily by the nursing staff. The skin was observed at all the pressure arrears. Pressure ulcer categorized according to the EPUAP-classification system** **Multiple ulcers: none reported**					

Table 31 – MOORE 2011

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Moore 2011 **Title: A randomised controlled clinical trial of repositioning, using the 30° tilt, for the prevention of pressure ulcers** **Journal: Journal of Clinical Nursing**	Patient group: 213 participants enrolled into study, 114 assigned to the control arm and 99 enrolled in the experimental arm. Seventy-nine percent were women, with 53% aged between 81-90 years, 13% aged between 91-100 years.	Group 1: repositioning by the clinical staff, using the 30° tilt (left side, back, right side, back) every three hours during the night. Group 2: Repositioning every six hours at night, using 90° lateral rotation. Night time was taken to mean between the hours of 8pm-8 am. No	Outcome 1: Incidence of pressure ulcer (proportion of patients developing ulcer)	Group 1: 3/99 (3%) Group 2: 13/114 (11%)	Funding: Health Research Board of Ireland Clinical Nursing and Midwifery Research Fellowship. Limitations: Blinding not
			Outcome 2: Time to pressure ulcer development	Group 1: Mean 26 days (range 3 days). Group 2: Mean 17 days (range 24 days)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Sequence generation: Cluster randomisation using computerised randomisation **Allocation concealment: Achieved through use of distance randomisation: statistician, not researcher controlled randomisation sequence.** **Blinding: Not reported** **Addressing incomplete outcome data: None reported. No loss to follow up reported.** **Analysis: no details** **Statistical analysis: Data were analysed using SPSS version 13 on an intention to treat (ITT) basis. Differences between the two arms of the study assessed using the chi-squared test. Multiple regression**	Eighty-seven per cent of the participants were chair-fast and 77% had very limited activity All patients Randomised N: 213 Completed N: 213 Drop-outs: None reported Group 1 Randomised N: 99 Completed N: 99 Dropouts: None reported Group 2 Randomised N: 114 Completed N: 114 Dropouts: none reported Inclusion criteria: An in-patient in a long term care of the older person hospital; >65 years; at	further manipulation of patient care was undertaken. Both groups were nursed during the day according to planned care. Pressure redistribution devises in current use on the bed and on the chair was continued. Patients' positions were altered every 2-3 hours.	Outcome 3: Location of pressure ulcer lesion	Ninety-four percent of pressure was located on the sacrum/buttocks. One was located on the knee, with no pressure ulcer on the heels. Sixteen pressure ulcers developed during the study period, seven classified as grade 1 (6 in control group; 1 in the experimental group). Nine classified as grade 2 (7 in control group; 2 in the experimental group).	reported. Sample size was lower than the desired power needed. Results should be interpreted with caution. Additional outcomes:

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
analysis was conducted to determine which risk factors reflected pressure ulcer risk. **Baseline differences: No statistical difference between the groups for age, sex and Braden activity scores. A statistically significant association was noted for Braden mobility scores, with more of the experimental group noted to be bed fast.** **Study power/sample size: Sample size was determined on the basis of an expected incidence of 15% in the control group and a 90% power to detect a reduction in pressure ulcer incidence from 15-10%. The sample size required was two groups of 398 participants.**	risk of pressure ulcer development; no pressure ulcer at the time of recruitment to the study; no medical condition that would preclude the use of repositioning; consent to participate in the study. Exclusion criteria: Not reported				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Setting: Participants were selected from 12 long-term care of the older person hospital settings in the Republic of Ireland **Length of study: 4-week study period** **Assessment of PUs: Patients' skin was assessed at each turning episode. If any changes in skin integrity were noted, the researcher was informed. The skin was then assessed by the assigned key staff member, the clinical nurse manager and the researcher. Agreement was achieved by comparing the participants' skin condition to the images on the EPUAP grading system.** **Multiple ulcers: none reported**					

Table 32 – YOUNG 2004

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Young 2004 **Title: The 30° tilt position vs the 90° lateral and supine positions in reducing the incidence of non-blanching erythema in a hospital inpatient population: a randomised controlled trial.** **Journal: Journal of Tissue Viability.** **Sequence generation: Randomisation was based on block allocation** **Allocation concealment: Sequential opening of sealed opaque envelopes.** **Blinding: Researcher was unaware of which method of repositioning had been used.** **Addressing incomplete outcome**	Patient group: 46 participants with 23 randomised to the experimental arm and 23 to the control arm of the study. Mean age of 70.3 years All patients Randomised N: 46 Completed N: 46 Drop-outs: None reported Group 1 Randomised N: 23 Completed N: 23 Dropouts: None reported Group 2 Randomised N: 23 Completed N: 23 Dropouts: none reported Inclusion criteria: Elderly, at risk of developing pressure	Group 1: 30° tilt position during the night. Group 2: 90° side-lying position during the night.	Outcome 1: Incidence of pressure ulcer (proportion of patients developing ulcer)	Group 1: 3/23 (13%) Group 2: 2/23 (9%)	Funding: Not reported Limitations: Study lacks generalisability (small sample size; one night study). Results should be interpreted with caution. Additional comment: Among the subjects who completed the study, the experimental intervention (30° tilt repositioning) was difficult to implement for 20 subjects (87%), whereas only five subjects (22%) in the control group (90° side-lying position) experienced
			Outcome 2: Location of pressure ulcer lesion	Group 1: one (4%) over the sacrum, 2 (9%) developed two discrete areas of damage (one on the left trochanter and heel, and the other on the right trochanter and heel). Group 2: 2 (9%) developed pressure damage at the sacrum.	
			Outcome 3: Patient acceptability	Group 1: 5/23 (22%) were unable to tolerate intervention Group 2: None reported for the control group	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
data: None reported. No loss to follow up reported. **Statistical analysis: Statistical comparisons were made on an intention-to-treat basis. Primary outcome analysed using Fisher's exact test** **Baseline differences: Groups were similar with respect to identified variables** **Study power/sample size: Eighty per cent power of detecting a difference, significant at a 5% level, 46 subjects were recruited into the study** **Setting: Acute inpatient district general hospital** **Length of study: One night** **Assessment of PUs: Non-blanching erythema was used**	ulcers (confirmed by a Waterlow risk assessment score of above ten), able to lie 30° tilt position, had given informed consent Exclusion criteria: Not reported				difficulty with repositioning. Reported reasons for difficulty with repositioning includes: inability to get into and stay in position, joint stiffness, pain, anxiety.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
as a definition of pressure damage. This is ascertained by applying light finger pressure to any reddened areas. If the area does not blanch under exertion then tissue damage is said to have occurred. **Multiple ulcers: not reported**					

Table 33 – VAN NIEUWENHOVEN 2006

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Van Nieuwenhoven 2006 **Title: Feasibility and effects of the semi recumbent position to prevent ventilator-associated pneumonia.** **Journal: Critical Care medical journal.** **Sequence generation: Patients were randomly**	Patient group: 221 participants with 112 randomised to the experimental arm and 109 to the control arm of the study. Mean age of 63.9 years All patients Randomised N: 221 Completed N: Not clear Drop-outs: Not clear	Group 1: Semi recumbent position. Aim was to achieve 45° position of the head and back. The 45° position was not achieved for 85% of the study time, and these patients more frequently changed position than supine positioned patients. Group 2: Standard care (supine position)	Outcome 1: Incidence of pressure ulcer (proportion of patients developing ulcer)	Group 1: 31/112 (28%) Group 2: 33/109 (9%) .	Funding: Not reported Limitations: Additional outcomes:

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
assigned on a one to one allocation basis. **Allocation concealment: Closed, non transparent, numbered envelopes.** **Blinding: Investigators remained blinded for the results of interim analysis** **Addressing incomplete outcome data: None reported.** **Statistical analysis: Power calculation was carried out. Study did not achieve estimated sample calculated. Intention to treat analysis done.** **Baseline differences: Groups were similar with respect to identified variables** **Study power/sample size: an expected total of 252 patients would be needed to**	Group 1 Randomised N: 112 Completed N: Not clear Dropouts: Not clear Group 2 Randomised N: 109 Completed N: not clear Dropouts: not clear Inclusion criteria: Adult patients intubated within 24hrs of ICU admission and had an expected duration of ventilation of at least 48hrs. Exclusion criteria: If patients were undergoing selective decontamination of their digestive tract or if they could not be randomised to one or two positions.				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
reject the null hypothesis and an expected total sample size of 176 patients would be needed to accept the hypothesis. **Setting: Adults patients admitted to four ICUs in three university hospitals in the Netherlands.** **Length of study: 7 days** **Assessment of PUs: Pressure sore development was staged daily by research nurses according to the four stages described by the National Pressure Ulcer Advisory Panel system (stage I-IV)** **Multiple ulcers: not reported**					

Table 34 – GENTILELLO1988

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Gentilello 1988 **Title: Effect of a rotating bed on the incidence of pulmonary complications in critically ill patients** **Journal: Critical Care Medicine 1988, 16(8), 783-786.** **Study type: RCT** **Sequence generation: randomisation performed by drawing a card** **Allocation concealment: not reported** **Blinding: study only reported that the physician in charge of interpreting x-rays was blinded to treatment allocation.** **Addressing incomplete outcome data: no reasons/numbers for attrition/exclusions**	Patient group: critically ill patients in surgical ICU immobilised because of head injury, spinal injuries of traction. All patients Randomised N: 65 Completed N: 64 Drop-outs: 1 withdrew, not included in analysis Group 1 Randomised N:27 Completed N: unclear Dropouts: unclear Sex (% male): 74.1 Age: 34.8 (s.d 20.6) years Injury of spinal cord (%): 14.8 Group 2 Randomised N: 38 Completed N: unclear Dropouts: unclear	Group 1: Kinetic treatment table (rotates through arc of 124^{o} every 7 minutes). Nurses left bed rotating except when vital signs recorded and treatments given. IF there were serious complications due to the table they were moved to a conventional bed. Group 2: Conventional bed. Patients turned in usual way every 2 hours. Patients who developed a chest infection which was thought due to positioning were moved to the kinetic treatment table.	Outcome 1: Incidence of pressure ulcer s	Group 1: 30% Group 2: 26% .	Funding: Kinetic Cocnepts. *Limitations: Unclear allocation concealment and blinding and addressing of incomplete outcome data.* Additional outcomes: the trial was not primarily a pressure ulcer trial and the primary outcome was incidence of pulmonary complications

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
reported. **Statistical analysis: Incidence of PUs by Z-statistic.** **Baseline differences: similar for most demographic variables. The conventional bed group had higher incidence of smoking** **Study power/sample size: no a priori sample size calculation but small sample size.** **Setting: a surgical ICU** **Length of study: follow-up unclear.** **Assessment of PUs: evaluated daily, no details of method.** **Multiple ulcers: N/A**	Sex (% male): 76.3 Age: 35.1 (s.d 15.4) years Injury of spinal cord (%): 10.5 Inclusion criteria: patients with orthopaedic injuries requiring traction, head injuries or spinal injuries Exclusion criteria: not reported see above for inclusion criteria				

Table 35 – SUMMER1989

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Summer 1989 **Title: Continuous mechanical turning of intensive care unit patients shortest length of stay in some diagnostic-related groups** **Journal: Journal of Critical Care 1989, 4, 45-53.** **Sequence generation: random sequences of letters corresponding to the treatment groups** **Allocation concealment: not reported** **Blinding: the study nurse collecting APACHE score data was not involved in patient management of triage decisions, but there is no indication that outcome assessors were blinded.** **Addressing**	Patient group: patients admitted to the ICU in diagnostic groups – sepsis-sepsis syndrome/pneumonia; respiratory failure; drug overdose; metabolic coma; stroke/neuromuscular disease; adult respiratory distress syndrome All patients Randomised N: 86 Completed N: 83 Drop-outs: 3 lost to follow-up Groupings: Sepsis n=30 COPD/asthma n=16 Overdose n=11 Metabolic coma n=12 Stroke/neuromuscular n=14 Group 1 Randomised N:43	Group 1: Kinetic treatment table (7 feet x 3 feet padded, vinyl-covered platform on central rotating pivot which turns through an arc every 1.7 seconds). Reported to be of value in respiratory failure. Group 2: Routine 2-hourly turning on conventional beds	Outcome 1: Incidence of pressure ulcer	Group 1: 1/43 (small facial ulcer) Group 2: 0/43	Funding: not reported Limitations: Unclear allocation concealment and blinding. Unclear if similar at baseline Patients randomised only obtunded or unconscious patients (although this was not the initial intention) Additional outcomes:

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
incomplete outcome data: no **Statistical analysis: covariance analysis.** **Baseline differences: comparable for APACHE score, condition of pressure area at baseline not discussed.** **Study power/sample size: no a priori sample size calculation but small sample size** **Setting: ICU** **Length of study: follow-up unclear** **Assessment of PUs: APACHE-II scores** **Multiple ulcers: N/A**	Completed N: unclear Dropouts: unclear Group 2 Randomised N: 43 Completed N: unclear Dropouts: unclear Inclusion criteria: most patients admitted to the ICU: sepsis-sepsis syndrome or pneumonia; respiratory failure secondary to chronic obstructive pulmonary disease or asthma; drug overdose; diabetic ketoacidosis or other metabolic coma (uremia, hepatic encephalopathy); stroke or neuromuscular disease; adult respiratory distress syndrome. Exclusion criteria: not reported but see above for inclusion criteria				

7. RE-DISTRIBUTING DEVICES

7.1. Review protocol

Table 1 – Protocol review question

Protocol	Re-distributing devices
Review question	What are the most clinically effective pressure re-distributing devices for the prevention of pressure ulcers?
Population	Individuals of all ages in all settings
Intervention	**Mattresses/overlays** • Standard foam mattresses (needs to be identified) • Alternative foam mattresses/ overlays (e.g. convoluted foam, cubed foam) • Specialised foam mattresses • Gel-filled mattresses/ overlays • Fibre-filled mattresses/ overlays • Air-filled mattresses/ overlays • Water-filled mattresses/ overlays • Bead-filled mattresses/ overlays • AP mattresses/ overlays (air-filled sacs which inflate and deflate) • Low-air-loss mattresses • Operating-table overlays • Sheepskins (synthetic/natural) **Beds** • Air-fluidised beds • Low-air-loss beds – patients are supported on a series of air sacs through which warmed air passes • Air flotation beds • Bead-filled beds

Protocol	Re-distributing devices

	Seating
	• Standard Chair
	• Tilt in space
	• Pressure relieving chairs
	• Cushions
	  o foam-filled cushions
	  o gel-filled cushions
	  o fluid-filled cushions
	  o air/dry flotation cushions
	  o alternating pressure cushions
	  o tilt-in-space cushions
	• Wheelchair support surfaces
	
	Other
	• Pillows
	• Postural support
	• Limb protectors: pads and cushions of different forms to protect bony prominences
	• As prevention strategies

Comparison	• Each other • No intervention
Outcomes	**Critical outcomes for decision-making:** • Proportion of participants developing new pressure ulcers (dichotomous outcome)(describe different categories of ulcer) **Important outcomes:** • Patient acceptability • Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital or other healthcare setting (continuous data)

Protocol	Re-distributing devices
	• Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised o Short-form health survey (SF36) o Manchester Short Assessment of Quality of Life o EQ-5D o WHO-QOL BREF o Cardiff HRQoL tool o HUI o Pressure ulcer quality of life (Gorecki)
Study design	• High quality systematic reviews of RCTs and/or RCTs only. • Cochrane reviews will be included if they match our inclusion criteria and have appropriate assumptions for missing data such as available case analysis or ITT (with the appropriate assumptions) • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies with outcomes that do not involve pressure ulcers • Abstracts unless no RCTs are found • Non-English language papers
The search strategy	**The databases to be searched are:** • Medline, Embase, Cinahl, the Cochrane Library. • All years. • Studies will be restricted to English language only
Review strategy	**How will individual PICO characteristics be combined across studies in a meta-analysis (for intervention reviews)** • Population – any population will be combined for meta-analysis except for different strata • Intervention – Different categories of device will not be combined for meta-analysis • Comparison – any comparison which fits the inclusion criteria will be meta-analysed • Outcomes – single side effects will be meta-analysed separately from other side effects • Study design – randomised and quasi-randomised studies will be meta-analysed together. Blinded and unblinded studies will be meta-analysed together. Crossover trials will be meta-analysed together with parallel trials • Unit of analysis – patients, clusters (hospital wards), individual pressure ulcers – for those where patients are the

Protocol	Re-distributing devices
	unit of analysis and the patient has multiple ulcers it should be the first pressure ulcer occurring (describe different categories of ulcer) • Minimum duration of treatment = no minimum. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use available case analysis for dealing with missing data if there is a 10% differential or higher between the groups or if the missing data is higher than the event rate, if cannot work out the available case analysis will take the author's data.. • MIDs: 0.75 to 1.25 for dichotomous variables and 0.5 x standard deviation for continuous variables.
Analysis	**Strata:** The following groups will be considered separately as strata if data are present: • Children (neonates, infants, children) and adults • People with neurological impairment or spinal cord damage or injury • People with sensory impairment • Patients with a BMI >40 **Subgroups:** The following groups will be considered separately as subgroups if data are present and there is inconsistency: • Different categories of pressure ulcer (from category 2 upwards where outcomes are reported separately) • Different ulcer locations: sacral, heel and others.
Other terms	Support surfaces, pressure relieving, pressure reducing, pressure preventing
Notes	Where have said 'describe' or 'descriptive' this will be noted in the summary table.

7.2. search strategy

7.2.1. Search filters

Table 2 – Search filters in OVID Medline

Search strategy	Re-distributing devices		Results
Date	27th Mar 2012		
Database	Medline-Ovid		
Search strategy	1	pressure ulcer/	8894
	2	decubit*.ti,ab.	3865
	3	(pressure adj (sore* or ulcer* or damage)).ti,ab.	6062
	4	(bedsore* or bed-sore*).ti,ab.	501
	5	(incontinen* adj2 dermatitis).ti,ab.	50
	6	((moist* or friction or shear) adj2 (sore* or ulcer* or damage or wound* or injur* or lesion*)).ti,ab.	622
	7	or/1-6	13487
	8	limit 7 to english language	10757
	9	randomized controlled trial.pt.	322734
	10	controlled clinical trial.pt.	83763
	11	randomi#ed.ab.	285035
	12	placebo.ab.	134079
	13	drug therapy.fs.	1512984
	14	randomly.ab.	175416
	15	trial.ab.	246425
	16	groups.ab.	1148425
	17	or/9-16	2901023
	18	Clinical Trials as topic.sh.	158570
	19	trial.ti.	102055
	20	or/9-12,14,18-19	789946
	21	letter/	752856
	22	editorial/	302491

Search strategy	Re-distributing devices		Results
	23	news/	143966
	24	exp historical article/	302413
	25	Anecdotes as Topic/	4185
	26	comment/	493095
	27	case report/	1558286
	28	(letter or comment*).ti.	83156
	29	or/21-28	3025178
	30	randomized controlled trial/ or random*.ti,ab.	674026
	31	29 not 30	3010191
	32	animals/ not humans/	3594930
	33	exp Animals, Laboratory/	665788
	34	exp Animal Experimentation/	5218
	35	exp Models, Animal/	365269
	36	exp Rodentia/	2460341
	37	(rat or rats or mouse or mice).ti.	1032770
	38	or/31-37	7127677
	39	Meta-Analysis/	32205
	40	Meta-Analysis as Topic/	11873
	41	(meta analy* or metanaly* or metaanaly*).ti,ab.	42057
	42	((systematic* or evidence*) adj2 (review* or overview*)).ti,ab.	50096
	43	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.	19856
	44	(search strategy or search criteria or systematic search or study selection or data extraction).ab.	21391
	45	(search* adj4 literature).ab.	19634
	46	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.	61940
	47	cochrane.jw.	7944
	48	or/39-47	145126
	49	20 or 48	893674

Search strategy	Re-distributing devices		Results
	50	49 not 38	782841
	51	8 and 50	995
	52	exp beds/	3372
	53	(mattress* or cushion* or foam or transfoam or overlay* or pad or pads or gel).ti,ab.	250061
	54	(pressure adj2 (device* or support* or constant)).ti,ab.	6845
	55	(static adj air).ti,ab.	72
	56	(air adj (suspension or bag*)).ti,ab.	439
	57	(pressure adj2 (relie* or reduc* or alleviat* or redistribut* or re-distribut* or alternat*)).ti,ab.	16888
	58	water suspension*.ti,ab.	280
	59	(elevation adj2 device*).ti,ab.	10
	60	(clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or foot waffle or silicore or pegasus or cairwave).ti,ab.	448
	61	((turn* or tilt*) adj2 (bed* or frame*)).ti,ab.	454
	62	(kinetic adj (therapy or table*)).ti,ab.	77
	63	net bed*.ti,ab.	9
	64	(positioning or repositioning or re-positioning).ti,ab.	33140
	65	or/52-64	309311
	66	(seat* or chair* or wheelchair* or pillow*).ti,ab.	36394
	67	wheelchairs/	3172
	68	65 or 66 or 67	344756
	69	51 and 68	323
	70	limit 69 to yr="2010 -Current"	49
Notes			

Table 3 – Search filters in Embase

Search strategy	Re-distributing devices		Results
Date	27th Mar 2012		
Database	Embase-OVID		
Search strategy	1	random*.ti,ab.	711167
	2	factorial*.ti,ab.	18452
	3	(crossover* or cross over*).ti,ab.	60004
	4	((doubl$ or singl$) adj blind$).ti,ab.	136181
	5	(assign* or allocat* or volunteer* or placebo*).ti,ab.	549213
	6	crossover procedure/	33346
	7	double blind procedure/	107813
	8	single blind procedure/	15595
	9	randomized controlled trial/	318508
	10	or/1-9	1177104
	11	letter.pt. or letter/	775094
	12	note.pt.	511290
	13	editorial.pt.	399508
	14	case report/ or case study/	1825147
	15	(letter or comment*).ti.	134926
	16	or/11-15	3380104
	17	randomized controlled trial/ or random*.ti,ab.	794389
	18	16 not 17	3354078
	19	animal/ not human/	1321445
	20	nonhuman/	3806953
	21	exp Animal Experiment/	1498332
	22	exp experimental animal/	408085
	23	animal model/	629106
	24	exp Rodent/	2520889
	25	(rat or rats or mouse or mice).ti.	1103508

Search strategy	Re-distributing devices		Results
	26	or/18-25	8855378
	27	systematic review/	48030
	28	meta-analysis/	61737
	29	(meta analy* or metanaly* or metaanaly*).ti,ab.	54972
	30	((systematic or evidence) adj2 (review* or overview*)).ti,ab.	58719
	31	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.	24411
	32	(search strategy or search criteria or systematic search or study selection or data extraction).ab.	26081
	33	(search* adj4 literature).ab.	24044
	34	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.	75039
	35	((pool* or combined) adj2 (data or trials or studies or results)).ab.	31034
	36	cochrane.jw.	11048
	37	or/27-36	222072
	38	decubitus/	12420
	39	decubit*.ti,ab.	4747
	40	(pressure adj (sore* or ulcer* or damage)).ti,ab.	7047
	41	(bedsore* or bed-sore*).ti,ab.	655
	42	((moist* or friction or shear) adj2 (sore* or ulcer* or damage or wound* or injur* or lesion*)).ti,ab.	759
	43	(incontinen* adj2 dermatitis).ti,ab.	53
	44	or/38-43	16890
	45	limit 44 to english language	13015
	46	(10 or 37) not 26	1103384
	47	45 and 46	1435
	48	(mattress* or cushion* or foam or transfoam or overlay* or pad or pads or gel).ti,ab.	265218
	49	(pressure adj2 (device* or support* or constant)).ti,ab.	7910
	50	(static adj air).ti,ab.	100
	51	(air adj (suspension or bag*)).ti,ab.	513
	52	(pressure adj2 (relie* or reduc* or alleviat* or redistribut* or re-distribut* or alternat*)).ti,ab.	20059

Search strategy	Re-distributing devices		Results
	53	water suspension*.ti,ab.	370
	54	(elevation adj2 device*).ti,ab.	13
	55	(clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or foot waffle or silicore or pegasus or cairwave).ti,ab.	525
	56	((turn* or tilt*) adj2 (bed* or frame*)).ti,ab.	525
	57	(kinetic adj (therapy or table*)).ti,ab.	100
	58	net bed*.ti,ab.	9
	59	(positioning or repositioning or re-positioning).ti,ab.	38650
	60	(seat* or chair* or wheelchair* or pillow*).ti,ab.	40750
	61	exp bed/	7588
	62	exp wheelchair/	5032
	63	or/48-62	378050
	64	47 and 63	427
	65	limit 64 to yr="2010 -Current"	69
Notes			

Table 4 – Search filters in CINAHL

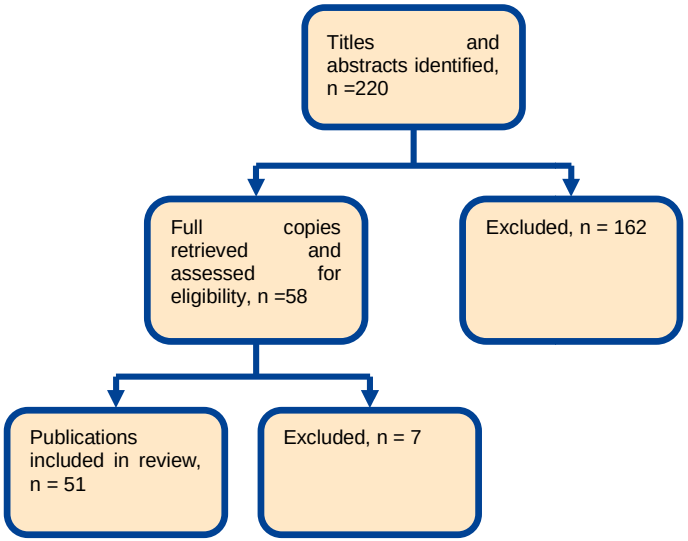
Search strategy	Re-distributing devices		Results
Date	27th Mar 2012		
Database	CINAHL		
Search strategy	S26	S7 and S24 Limiters – Published Date from: 20101201-20121231; English Language; Exclude MEDLINE records	133
	S25	S7 and S24	3354
	S24	S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23	48691
	S23	seat* or chair* or wheelchair* or pillow*	12957
	S22	positioning or repositioning or re-positioning	7537
	S21	net bed*	4
	S20	kinetic and (therapy or table*)	370
	S19	(turn* or tilt*) and (bed* or frame*)	1366
	S18	clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or foot waffle or silicore or pegasus or cairwave	57
	S17	elevation N2 device*	6
	S16	water suspension*	0
	S15	pressure and (relie* or reduc* or alleviat* or redistribut* or re-distribut* or alternat*)	14412
	S14	air suspension or air bag*	131
	S13	static air	12
	S12	pressure and (device* or support* or constant)	8690
	S11	mattress* or cushion* or foam or transfoam or overlay* or pad or pads or gel	9244
	S10	(MH "Wheelchairs+")	2956
	S9	(MH "Pillows and Cushions")	456
	S8	(MH "Beds and Mattresses+")	2576
	S7	S1 or S2 or S3 or S4 or S5 or S6	9607
	S6	((moist* or friction or shear) and (sore* or ulcer* or damage or wound* or injur* or lesion*))	1368
	S5	incontinen* n2 dermatitis	69
	S4	bedsore* OR bed-sore*	155
	S3	pressure n1 sore* OR pressure n1 ulcer* OR pressure n1 damage*	8277
	S2	decubit*	474
	S1	(MH "Pressure Ulcer")	7513
Notes			

Table 5 – Search filters in Cochrane

Search strategy	Re-distributing devices		Results
Date	27th Mar 2012		
Database	Cochrane (- CDSR [3/2012]; DARE; Central [3/2012]; NHS EED; HTA)		
Search strategy	#1	MeSH descriptor Pressure Ulcer explode all trees	481
	#2	decubit*:ti,ab,kw	348
	#3	(pressure near/2 (sore* or ulcer* or damage)):ti,ab,kw	821
	#4	(bedsore* or bed-sore*):ti,ab,kw	32
	#5	(incontinen* near/2 dermatitis):ti,ab,kw	10
	#6	((moist* or friction or shear) near/2 (sore* or ulcer* or damage or wound* or injur* or lesion*)):ti,ab,kw	63
	#7	(#1 OR #2 OR #3 OR #4 OR #5 OR #6)	1161
	#8	MeSH descriptor Beds explode all trees	243
	#9	MeSH descriptor Wheelchairs explode all trees	127
	#10	(mattress* or cushion* or foam or transfoam or overlay* or pad or pads or gel):ti,ab,kw	7516
	#11	(pressure NEAR/2 (device* or support* or constant)):ti,ab,kw	800
	#12	(static NEAR/2 air):ti,ab,kw	4
	#13	(air NEAR/2 (suspension or bag*)):ti,ab,kw	8
	#14	(pressure NEAR/2 (relie* or reduc* or alleviat* or redistribut* or re-distribut* or alternat*)):ti,ab,kw	3643
	#15	water suspension*:ti,ab,kw	118
	#16	(elevation NEAR/2 device*):ti,ab,kw	5
	#17	(clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or foot waffle or silicore or pegasus or cairwave):ti,ab,kw	53
	#18	((turn* or tilt*) NEAR/2 (bed* or frame*)):ti,ab,kw	47
	#19	((turn* or tilt*) NEAR/2 (bed* or frame*)):ti,ab,kw	47
	#20	net bed*:ti,ab,kw	289
	#21	(positioning or repositioning or re-positioning):ti,ab,kw	8906
	#22	(seat* or chair* or wheelchair* or pillow*):ti,ab,kw	2653
	#23	(#8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22)	22993
	#24	(#7 AND #23)	498
	#25	(#24), from 2010 to 2012	48
Notes			

7.2.2. Selection of articles

Figure 1 – Flow chart of clinical article selection



7.2.3. Excluded clinical studies

Reference	Reason for exclusion
ALLEN1993	No clinical outcomes, only interface pressure recorded
ANDREWS1989	Did not fulfil study design criteria
BALLARD1997	Data recorded were comfort data; no pressure ulcer outcomes
BARHYTE1995	Did not fulfil study design criteria. No data presented
BLISS1967	Did not fulfil study design criteria. Patients were recruited to the trial on the basis of their risk score
BLISS1995	Whilst 8 surfaces were evaluated in this prospective trial, not all surfaces were in the trial at the same time, therefore, the surfaces were not truly compared with one another contemporaneously. Furthermore, it was possible for patients to be re-randomised back into the study, which occurred frequently, with a total of 457 mattress trials reported for only 238 patients. The data were not presented by patient only by mattress trial. *Duplicate citation of Bliss 1994 [conference abstract]*
BRANIFF-MATTHEWS1997	Healing and prevention outcome data were not separated.
BRIENZA2001	Study of pressure measurement
BUCHNER1995	Did not fulfil study design criteria. Criteria for anti-decubitus management not reported and decided by nurses. Number of pillows provided to third arm of the study was limited and not given to all participants.
CADUE2008	More relevant to heel ulcer review.
CHALONER2000	Did not fulfil study design criteria, randomisation corrupted, authors reported that randomisation was compromised on the basis of bed availability
COLIN1996	No clinical outcomes recorded; only measurements taken were for transcutaneous oxygen tension
CONINE1991	Did not fulfil study design criteria
DEBOISBLANC1993	Outcome incidence of pneumonia, no pressure ulcer outcomes
DEFLOOR1997	Compared turning
DEFLOOR2000	Did not compare surfaces
DEFLOOR2004	Compared turning
DELLAVALLE2001	Outcome of interface pressure
ECONOMIDES1995	Wound breakdown rather than pressure ulcers
EWING1964	More relevant to heel ulcer review.
FLAM1995	Outcome skin temperature and skin moisture level, no pressure ulcer outcomes
FLEISCHER1997	Did not fulfil study design criteria
GEELKERKEN1994	Did not fulfil study design criteria. No data presented.
GENTILELLO1988	More relevant to repositioning review
GILAGUDO2009	Outcome measure of interface pressure

Reference	Reason for exclusion
GILCREAST2005	More relevant to heel ulcer review.
GRAY2008	Not an RCT, but a clinical audit
GRINDLEY1996	Patients were crossed between intervention groups at 3 days. Outcome used was the assessment of patient comfort.
GUNNINGBERG1998	Did not fulfil study design criteria. Study of risk calculation rather than prevention
HAALBOOM1994	Did not fulfil study design criteria
HAMPTON1998	Did not fulfil study design criteria
HAWKINS1997	Did not fulfil study design criteria
HEYNEMAN2009	Meta-analysis of 2 previously published RCTs (Vanderwee 2005; Vanderwee 2007). Vanderwee 2005 already included in this review. Vanderwee 2007 excluded as it is a turning trial
HOLZGREVE1993	Full paper unavailable. Insufficient information to assess
HUANG2009	Evaluated dressings
INMAN1999	Comparisono of a bed rental versus a bed purchase strategy, not a comparison of surfaces
JACKSICH1997	Did not fulfil study design criteria
JESURUM1996	Did not fulfil study design criteria
KOO1995	Did not fulfil study design criteria, study of interface pressure in healthy volunteers
MARCHAND1993	Did not fulfil study design criteria, was a retrospective chart audit

Reference	Reason for exclusion
MCMICHAEL2008	Outcome measure of interface pressure
NEANDER1996	Paper in german – translator state it was not an RCT. There were no data on how the decision to include patients in the control and intervention groups was made
OOKA1995	Did not fulfil study design criteria, convenience sample used
PHILLIPS1999	N of 1 trial design, only one participant in the trial
REGAN1995	This study reported an audit of pressure ulcer incidence after implementation of a comprehensive pressure ulcer policy; it is not a prospective rCT
REYNOLDS1994	This study Did not fulfil study design criteria
ROSENTHAL1996	Did not fulfil study design criteria. Outcome measure of interface pressure
SCOTT1995	Insufficient information available to make a decision
SCOTT1999	No clinical outcomes, healthy volunteer study of interface pressures
SCOTT2000	Not an RCT of beds and mattresses
STONEBERG1986	Historical control group
SUAREZ1995	Controlled clinical trial which recorded only pressure measurements
SUMMER1989	More relevant to repositioning review
TAKALA1994	Not an RCT, outcome measure of interface pressure

Reference	Reason for exclusion
THOMAS1994	Did not fulfil study design criteria
TIMMONS2008	Did not fulfil study design criteria. Review of a product not a trial
TORRAIBOU2002	Evaluated dressings
TURNAGE-CARRIER2008	Outcome measure of interface pressure
TYMEC1997	More relevant to heel ulcer review.
VANDERWEE2007	Compared turning
VANDERWEE2008	Literature review of previously conducted studies
WELLS1984	Only recorded interface pressure measurements
WILD1991	Interface pressure measurements
ZERNIKE1997	Incidence of pressure ulcers not reported
ZERNIKE1994	Unable to assess due to information in research paper. Email address provided was no longer valid and we were unable to find other contact details.

7.3. Clinical evidence

7.3.1. Search strategy

A Cochrane review by McInnes et al (2011) [73] was identified from the search and was adapted for this review. We quality assured the McInnes Cochrane review and as it was of very high quality and matched the majority of our protocol we used the information within it to populate our review for the summary of studies, forest plots and for the quality assessment of studies. Changes or additions were made based on differences in the protocol or to adapt for the purposes of GRADE.

7.3.2. Clinical evidence

We removed 7 of the 53 studies that were included in the Cochrane review. Four studies[74, 75, 76, 77] were removed from this review as they included only heel ulcers and will be covered in the heel ulcer prevention review (see **Error! Reference source not found.**). One other study (Economides, 1995)[78] was excluded as it looked at wound breakdown rather than incidence of pressure ulcers. Two other studies (Gentilello, 1988[70] and Summer, 1989[71]) were excluded from this review as they were deemed more relevant to the repositioning review.

Five additional studies[79, 80, 81, 82, 83] were identified in our search, which were not included in the review, and have been extracted (see Appendix 7).

Fifty-one studies in total were included in this review.[16, 78-126]

This review identified studies in different settings: operating theatre[85, 95, 111, 114], intensive care units[82, 102, 106, 118, 120, 122, 125], orthopaedic ward[92, 94, 97, 101, 109, 113, 117, 119], accident and emergency ward[99], extended care facilities[89, 90, 91, 93, 108], nursing homes[79, 83, 96, 107, 110],different types of hospital wards[80, 84, 86, 87, 98, 104, 114, 126]. Several studies did not specify the study setting[16, 88, 100, 101, 103, 105, 112, 116, 121, 123, 124, 127].

Various types of redistributing devices are used, and the Cochrane review[73] categorised them as:

- Low-tech (non-powered) constant low pressure support surfaces;
- High-tech support surfaces;
- Other support surfaces (e.g. operating table overlay, turning beds/frames, wheelchair cushions and limb protectors).

The high-tech support surfaces included:

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

The other support surfaces included:

- Turning beds/frames: these work by aiding manual repositioning of the patient, or by motor driven turning and tilting.
- Operating table overlays: mode of action as above.
- Wheelchair cushions: either conforming cushions that reduce contact pressures by increasing surface area in contact, or mechanical cushions e.g. alternating pressure.
- Limb protectors: pads and cushions of different forms to protect bony prominences.

As part of our protocol we were required to look at grades 2 pressure ulcers and above as well as all grades of ulcer. This deviates from the McInnes Cochrane review however they do state that studies that compare the incidence of pressure ulcers of grade 2 or greater are more likely to be reliable. They included studies regardless of whether grade 1 ulcers were described separately. Grading systems are variable but from the studies which reported grades 2 and above separately used the EPUAP or NPUAP classification system (see table of grading systems below). For those studies that did not use the EPUAP/NPUAP and reported grades of ulcer separately the distinction was usually a break in the skin or blister.

The McInnes Cochrane also found that methods for measuring secondary outcomes such as comfort, durability, reliability and acceptability were not well developed. Where data were presented they did give details in the Characteristics of included studies table, but did not incorporate into their analysis. As these were critical outcomes for this review, we have included these outcomes in the GRADE evidence tables.

The McInnes Cochrane did Meta-analyse studies where there was more than one trial for an outcome which compared similar devices. The results were pooled using a fixed effect model, but if heterogeneity (I^2 = 50% or above and the p value was less than 0.10) was found they used a random-effects model. They state that they assumed that the risk ratio remained constant for different lengths of follow-up and so were pooled if participants were followed-up for different lengths of time.

No studies were found for standard or pressure-relieving chairs, tilt-in-space wheelchairs, postural support or limb protectors.

7.3.3. Glossary of terms

Table 6 –Glossary of terms (NPUAP 2007)[128]

Term	Definition
Physical concepts related to support surfaces	
Static	Not active or moving; stationary. However with regards to support surfaces the description has now changed to mean ‘non-powered’
Dynamic	Relating to energy or to objects in motion. However with regards to support surfaces the description has now changed to mean ‘powered’.
Friction (frictional force)	The resistance to motion in a parallel direction relative to the common boundary of two surfaces
Coefficient of friction	A measurement of the amount of friction existing between two surfaces
Envelopment	The ability of a support surface to conform, so to fit or mold around irregularities in the body
Fatigue	The reduced capacity of a surface or its components to perform as specified. This change may be the result of intended or unintended use and/or prolonged exposure to chemical, thermal, or physical forces

Force	A push-pull vector with magnitude (quantity) and direction (pressure, shear) that is capable of maintaining or altering the position of a body
Immersion	Depth of penetration (sinking) into a support surface
Life expectancy	The defined period of time during which a product is able to effectively fulfil its designated purpose
Mechanical load	Force distribution acting on a surface
Pressure	The force per unit area exerted perpendicular to the plane of interest
Pressure redistribution	The ability of a support surface to distribute load over the contact areas of the human body. This term replaces prior terminology of pressure reduction and pressure relief surfaces
Pressure reduction	This term is no longer used to describe classes of support surfaces. The term is pressure redistribution; see above
Pressure relief	This term is no longer used to describe classes of support surfaces. The term is pressure redistribution; see above
Shear (shear stress)	The force per unit area exerted parallel to the plane of interest
Shear strain	Distortion or deformation of tissue as a result of shear stress
Components of support surfaces	
Air	A low density fluid with minimal resistance to flow
Cell/bladder	A means of encapsulating a support medium
Viscoelastic foam	A type of porous polymer material that conforms in proportion to the applied weight. The air exists and enters the foam cells slowly which allows the material to respond slower than a standard elastic foam (memory foam)
Elastic foam	A type of porous polymer material that conforms in proportion to the applied weight. Air enters and exits the foam cells more rapidly, due to greater density (non memory)
Closed cell foam	A non-permeable structure in which there is a barrier between cells, preventing gases or liquids from passing through the foam
Open cell foam	A permeable structure in which there is no barrier between cells and gases or liquids can pass through the foam
Gel	A semisolid system consisting of a network of solid aggrtegates, colloidal dispersions or polymers which may exhibit elastic properties (can range from a hard gel to a soft gel)
Pad	A cushion-like mass of soft material used for comfort, protection or positioning
Viscous fluid	A fluid with a relatively high resistance to flow of the fluid
Elastomer	Any material that can be repeatedly stretched to at least twice its original length; upon release the stretch will return to approximately its original length
Solid	A substance that does not flow perceptibly under stress. Under ordinary conditions retains its size and shape
Water	A moderate desnity fluid with moderate resistance to flow
Features of support surfaces	
Air fluidised	A feature of a support surface that provides pressure redistribution via a fluid-like mediaum

	created by forcing air through beads as characterised by immersion and envelopment
Alternating pressure	A feature of a support surface that provides pressure redistribution via cyclic changes in loading and unloading as characterised by frequency, duration , amplitude, and rate of change parameters
Lateral rotation	A feature of a support surface that provides rotation about a longitudinal axis as characterised by degree of patient turn, duration and frequency
Low air loss	A feature of a support surface that provides a flow of air to assist in managing the heat and humidity (microclimate) of the skin
Zone	A segment with a single pressure redistribution capability
Multi-zoned surface	A surface in which different segments can have different pressure redistribution capabilities
Categories of support surfaces	

Reactive support surface	A powered and non-powered support surface with the capability to change its load distribution properties only in response to applied load
Active support surface	A powered support surface, with the capability to change its load distribution properties, with or without applied load
Integrated bed system	A bed frame and support surface that are combined into a single unit whereby the surface is unable to function separately
Non-powered	Any support surface not requiring or using external sources of energy for operation (Enedrgy = D/C or A/C)
Powered	Any support surface requiring or using external sources of energy to operate (Energy = D/C or A/C)
Overlay	An additional support surface designed to be placed directly on top of an existing surface
Mattress	A support surface designed to be placed directly on the existing bed frame

7.3.4. Summary of included studies

Table 7 – Summary of studies included in the review

Study	Intervention/comparator	Population	Outcomes	Study length
Anderson 1983[129]	Standard hospital mattress vs alternating air mattress vs water-filled mattress (air mattress for camping filled with water)	Patients in acute setting at high risk of pressure ulcer development (Anderson scale) and without pressure ulcers	Incidence of pressure ulcers (all grades)	10-day follow-up
Aronovitch 1999 [85]	Alternating pressure system intra and postoperatively (MICROPULSE) vs conventional management (gel pad (ACTION PAD) or standard pad in operating room and a replacement mattress (PRESSURE GUARD II) postoperatively)	Patients undergoing elective surgery under general anaesthetic	Occurrence of pressure ulcer within 7 days of surgery (all grades of ulcer)	7-day follow-up
Bennett 1998 [84]	Low air loss hydrotherapy (Permeable fast drying filter sheet over low-air-loss cushions (circulating air) (clensicair) vs standard care (standard bed or foam, air, alternating-pressure mattresses, skin care not standardised)	Acute and long-term care patients incontinent of urine and/or faces with pressure ulcers grade 2 or below	Number of patients who developed pressure ulcers grade 2-4; number of patients with non-blanchable erythema (grade 1)	60-day follow-up
Brienza 2010 [79]	Skin protection cushion (SPC) vs segmented foam cushion (SFC) The skin protection cushion was a commercially available cushion with an incontinence cover. Cushions were selected from three which were designed to improve tissue tolerance by reducing peak pressures near bony prominences, accommodating orthopaedic deformities through immersion,	Elderly, nursing home population who used wheelchairs as primary means of seating and mobility and were at-risk for developing pressure ulcers.	Incidence of pressure ulcers (different areas of the body) (all grades of ulcer)	6 months

Study	Intervention/comparator	Population	Outcomes	Study length
	enveloping small irregularities at the seating interface without causing height pressure gradients, and dissipating heat and moisture. Solid seat inserts were provided. The segmented foam cushion was a cross-cut, 7.6cm thick, segmented foam cushion with fitted incontinence cover and solid seat insert.			
Cavicchioli 2007 [86]	High-tech (HILL-ROM, DUO 2) mattress on alternating low-pressure setting vs high-tech (HILL-ROM DUO 2), mattress on continuous low-pressure setting	Acute and long-term care participants deemed at risk of pressure ulceration (Braden score <17 activity or mobility sub-scales < 3)	Number of participants with incidence of pressure ulcer (grade 1 and 2)	2-week follow-up
Cobb 1997 [87]	Low air loss bed (KINAIR) vs static air mattress overlay (EHOB WAFFLE)	Hospital and ICU patients considered high risk on Braden score	Number of participants with incidence pressure ulcer (grade 1 and 2)	40-day follow-up
Collier 1996 [88]	Comparison of 8 foam mattresses: new standard hospital mattress vs pressure-redistributing foam mattresses (CLINIFLOAT, OMNIFOAM, SOFTFORM, STM5, THERAREST, TRANSFOAM, VAPOURLUX)	Patients on a general medical ward, no further details	Incidence of pressure ulcers (all grades of ulcers)	Not clear but assessed weekly
Conine 1990 [89]	Alternating-pressure overlay vs silicore overlay over standard hospital mattress (spring or foam) All patients received usual care including 2-3 hourly turning; daily bed baths; weekly bath/shower; use of heel, ankle and other protectors	Patients with chronic neurological diseases	Incidence of pressure ulcers (including grade 1)	3-month follow-up
Conine 1993 [90]	Slab cushion bevelled at base to prevent seat sling vs contoured	Extended care patients at high risk	Incidence of pressure ulcers (all	3-month follow-up

Study	Intervention/comparator	Population	Outcomes	Study length
	foam cushion with a posterior cut out in the area of ischial tuberosities and an anterior ischial bar	of pressure ulcers	grades of ulcers)	
Conine 1994 [91]	Gel cushion with foam base (JAY) vs foam cushion	Elderly patients in an extended care hospital deemed at high risk of pressure ulcers	Pressure ulcer incidence (all grades of ulcers)	3-month follow-up
Cooper 1998 [92]	Dry flotation mattress (ROHO) vs dry flotation mattress (SOFFLEX)	Mixed emergency orthopaedic trauma ward patients with waterlow risk scores of >/=15	Incidence of grade 2 ulcers and above	7-day follow-up
Daechsel 1985 [93]	Alternating-pressure mattress vs silicore overlay	Neurological conditions in a long-term care hospital at high risk	Incidence of grade 1 and above pressure ulcers	3-month follow-up
Demarre 2012 [80]	Alternating low pressure air mattress with multi-stage inflation and deflation of the air cells (CLINACTIV, HILL-ROM) vs standard Alternating low pressure air mattress with single stage, steep inflation and deflation of air cells (HILL-ROM).	Hospitalised patients. The wards were neurology, rehabilitation, cardiology, dermatology, pneumology oncology and chronic care or a combination of different types of medical conditions	Incidence of all grades of ulcer and grade 2 ulcer or greater; withdrawal due to discomfort; time to develop new pressure ulcers	14 days
Exton-Smith 1982 [94]	Alternating-pressure mattress with two layers of air cells (PEGASUS AIRWAVE SYSTEM) vs alternating-pressure large cell ripple mattress	Geriatric patients, with fractured neck of femur and long-stay patients without pressure ulcers of grade 2 or greater, Norton score <14.	Incidence of grade 2 ulcer or greater	2-week follow-up
Feuchtinger 2006 [95]	Operating table with waterfilled warming mattress and a 4-cm thermoactive viscoelastic foam overlay vs standard OR table configuration (OR table with waterfilled warming mattress)	Patients scheduled for cardiac surgery with extracorporal circulation, not required to be free of pressure ulcers	Number of participants with incidence of pressure ulcers (all grades and grades 2 and above)	5-day follow-up
Gebhardt 1996 [125]	Alternating-pressure air mattresses (shallow small cell overlays,	Patients in ICU with a Norton score <13 with no pressure ulcers	Support provided; incidence of pressure ulcers (all grades and	unclear

Study	Intervention/comparator	Population	Outcomes	Study length
	medium depth large cell overlays, deep mattresses and deep pulsating low air loss bed) vs constant low-pressure supports (fibre overlays, foam mattresses/overlays, static air overlays, gel overlay, water overlay, bead overlay, low air loss mattresses, static air overlay, low-air-loss beds and air-fluidised bead beds)		grades 2 and above); cost	
Geyer 2001 [96]	Pressure-reducing wheelchair cushions (a commercial cushion, chosen by nurse based on patient, from a group of cushions designed specifically to improve tissue tolerance in sitting by providing more surface area and/or reducing peak pressure near the ischial tuberosities, sacrum and coccygeal areas. A fitted incontinence cover was also included vs standard 3-inch convoluted foam (EGGRATE) cushion	Elderly patients in nursing homes; wheelchair users with Braden score </=18	Number of participants with incidence of pressure ulcer (all grades)	12-month follow-up
Goldstone 1982 [97]	Bead bed system (BEAUFORT) (includes bead-filled mattress on A&E trolley; bead-filled operating table overlay; bead-filled sacral cushion for operating table; bead-filled boots to protect heels on operating table	Over 60 years with femur fracture	Pressure ulcer incidence (all grades of pressure ulcers)	Follow-up not clear
Gray 1994 [98]	Pressure-redistributing foam mattress (SOFTFOAM) vs standard 130mm NHS foam mattress	Patients with orthopaedic trauma, vascular and medical oncology units without breaks in the skin	Incidence of pressure ulcers (grade 2 or greater ulcer)	10-day follow-up

Study	Intervention/comparator	Population	Outcomes	Study length
Gray 1998 [127]	Pressure-redistributing foam mattress (TRANSFOAM) vs pressure-redistributing foam mattress (TRANSFOAMWAVE)	General hospital patients admitted for bed-rest or surgery with intact skin, no terminal illness	Incidence of pressure ulcers (all grades of ulcers)	10-day follow-up
Grisell 2008 [81]	A neoprene air filled bladder (dry flotation) device (ROHO) vs a disposable polyurethane foam prone head positioner (OSI) vs a prone view protective helmet system with a disposable polyurethane foam head positioner)	Elective surgery patients – thoracic, lumbar or thora-columbar spinal surgery that required prone positioning	Incidence of all pressure ulcers and of grade 2 and above pressure ulcers	No details
Gunningberg 2000 [99]	10cm visco-elastic foam mattress (TEMPUR-PEDIC) on arrival in A&E, and visco-elastic foam overlay on standard ward mattress vs standard A&E trolley mattress (5cm) and ward mattress (10cm foam)	Patients admitted with a suspected hip fracture via an A&E department; over 65 years; did not have pressure ulcers	Grade 2 to 4 incidence; mean comfort rating	Follow-up until discharge or 14 days postoperatively
Hampton 1997 [100]	Alternating-pressure mattress (CAIRWAVE SYSTEM) vs alternating pressure mattress (AIRWAVE SYSTEM)	Little detail, average age 77 years; number of patients at high-very high risk	Incidence of pressure ulcers (grade 2 and above)	20 days maximum follow-up
Hofman 1994 [101]	Cubed foam mattress (COMFORTEX DECUBE) vs standard hospital foam mattress (standard polypropylene SG40)	Patients with a femoral-neck fracture and risk score >8 (Dutch consensus scale)	Incidence of ulcers (grade 2 or greater)	2-week followup
Inman 1993 [102]	Low-air-loss air-suspension beds (KINAIR) vs standard Intensive care unit bed (patients rotated every 2 hours)	Patients >17 years with APACHE II score >15	Incidence of pressure ulcers (ulcers per patient and patients with ulcers) (grade 2 or greater)	Average 17 days follow-up
Jolley 2004 [103]	Australian medical sheepskin mattress overlay (leather-backed with a dense uniform 25 mm wool	Low to moderate risk of developing a pressure ulcer; aged >18 years.	Number of participants with incidence of pressure ulcer (all grades of pressure ulcers)	Unclear follow-up period; average 7 days.

Study	Intervention/comparator	Population	Outcomes	Study length
	pile vs usual care determined by staff (repositioning and any other pressure-redistributing device or prevention strategy with/without low-tech constant pressure relieving devices			
Kemp 1993 [104]	Convoluted foam overlay (either 3 inch overlay with density of 1.42lb per cubic foot (acute settings) or a 4 inch overlay with unknown density (long-term settings)) vs solid foam overlay (4 inches solid sculptured overlay with density to 1.33lb per cubic foot)	>65 years, inpatients with Braden Score of </=16 from general medicine, acute geriatric medicine and long term care. Free from pressure ulcers.	Incidence of pressure ulcers (all grades of pressure ulcers)	1-month follow-up
Keogh 2001 [105]	Profiling bed with a pressure reducing foam mattress/cushion vs flat-based bed with a pressure relieving/redistributing mattress/cushion	Patients from 2 surgical and 2 medical wards; >18 years; waterlow score of 15-25; tissue damage no greater than grade 1	Incidence of pressure ulcers (all grades of ulcers); healing of existing grade 1 ulcers	5-10 days follow-up
Laurent 1998 [106]	Standard mattress in ICU; standard mattress postoperatively vs alternating pressure mattress (NIMBUS)in ICU; standard mattress postoperatively vs standard mattress in ICU; Constant low pressure mattress (TEMPUR) postoperatively vs alternating pressure mattress (NIMBUS) in ICU; constant low pressure mattress (TEMPUR) postoperatively	Adults over 15 years of age, admitted for major cardiovascular surgery	Incidence of ulcers of grade 2 or above	unclear
Lazzara 1991 [107]	Air-filled (SOFCARE) overlay vs gel mattress	Nursing home residents at risk of pressure ulcers (Norton score >15)	Incidence of pressure ulcer (all grades and grade 2 or greater ulcers)	6-month follow-up

Study	Intervention/comparator	Population	Outcomes	Study length
Lim 1988 [108]	Foam slab cushion (2.5cm medium density foam glued to 5cm firm chipped foam) vs contoured foam cushion (same foam as above; cut into a customised shape to relieve pressure on ischial tuberosities).	Residents of an extended care facility; aged >/=60; free of pressure ulcers but at high risk of developing one (Norton score </=14); using a wheelchair for >/=3 hours/day; without progressive disease or confined to bed	Incidence of all ulcers (grade 1 and above)	5-month follow-up
Malbrain 2010 [82]	Reactive dry floatation mattress overlay (ROHO) vs the active alternating pressure mattress (NIMBUS 3)	ICU patients at high risk of pressure ulcers (Norton score </= 8) and requiring mechanical ventilation for at least 5 days with intact skin or with PUs on admission	Incidence of pressure ulcers (all grades of ulcers and grade 2 and above)	No details but mean study duration reported for patients was 15 (s.d 14) in the NIMBUS group and 12.2 (s.d 5.5) in the ROHO group
McGowan 2000 [109]	Standard hospital mattress, sheet and an Australian Medical Sheepskin overlay; sheepskin heel and elbow protectors as required vs standard hospital mattress, sheet with or without other low tech constant pressure devices as required.	Orthopaedic patients aged >/60 years; low or moderate risk (Braden scale)	Incidence of ulcers (grade 1 and above)	Discharge from hospital, transfer to a rehabilitation ward.
Mistiaen 2009 **Mistiaen 2010** [110]	Australian medical sheepskin vs usual care Cointerventions: usual intervention for prevention of pressure ulcers in study settings	Patients from aged care facility (predominantly rehabilitation department) and rehabilitation centre. Grade 1 pressure ulcers included in sample	Incidence of pressure ulcers (all grades of ulcers)	30-day follow-up
Nixon 1998 [111]	Dry visco-elastic polymer pad on operating table vs standard operating theatre table mattress plus Gamgee heel support	Patients >/=55 years; admitted for elective major general, gynaecological or vascular surgery in supine or lithotomy position and free of preoperative pressure damage greater than grade 1	Incidence of pressure ulcers (all grades of ulcers)	8-day follow-up

Study	Intervention/comparator	Population	Outcomes	Study length
Nixon 2006 [130]	Alternating-pressure overlay (alternating cell height minimum 8.5cm, max 12.25 cm) vs alternating-pressure mattress (alternating cell height min 19.6cms, max 29.4cms)	Acute or elective hospital patients aged >/=55 years with limited Braden activity and mobility score (1 or 2)	Incidence of pressure ulcer (grade 2 and above)	30-day follow-up and a further 30-day follow-up
Price 1999[113]	Low-pressure inflatable mattress (REPOSE SYSTEM) and cushion in polyurethane material) vs dynamic flotation Nimbus II plus alternating-pressuyre cushion for a chair (ALPHA TRANSCELL): all other care standard best practice, including regular repositioning	Patients with fractured neck of femur and Medley score of >25 (very high risk) aged over 60 years	Incidence of pressure ulcers (grade 2 and above)	14-day follow-up
Russell 2000[114]	Multi-cell pulsating dynamic mattress system (MICROPULSE SYSTEM)in the operating roomand postoperatively vs Conventional care (gel pad (ACTION PAD) in operating room, standard mattress(HILL_ROM CENTRA with 6 inch foam overlay or HILL-ROM CENTRA with 4 inch foam overlay) postoperatively)	Patients >/= 18 years; undergoing scheduled cardiothoracic surgery under GA; surgery of at least 4 hours duration; free of pressure ulcers	Incidence and severity of pressure ulcers	7-day follow-up
Russell 2003 [131]	Visco-polymer energy absorbing foam mattress (CONFOR-MED 3 inch layer viscoelastic foam and a 3 inch layer of standard polyurethane foam)/cushion combination vs standard mattress/cushion combination (KING'S FUND, LINKNURSE, SOFTFOAM, TRANSFOAM, KING'S FUND MATTRESS with a SPENCO or	Elderly acute, orthopaedic and rehabilitation wards; >65 years; Waterlow score of 15-20	Development of non-blanching erythema	Median 8-14 (experimental) and 9-17 (control)

Study	Intervention/comparator	Population	Outcomes	Study length
	PROPAD mattress overlay)			
Sanada 2003[116]	Double-layer cell overlay (TRICELL) – (two layers consisting of 24 narrow cylinder air cells, 10 cm) vs single-layer air cell overlay (AIR DOCTOR single layer consisting of 20 round air cells, 7.5 cm) vs standard hospital mattress (PARACARE 8.5cm polyester)	Acute care unit patients; Braden score of </=16; bed bound; free of pressure ulcers	Incidence pressure ulcer (all grades of ulcer and grade 2 and above)	Follow-up duration not reported
Santy 1994 [117]	Pressure-redistributing mattresses (CLINIFLOAT, OMNIFOAM, THERAREST, TRANSFOAM, VAPERM) vs NHS contract surface – standard foam (REYLON 150mm)	Patients aged >55 years with hip fracture, with or without pressure ulcers	Incidence of pressure ulcers (all grades).	14-day follow-up
Schultz 1999 [132]	Experimental mattress overlay in operating room made of foam with a 25% indentation load deflection of 30lb and density of 1.3 cubic feet vs usual care (padding as required, including gel pads, foam mattresses, ring cushions (donuts etc…)	Patients admitted for surgery; aged>18 years; admitted with intact skin	Incidence of pressure ulcers (all grades)	6-day follow-up
Sideranko 1992 [118]	Alternating air mattress (LAPIDUS AIRFLOAT SYSTEM 1.5 inch thick) vs static air mattress (GAY MAR SOFCARE 4-inch thich) vs Water mattress (LOTUSs PXM 3666,4 inch thick)	Adult, surgical IC U patients; without existing skin breakdown	Incidence of pressure ulcers (all grades of ulcers)	Mean 9.4 days follow-up
Stapleton 1986 [119]	Large cell ripple bed pad (TALLEY) vs polyether foam pad 2 feet x 2 feet x 3 inch thickness vs silicore bed pad (SPENCO)	Female elderly patients with fractured neck of femur; without existing pressure ulcers; Norton score 14 or less	Incidence of pressure ulcers (all grades and grade 2 or greater)	Duration of follow-up unclear
Takala 1996 [133]	Constant low pressure mattress	Non-trauma patients admitted to	Incidence of pressure ulcers (all	14-day follow-up

Study	Intervention/comparator	Population	Outcomes	Study length
	(CARITAL OPTIMA) (21 double air bags on a base) vs standard hospital foam mattress (10cm thick foam density 35kg/m3)	ICU	grades of ulcers)	
Taylor 1999[121]	Alternating-pressure mattress with pressure-redistributing cushion (PEGASUS TRINOVA) vs alternative alternating-pressure system (unnamed) with pressure-redistributing cushion	Hospital inpatients aged 16 or over; intact skin, requiring a pressure-relieving support	Incidence of pressure ulcers (all grades of ulcers)	Discharge from hospital or death
Theaker 2005[122]	Alternating pressure mattress (KCI THERAPULSE) vs alternating pressure mattress(HILL-ROM DUO)	High risk patients in ICU	Number of participants with incidence of pressure ulcers (all grades of ulcers)	2 weeks follow-up after discharge from ICU
Vanderwee 2005[126]	Alternating pressure air mattress (aLPHA-X-CELL) vs visco-elastic foam mattress (TEMPUR)	Surgical, internal medicine or geriatric hospital patients; at risk of developing pressure ulcer (Braden score <17)	Incidence of pressure ulcers (all grades)	unclear
Vyhlidal 1997[123]	Foam mattress overlay (IRIS 3000, 4-inch thick 1.8lb density with dimpled surface) vs foam mattress replacement (MAXIFLOAT)	Patients newly admitted to a skilled nursing facility; free of pressure ulcers but at risk (Braden score <18 years)	Incidence of pressure ulcers (all grades)	10-21 day follow-up
Whitney 1984[124]	Alternating-pressure mattress (134 3-inch diameter air cells, 3 minute cycle) vs convoluted foam pad (EGGCRATE) Patients in both groups were turned every 2 hours	Patients on medical –surgical units; relatively little skin breakdown; aged 19-91 years	Changes in skin conditions (all grades)	8-day follow-up
Van Leen 2011[83]	**C**ombination of a standard 15cm cold foam mattress with a static air overlay vs a standard 15cm cold foam mattress	Nursing home residents	Incidence of pressure ulcers (grade 2 and above)	6 months follow-up

Table 8 – Classification systems used in the studies included in the review

Classification System	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
EPUAP/NPUAP	**Non-blanchable redness of intact skin** Intact skin with non-blanchable erythema of a localized area usually over a bony prominence. Discoloration of the skin, warmth, edema, hardness or pain may also be present. Darkly pigmented skin may not have visible blanching.	**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-sanginous filled blister.	**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 tunneling.	**Full thickness tissue loss (muscle/bone visible)** Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present. Often include undermining and tunneling.	N/A
Exton-Smith	Persistent erythema	Localised blister	Superficial sore	Deep sore	Extensive gangrenous sore.
Stirling grade	Discoloration of intact skin (light finger pressure applied to the site does not alter the discoloration.	Partial-thickness skin loss or damage involving epidermis and/or dermis	Full-thickness skin loss involving damage or necrosis of subcutaneous tissue but not extending to underlying bone.	Full-thickness skin loss with extensive destruction and tissue necrosis extending to underlying bone, tendon or joint capsule	N/A
Torrance	Redness to the skin – blanching occurs	2a redness to the skin – non-blanching occurs; 2b superficial damage to the epidermis	Ulceration progressed through the dermis	ulceration extended into the subcutaneous fat;	necrosis penetrating the deep fascia and extending to muscle
Lowthian scale	Discolorations of intact skin, including non-blanchable erythema, blue/purple and black discoloration	Partial thickness skin loss or damage involving the dermis and/or epidermis	Full thickness skin loss involving damager or necrosis of subcutaneous tissue, but not through the underlying fascia and not extending to	Full thickness skin loss with extensive destruction and tissue necrosis extending to underlying bone, tendon or joint capsule.	N/A

Classification System	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
			underlying bone, tendon or joint capsule		
Agency for Health care policy and research	Non-blanching erythema or erythema not resolving within 30 minutes of pressure relief. Epidermis remains intact. Reversible with intervention.	Partial thickness loss of skin layers involving epidermis and possibly penetrating into but not through dermis. May present as blistering with erythema and/or induration; wound base moist and pink; painful; free of necrotic tissue.	Full thickness tissue loss extending through dermis to involve subcutaneous tissue. Presents as shallow crater unless covered by eschar. May include necrotic tissue, undermining, sinus tract formation, exudate, and/or infection. Wound base is usually not painful. If wound involves necrotic tissue, staging cannot be confirmed, therefore classified as stage 4	Deep tissue destruction extending through subcutaneous tissue to fascia and may involve muscle layers, joint and/or bone. Presents as a deep crater. May include necrotic tissue, undermining, sinus tract formation, exudate, and/or infection. Wound base is usually not painful.	N/A
Dutch consensus	Persistent erythema of the skin	Blister formation	Superficial (sub) cutaneous necrosis	Deep subcutaneous necrosis.	N/A
Shea	Involve the superficial breakdown of the epidermis. Non-blanchable erythema with edema, warmth, induration or discoloration. Red discoloration in lighter skin, blue or purple in darker skin	Partial thickness epidermal or skin loss that extends through the epidermis and upper dermis	Full thickness deficit with extension into the subcutaneous tissue. Does not extend into the fascia	Wound extends to the muscle, tendon, bone and or joint structures. Complications include osteomyelitis, dislocations, or fractures. Also assess for undermining.	N/A

7.4.1. Clinical evidence GRADE-tables

7.4.1.1. "Low-tech" constant low-pressure (CLP) supports

The Cochrane review compared standard foam hospital mattresses with other low specification (low-tech), constant low-pressure (CLP) supports. Sheepskin, static air-filled supports; water-filled supports; contoured or textured foam supports; gel-filled supports; bead-filled supports; fibre-filled supports, and alternative foam mattresses or overlays were considered to be low-tech CLP. However they point out that there is not an international definition of what a standard foam mattress is, and it can change over time, within countries, and even within hospitals. If a description of the standard was given it was included in the Characteristics of included studies table, which we have put in our summary table. They have assumed that standard mattresses are likely to vary less within countries than between countries, and undertook subgroup analysis by country, although they did not pre-specify this.

Standard foam hospital mattress compared with other "low-tech" CLP

Table 10 – Clinical evidence profile: Constant low-pressure supports (CLP) vs standard foam mattresses (SFM) for pressure ulcer prevention

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Constant low-pressure supports (CLP)	Standard foam mattresses (SFM)	Relative (95% CI)	Absolute		
Pressure ulcer incidence – Cubed foam mattress (COMFORTEX DECUBE) vs standard hospital mattress (standard polypropylene SG40) – grades 2-4 (Dutch consensus[10])												
1Hofman (1994)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	4/17 (23.5%)	13/19 (68.4%)	RR 0.34 (0.14 to 0.85)	452 fewer per 1000 (from 103 fewer to 588 fewer)	⊕OOO VERY LOW	Critical
								68.4%		451 fewer per 1000 (from 103 fewer to 588 fewer)		
Pressure ulcer incidence – Softform mattress (COMFORTEX DECUBE) vs standard hospital mattress (standard polypropylene SG40) – grades 2-4 (no details of grading system)												
1Gray (1994)	randomised trials	very serious[4]	no serious inconsistency	no serious indirectness	no serious imprecision	none	6/90 (6.7%)	27/80 (33.8%)	RR 0.2 (0.09 to 0.45)	270 fewer per 1000 (from 186 fewer to 307 fewer)	⊕⊕OO LOW	Critical
								33.8%		270 fewer per 1000 (from 186 fewer to 308 fewer)		

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Constant low-pressure supports (CLP)	Standard foam mattresses (SFM)	Relative (95% CI)	Absolute		
Pressure ulcer incidence – Cubed foam mattress (COMFORTEX DECUBE) vs standard hospital mattress (standard polypropylene SG40) – all grades of ulcers (Dutch consensus[10])												
1Hofman (1994)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	6/17 (35.3%)	14/19 (73.7%)	RR 0.48 (0.24 to 0.96)	383 fewer per 1000 (from 29 fewer to 560 fewer)	⊕OOO VERY LOW	Critical
								73.7%		383 fewer per 1000 (from 29 fewer to 560 fewer)		
Pressure ulcer incidence – Bead-filled mattress (BEAUFORT) vs standard hospital mattress – all grades												
1Goldstone (1982)	randomised trials	Very serious[3]	no serious inconsistency	no serious indirectness	serious[2]	none	5/32 (15.6%)	21/43 (48.8%)	RR 0.32 (0.14 to 0.76)	332 fewer per 1000 (from 117 fewer to 420 fewer)	⊕OOO VERY LOW	Critical
								48.8%		332 fewer per 1000 (from 117 fewer to 420 fewer)		
Pressure ulcer incidence – Water-filled mattress vs standard hospital mattress – all grades[11]												
1Andersen (1982)	randomised trials	very serious[5]	no serious inconsistency	no serious indirectness	serious[2]	none	7/155 (4.5%)	21/161 (13%)	RR 0.35 (0.15 to 0.79)	85 fewer per 1000 (from 27 fewer to 111 fewer)	⊕OOO VERY LOW	Critical
								13%		84 fewer per 1000 (from 27 fewer to 110 fewer)		
Pressure ulcer incidence – Alternative foam pressure-reducing mattresses (CLINIFLOAT, OMNIFOAM, SOFTFORM, STM5, THERAREST, TRANSFOAM, VAPOURLUX) vs standard hospital mattress – all grades (RCN and NPUAP grading system)[12]												
2 (Collier, 1996; Santy,	randomised trials	very serious[6]	no serious inconsistency	no serious indirectness	no serious imprecision	none	42/571 (7.4%)	17/73 (23.3%)	not pooled as Collier (1996)	149 fewer per 1000	⊕⊕OO	Critical

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Constant low-pressure supports (CLP)	Standard foam mattresses (SFM)	Relative (95% CI)	Absolute		
1994)									had 0 events but 0.36 (0.22 to 0.59) for Santy (1994)	(from 95 fewer to 182 fewer)	LOW	
								13.3%		85 fewer per 1000 (from 55 fewer to 104 fewer)		
Pressure ulcer incidence – Hi-spec foam mattress/cushion – visco-polymer energy absorbing foam mattress (CONFORM-ED) vs standard mattress/cushion (KING's FUND, LINKNURSE, SOFTFOAM, TRANSFOAM, KING'S FUND MATTRESS with a SPENCO or PROPAD mattress overlay – all grades (Torrance scale)[13]												
1 (Russell 2003)	randomised trials	very serious[7]	no serious inconsistency	no serious indirectness	serious[2]	none	48/562 (8.5%)	66/604 (10.9%)	RR 0.78 (0.55 to 1.11)	24 fewer per 1000 (from 49 fewer to 12 more)	⊕OOO VERY LOW	Critical
								10.9%		24 fewer per 1000 (from 49 fewer to 12 more)		
Comfort scores – very uncomfortable – pressure-reducing foam mattress (SOFTFOAM) vs standard 130mm NHS foam mattress												
1 (Gray 1994)	randomised trials	very serious[4]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/90 (0%)	0/80 (0%)	not pooled	not pooled	⊕⊕OO LOW	Critical
Comfort scores – uncomfortable – pressure-reducing foam mattress (SOFTFOAM) vs standard 130mm NHS foam mattress												
1 (Gray 1994)	randomised trials	very serious[4]	no serious inconsistency	no serious indirectness	very serious imprecision[9]	none	0/90 (0%)	2/80 (2.5%)	OR 0.12 (0.01 to 1.91)	22 fewer per 1000 (from 25 fewer to 22 more)	⊕OOO VERY LOW	Critical
								2.5%		22 fewer per 1000 (from 25 fewer to 22 more)		
Comfort scores – adequate – pressure-reducing foam mattress (SOFTFOAM) vs standard 130mm NHS foam mattress												
1 (Gray 1994)	randomised trials	very serious[4]	no serious inconsistency	no serious indirectness	no serious imprecision	none	6/90 (6.7%)	44/80 (55%)	RR 0.12 (0.05 to 0.27)	484 fewer per 1000	⊕⊕OO	Critical

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Constant low-pressure supports (CLP)	Standard foam mattresses (SFM)	Relative (95% CI)	Absolute		
										(from 402 fewer to 523 fewer)	LOW	
								55%		484 fewer per 1000 (from 402 fewer to 523 fewer)		
Comfort scores – comfortable – pressure-reducing foam mattress (SOFTFOAM) vs standard 130mm NHS foam mattress												
1 (Gray 1994)	randomised trials	very serious[4]	no serious inconsistency	no serious indirectness	no serious imprecision	none	62/90 (68.9%)	26/80 (32.5%)	RR 2.12 (1.5 to 2.99)	364 more per 1000 (from 162 more to 647 more)	⊕⊕OO LOW	Critical
								32.5%		364 more per 1000 (from 162 more to 647 more)		
Comfort scores – very comfortable – pressure-reducing foam mattress (SOFTFOAM) vs standard 130mm NHS foam mattress												
1 (Gray 1994)	randomised trials	very serious[4]	no serious inconsistency	no serious indirectness	Serious[14]	none	11/90 (12.2%)	0/80 (0%)	OR 7.45 (2.2 to 25.24)	-	⊕⊕OO LOW	Critical
Comfort – Hi-spec foam mattress/cushion – visco-polymer energy absorbing foam mattress (CONFORM-ED) vs standard mattress/cushion (KING's FUND, LINKNURSE, SOFTFOAM, TRANSFOAM, KING'S FUND MATTRESS with a SPENCO or PROPAD mattress overlay – all grades (Torrance scale)[13]												
1 (Russell 2003)	randomised trials	very serious[7]	no serious inconsistency	no serious indirectness	no serious imprecision	none	2.33 +/- 0.98 N=323	2.46 +/-1.01 N=383	-	MD 0.13 lower (0.28 lower to 0.02 higher)	⊕⊕OO LOW	Critical
Length of stay in hospital (days) – Cubed foam mattress (COMFORTEX DECUBE) vs standard hospital mattress (standard polypropylene SG40)												
1 Hofman 1994)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious	very serious[8]	Median 21 days (range 5-64)	Median 23 days (range 4-120)	-	See footnote[8]	⊕OOO VERY LOW	Important

1 Unclear sequence generation and allocation concealment. No blinding. Unclear if incomplete outcome data was addressed. Higher drop-out than event rate in CLP arm for grades 2-4 ulcer outcome. Hofman (1994).
2 Confidence interval crossed one MID point.

3 Inadequate sequence generation. Unclear allocation concealment and blinding. Incomplete outcome data was not addressed. Goldstone (1982).
4 Unclear sequence generation, allocation concealment, blinding, addressing of incomplete outcome data and if groups similar at baseline (Gray 1994).
5 Unclear sequence generation, allocation concealment, blinding and addressing of incomplete outcome data. Andersen (1982).
6 Unclear sequence generation, allocation concealment and addressing of incomplete outcome data. No blinding. Unclear if groups were similar at baseline. Collier (1996). Unclear sequence generation, blinding and addressing of incomplete outcome data. Differential drop-out with higher drop-out in standard hospital mattress group.Santy (1994).
7 Unclear allocation concealment. No blinding. Russell (2003).
8 Data given as median and range so unable to analyse data in Revman.
9 Confidence interval crossed both MID points.
10 Dutch consensus grading system (1985): 0= normal skin; 1= persistent erythema of the skin; 2= blister formation; 3= superficial (sub-cutaneous necrosis); 4= deep sub-cutaneous necrosis.
11 Bullae, black necrosis and skin defects were evidence of pressure ulcers.
12 Collier (1996) used RCN grading and Santy (1994) used NPUAP 1989.
13 Torrance scale, where blanching erythema represents a Torrrance grade I ulcer and non-blanching erythema represents a Torrance grade II ulcer.
14 Limited number of events.

Table 10 – Clinical evidence profile: Alternative foam mattress vs standard foam mattress for pressure ulcer prevention

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Alternative foam mattress	Standard foam mattress	Relative (95% CI)	Absolute		
Pressure ulcer incidence Various alternatives (pooled) – all grades of ulcer[5]												
5 (Collier 1996; Gray 1994; Hofman 1994; Russell 2003; Santy 1994)	randomised trials	very serious[1]	very serious[2]	no serious indirectness	Serious[4]	none	102/1240 (8.2%)	124/776 (16%)	RR 0.43 (0.24 to 0.76)	91 fewer per 1000 (from 38 fewer to 121 fewer)	⊕OOO VERY LOW	Critical
								26.6%		152 fewer per 1000 (from 64 fewer to 202 fewer		
Pressure ulcer incidence (pooled) grades 2+ ulcer[6] – pressure-reducing foam mattress (SOFTFOAM) vs standard 130mm NHS foam mattress												
2 (Gray 1994; Hofman 1994)	randomised trials	very serious[1]	No serious	no serious indirectness	no serious imprecision	none	10/107 (9.3%)	40/99 (40.4%)	RR 0.24 (0.13 to 0.45)	307 fewer per 1000 (from 222 fewer to 352 fewer)	⊕⊕OO LOW	Critical
								51.1%		388 fewer per 1000 (from 281 fewer to 445 fewer)		

1 Unclear sequence generation for three studies (Collier 1996, Gray 1994, Hofman 2003 and Santy 2004) Unclear allocation concealment in four studies (Collier 1996, Gray 1994, Hofman 2003 and Santy, 1994) No blinding in three studies (Collier 1996, Hofman 1994, Russell 2003) and unclear blindin g in two studies (Gray 1994 and Santy 1994) Unclear if incomplete outcome data addressed in four studies (Collier 1996, Gray 1994, Hofman 1994 and Santy 1994) Unclear if similar at baseline in two studies (Collier 1996 and Gray 1994) Different timing of outcome assessment in two studies (Collier 1996 and Gray 1994) Higher differential drop-out with higher rate in the standard hospital mattrtress group (Santy 1994). Highr drop-out than event rate for incidence of pressure ulcers all grades and 2 and above (Hofman 1994)

2 I2 = 77%, p=0.004

3 I2 =84%, p=0.002

4 Confidence interval crossed one MID point.

5 Collier (1996) used RCN grading system, Gray (1994) had no details of grading system, Hofman (1994) used Dutch consensus, Russell (2003) used the Torrance sc ale, Santy (1994) used NPUAP 1989 grading system.

Comparisons between alternative foam mattresses

Table 11 – Comparisons between alternative foam supports for pressure ulcer prevention

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Comparisons between alternative foam supports	Control	Relative (95% CI)	Absolute		
Pressure ulcer incidence – – Pressure-redistributing mattresses (CLINIFLOAT, OMNIFOAM, THERAREST, TRANSFOAM, VAPERM) vs standard nhs foam mattress (REYLON 150mm) – all ulcer grades (NPUAP)[8]												
1Santy (1994)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	42/441 (9.5%)	17/64 (26.6%)	RR 0.36 (0.22 to 0.59)	170 fewer per 1000 (from 109 fewer to 207 fewer)	⊕⊕OO LOW	Critical
								26.6%		170 fewer per 1000 (from 109 fewer to 207 fewer)		
Pressure ulcer incidence – Foam mattress replacement (MAXIFLOAT) vs foam mattress overlay (IRIS 3000) – all ulcer grades[9]												
1(Vyhlidal (1997)	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	serious[3]	none	5/20 (25%)	12/20 (60%)	RR 0.42 (0.18 to 0.96)	348 fewer per 1000 (from 24 fewer to 492 fewer)	⊕OOO VERY LOW	Critical
								60%		348 fewer per 1000 (from 24 fewer to 492 fewer)		
Pressure ulcer incidence – Solid foam overlay vs convoluted foam overlay – all ulcer grades (NPUAP)[10]												
1Kemp (1994)	randomised trials	Very serious[7]	no serious inconsistency	no serious indirectness	serious[3]	none	12/39 (30.8%)	21/45 (46.7%)	RR 0.66 (0.37 to 1.16)	159 fewer per 1000 (from 294 fewer to 75 more)	⊕⊕OO LOW	Critical
								46.7%		159 fewer per 1000 (from 294 fewer to		

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Comparisons between alternative foam supports	Control	Relative (95% CI)	Absolute		
										75 more)		
Pressure ulcer incidence – pressure-reducing foam mattress (TRANSFOAM) vs pressure=reducing foam mattress (TRANSFOAMWAVE) – all ulcer grades[11]												
1Gray (1998)	randomised trials	Very serious[4]	no serious inconsistency	no serious indirectness	very serious[5]	none	1/50 (2%)	1/50 (2%)	RR 1 (0.06 to 15.55)	0 fewer per 1000 (from 19 fewer to 291 more)	⊕OOO VERY LOW	Critical
								2%		0 fewer per 1000 (from 19 fewer to 291 more)		
Pressure ulcer incidence – Foam mattress replacement (MAXIFLOAT) vs foam mattress overlay (IRIS 3000) – – – grades 2+ ulcer[9]												
1(Vyhlidal (1997)	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	serious[3]	none	3/20 (15%)	8/20 (40%)	RR 0.38 (0.12 to 1.21)	248 fewer per 1000 (from 352 fewer to 84 more)	⊕OOO VERY LOW	Critical
								40%		248 fewer per 1000 (from 352 fewer to 84 more)		
Time to pressure ulcer development (days) – Foam mattress replacement (MAXIFLOAT) vs foam mattress overlay (IRIS 3000) –												
1(Vyhlidal (1997)	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	no serious	very serious[6]	9.2 days	6.5 days	P=0.3288	-	⊕OOO VERY LOW	Important

1 Unclear sequence generation, allocation concealment, blinding and addressing of incomplete outcome data. Santy (1994).
2 Unclear allocation concealment and blinding. Baseline differences. Vyhlidal (1997).
3 Confidence interval crossed one MID.
4 Unclear sequence generation and addressing of incomplete outcome data. Baseline data were provided for the treatment arm only. Gray (1998).
5 Confidence interval crosse both MIDs and limited number of events.
6 Not enough data to analyse in Revman.
7 Unclear allocation concealment, blinding and baseline differences and did not address incomplete outcome data. Kemp (1993).

8 NPUAP 1989 grading system.
9 Unclear grading system name, stage 0= no redness or breakdown; stage 1= erythema only, redness does not disappear for 24 hours after pressure is relieved; stage 2= break in skin such as blisters, or abrasions; stage 3= break in skin exposing subcutaneous tissue; stage 4= break in skin extending through tissue and subcutaneous layers, exposing muscle or bone.
10 NPUAP1989.
11 no details of grading system.

Comparisons between "low-tech" constant low-pressure supports

Table 12 – Comparisons between CLP supports for pressure ulcer prevention

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Comparisons between CLP supports	Control	Relative (95% CI)	Absolute		
Pressure ulcer incidence – Constant low pressure mattress (CARITAL OPTIMA) vs standard foam mattress (10cm thick foam density 35kg/m3)– – all grades of ulcers (Shea)[17]												
1Takala (1996)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	0/21 (0%)	7/19 (36.8%)	RR 0.06 (0 to 0.99)	346 fewer per 1000 (from 4 fewer to 368 fewer)	⊕OOO VERY LOW	Critical
								36.8%		346 fewer per 1000 (from 4 fewer to 368 fewer)		
Pressure ulcer incidence – dry flotation mattress (SOFFLEX) vs dry flotation mattress (ROHO) – all grades of ulcers (Stirling grade)[17]												
1Cooper (1998)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	very serious[4]	none	3/41 (7.3%)	5/43 (11.6%)	RR 0.63 (0.16 to 2.47)	43 fewer per 1000 (from 98 fewer to 171 more)	⊕OOO VERY LOW	Critical
								11.6%		43 fewer per 1000 (from 97 fewer to 171 more)		
Pressure ulcer incidence – dry flotation mattress (SOFFLEX) vs dry flotation mattress (ROHO) grades 2+ ulcers (Stirling grade)[17]												
1Cooper (1998)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	very serious[4]	none	1/41 (2.4%)	0/43 (0%)	RR 3.14 (0.13 to 75.02)	-	⊕OOO VERY LOW	Critical
								0%		-		

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Comparisons between CLP supports	Control	Relative (95% CI)	Absolute		
Pressure ulcer incidence – Gel mattress vs air-filled overlay (SOFCARE) – all grades of ulcers (NPUAP)[17]												
1Lazzara (1991)	randomised trials	very serious[5]	no serious inconsistency	no serious indirectness	very serious[4]	none	8/33 (24.2%)	10/33 (30.3%)	RR 0.8 (0.36 to 1.77)	61 fewer per 1000 (from 194 fewer to 233 more)	⊕OOO VERY LOW	Critical
								15.2%		30 fewer per 1000 (from 97 fewer to 117 more)		
Pressure ulcer incidence – Gel mattress vs air-filled overlay (SOFCARE) – grades 2+ ulcers (NPUAP)[17]												
1Lazzara (1991)	randomised trials	very serious[5]	no serious inconsistency	no serious indirectness	very serious[4]	none	4/33 (12.1%)	5/33 (15.2%)	RR 0.8 (0.24 to 2.72)	23 fewer per 1000 (from 2 fewer to 35 fewer)	⊕OOO VERY LOW	Critical
								15.2%		30 fewer per 1000 (from 116 fewer to 261 more)		
Pressure ulcer incidence – Static air mattress (GAY MAR SOFCARE) vs water mattress (LOTUS PXM 3666) – all grades of ulcers (grading system not reported)[17]												
1Sideranko (1992)	randomised trials	very serious[6]	no serious inconsistency	no serious indirectness	very serious[4]	none	1/20 (5%)	2/17 (11.8%)	RR 0.43 (0.04 to 4.29)	67 fewer per 1000 (from 113 fewer to 387 more)	⊕OOO VERY LOW	Critical
								11.8%		67 fewer per 1000 (from 113 fewer to 388 more)		
Pressure ulcer incidence – Foam overlay vs Silicore overlay (SPENCO) – grades 2 and above[17]												
1Stapleton (1986)	randomised trials	very serious[7]	no serious inconsistency	no serious indirectness	very serious[4]	none	14/34 (41.2%)	12/34 (35.3%)	RR 1.17 (0.64 to 2.14)	60 more per 1000 (from 127 fewer to 402 more)	⊕OOO VERY LOW	Critical
								29.4%		60 more per 1000 (from 127 fewer to		

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Comparisons between CLP supports	Control	Relative (95% CI)	Absolute		
										402 more)		
Pressure ulcer incidence – Australian medical sheepskin vs no sheepskin (all grades of ulcer)[17]												
3 (Jolley 2004; McGowan 2000; Mistiaen 2009)	randomised trials	Very serious[8]	serious[9]	no serious indirectness	no serious	none	59/644 (9.2%)	120/637 (18.8%)	RR 0.48 (0.31 to 0.74)	98 fewer per 1000 (from 49 fewer to 130 fewer)	⊕OOO VERY LOW	Critical
								16.6%		86 fewer per 1000 (from 43 fewer to 115 fewer)		
Pressure ulcer incidence – Australian medical sheepskin vs no sheepskin (grade 2 + ulcers)[17]												
3 (Jolley 2004; McGowan 2000; Mistiaen 2009)	randomised trials	Very serious[8]	no serious inconsistency	no serious indirectness	serious[2]	none	18/644 (2.8%)	33/637 (5.2%)	RR 0.56 (0.32 to 0.97)	23 fewer per 1000 (from 2 fewer to 35 fewer)	⊕OOO VERY LOW	Critical
								3.5%		15 fewer per 1000 (from 1 fewer to 24 fewer)		
Pressure ulcer incidence – static air overlay (and cold foam mattress) vs cold foam mattress – grade 2+ ulcers[17]												
1 Van Leen (2011)	randomised trials	very serious[12]	no serious inconsistency	no serious indirectness	Serious[2]	none	2/38 (5.3%)	7/36 (19.4%)	RR 0.27 (0.06 to 1.22)	142 fewer per 1000 (from 183 fewer to 43 more)	⊕OOO VERY LOW	Critical
								19.4%		142 fewer per 1000 (from 182 fewer to 43 more)		
Comfort – Australian medical sheepskin vs no sheepskin												
1 Jolley (2004)	randomised trials	Very serious[8]	no serious inconsistency	no serious indirectness	no serious	very serious[13]	-	-	-	See footnote[13]	⊕OOO VERY LOW	Critical
Withdrawal due to discomfort – Australian medical sheepskin vs no sheepskin												
1 McGowan	randomised	serious[8]	no	serious	no	serious	no serious	very serious[14]	-	-	-	See	⊕OOO	Critical

Quality assessment								No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations		Comparisons between CLP supports	Control	Relative (95% CI)	Absolute		
(2000)	trials		inconsistency	indirectness							footnote[14]	VERY LOW	
Patient acceptability – very uncomfortable – dry flotation mattress (SOFFLEX) vs dry flotation mattress (ROHO)													
1 (1998)	**Cooper** randomised trials	serious[3]	no serious inconsistency	no serious indirectness	no serious	none		0/41 (0%)	0/43 (0%)	Not pooled as event rate is zero	Not pooled as event rate is zero	⊕⊕⊕O MODERATE	Critical
Patient acceptability – uncomfortable – dry flotation mattress (SOFFLEX) vs dry flotation mattress (ROHO)													
1 (1998)	**Cooper** randomised trials	serious[3]	no serious inconsistency	no serious indirectness	Serious[2]	none		0/41 (0%)	5/43 (11.6%)	OR 0.13 (0.02 to 0.77)	99 fewer per 1000 (from 24 fewer to 114 fewer)	⊕⊕OO LOW	Critical
									11.6%		99 fewer per 1000 (from 24 fewer to 113 fewer)		
Patient acceptability – adequate – dry flotation mattress (SOFFLEX) vs dry flotation mattress (ROHO)													
1 (1998)	**Cooper** randomised trials	serious[3]	no serious inconsistency	no serious indirectness	very serious[4]	none		4/41 (9.8%)	4/43 (9.3%)	RR 1.05 (0.28 to 3.92)	5 more per 1000 (from 67 fewer to 272 more)	⊕OOO VERY LOW	Critical
									9.3%		5 more per 1000 (from 67 fewer to 272 more)		
Patient acceptability – comfortable – dry flotation mattress (SOFFLEX) vs dry flotation mattress (ROHO)													
1 (1998)	**Cooper** randomised trials	serious[3]	no serious inconsistency	no serious indirectness	very serious[4]	none		24/41 (58.5%)	24/43 (55.8%)	RR 1.05 (0.72 to 1.52)	28 more per 1000 (from 156 fewer to 290 more)	⊕OOO VERY LOW	Critical
									55.8%		28 more per 1000 (from 156 fewer to 290 more)		
Patient acceptability – very comfortable – dry flotation mattress (SOFFLEX) vs dry flotation mattress (ROHO)													

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Comparisons between CLP supports	Control	Relative (95% CI)	Absolute		
1 Cooper (1998)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	very serious[4]	none	13/41 (31.7%)	10/43 (23.3%)	RR 1.36 (0.67 to 2.76)	84 more per 1000 (from 77 fewer to 409 more)	⊕OOO VERY LOW	Critical
								23.3%		84 more per 1000 (from 77 fewer to 410 more)		
Time to onset of first ulcer – Australian medical sheepskin vs no sheepskin												
1 Jolley (2004)	randomised trials	serious[8]	no serious inconsistency	no serious indirectness	no serious	Serious[15]	-	-	HR 0.39 (95% CI 0.22 to 0.69)	P<0.001	⊕⊕OO LOW	Important
Time to onset of first ulcer – Australian medical sheepskin vs no sheepskin												
1 Mistiaen (2010E)	randomised trials	serious[8]	no serious inconsistency	no serious indirectness	no serious	very serious[16]	12 days	9 days	-	-	⊕OOO VERY LOW	Important

1 Unclear sequence generation but may have been block randomised and some outcome assessors may have been blinded but unclea , no allocation concealementr. Higher drop out than event rate for incidence of pressure ulcers. Takala (1996).
2 Confidence interval crossed one MID.
3 Unclear blinding. Higher drop out than event rate for incidence of all grades of pressure ulcers and grades 2 and above pressure ulcers Cooper (1998).
4 Confidence interval crossed both MIDs.
5 Unclear allocation concealment, blinding and addressing incomplete outcome data. Lazzara (1991).
6 Unclear sequence generation, allocation concealment, blinding, addressing incomplete outcome data, similarity at baseline. Sideranko (1992).
7 Unclear sequence generation, allocation concealment and blinding. Stapleton (1986).
8 Unclear sequence generation (Jolley 2004), unclear allocation concealment (McGowan 2000) and no blinding (Jolley 2004, McGo wan 2000 and Mistainen 2009, 2010). Unclear addressing of incomplete outcome data (Mistainen 2009, 2010) and no addressing (Jolley 2004). Unclear if baseline dif ferences (Jolley 2004). Higher drop out than event rate for incidence of all grades of pressure ulcers and grades 2 and above p ressure ulcers(Jolley 2004, Mistiaen 2009, 2010)
9 I2 = 52%, p=0.12.
10 Confidence interval crossed one MID.
11 Ethical issues of not using repositioning. Limited details of sequence generation and allocation concealment. No details of b linding of outcome assessors.). Higher drop out than event rate for incidence of pressure ulcers .Van leen (2011)
12 Comfort data not given for both groups. 10 patients in the sheepskin group complained about its comfort (too hot, 6; sensitiv e to the wool surface, 2; uncomfortable, 2) and requested its removal.
13Study did not give details of comfort in both groups. Six patients in the experimental group withdrew before completion of d ata collection because the sheepskin caused an irritation, was too hot or uncomfortable.

14 No data given for each arm but HR presented. Kaplan-Meier survival curves used (p<0.001, log-rank test).
15 Not enough data to analyse in Revman.
16 Takala (1996) used Shea 1975 grading system; Cooper (1998) used the Stirling grading system; Lazzara (1991) used NPUAP 1989 system; Sideranko (1992)did not report the grading system; Stapleton (1986) adapted the grading system from Kenedi et al (1976) bed sore biomechanics study, where c ategory A= superficial/blister, category B = a break in skin (no crater) and category C= a break in skin (with crater) and category D= blackened tissue; Jolley (2004) and McGowan (2000) used the US Agency for Health Care and Policy Research grading system; Mistiaen (2009, 2010) and Van Leen 2011 used the EPUAP grading system.

7.4.1.2. "High-tech" pressure supports

This section outlines three main groups of supports; alternating pressure (AP) supports, low-air loss beds and air-fluidised low beds.

Alternating-pressure compared with constant low pressure

Table 13 – Alternating-pressure vs standard foam mattress for pressure ulcer prevention

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Alternating-pressure	Standard foam mattress	Relative (95% CI)	Absolute		
Pressure ulcer incidence – alternating air mattress/overlay vs standard foam mattress – all grades of ulcer[3]												
2 (Andersen 1982 Sanada 2003)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	13/221 (5.9%)	31/188 (16.5%)	RR 0.31 (0.17 to 0.58)	114 fewer per 1000 (from 69 fewer to 137 fewer)	⊕⊕OO LOW	Critical
								25%		172 fewer per 1000 (from 105 fewer to 207 fewer)		
Pressure ulcer incidence – alternating air mattress vs standard foam mattress – grade 2+ ulcers[3]												
1 Sanada (2003)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	5/55 (9.1%)	6/27 (22.2%)	RR 0.41 (0.14 to 1.22)	131 fewer per 1000 (from 191 fewer to 49 more)	⊕OOO VERY LOW	Critical
								22.2%		131 fewer per 1000 (from 191 fewer to 49 more)		

1 Unclear sequence generation, allocation concealment, blinding and addressing incomplete outcome data (Andersen 1982). Unclear blinding and no addressing of incomplete outcome data . Higher drop out than event rate for incidence of all grades of pressure ulcers and grades 2 and above pressure ulcers (Sanada 2003).
2 Confidence interval crossed one MID point.
3 Andersen 1982 used the classification of Bullae, black necrosis, and skin defects as evidence of pressure sores. Sanada (2003) used NPUAP 1989 grading system.

Alternating-pressure compared with constant low pressure

Table 14 – Alternating-pressure (AP) vs constant low-pressure for pressure ulcer prevention

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Alternating-pressure (AP)	Constant low-pressure	Relative (95% CI)	Absolute		
Pressure ulcer incidence – Alternating pressure (all studies meta-analysed all had various types of alternating pressureand various types of constant low-pressure – all grades of ulcer[12]												
11 (Conine 1990; Daechsel 1985; Stapleton 1986; Whitney 1984; ;Gebhardt 1996; Andersen 1982; Price 1999; Sideranko 1992; Vanderwee, 2005; Malbrain, 2010, Cavicchioli 2007)	randomised trials	very serious[1,2,3,4,5]	no serious inconsistency	no serious indirectness	serious[6]	none	125/785 (15.9%)	170/837 (20.3%)	RR 0.85 (0.65 to 1.11)	30 fewer per 1000 (from 71 fewer to 22 more)	⊕OOO VERY LOW	Critical
								23.1%		35 fewer per 1000 (from 81 fewer to 25 more)		
Pressure ulcer incidence – Alternating pressure (various) vs Constant low pressure (various) – one study which included patients with various types of alternating pressure and constant low pressure devices– all grades of ulcer[12]												
1 Gebhardt (1996)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	15/115 (13%)	39/115 (33.9%)	RR 0.38 (0.22 to 0.66)	210 fewer per 1000 (from 115 fewer to 265 fewer)	⊕⊕OO LOW	Critical
								33.9%		210 fewer per 1000 (from 115 fewer to 264 fewer)		
Pressure ulcer incidence – Alternating pressure vs Silicore or foam overlay[11] – all grades of ulcer and all types of patients[12]												
4 (Conine 1990; Daechsel 1985; Stapleton 1986;	randomised trials	very serious[2]	no serious inconsistency	no serious indirectness	serious[6]	none	59/145 (40.7%)	81/186 (43.5%)	RR 0.91 (0.72 to 1.16)	39 fewer per 1000 (from 122	⊕OOO VERY	Critical

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Alternating-pressure (AP)	Constant low-pressure	Relative (95% CI)	Absolute		
Whitney 1984)										fewer to 70 more)	LOW	
								31.6%		28 fewer per 1000 (from 88 fewer to 51 more)		
Pressure ulcer incidence – Alternating pressure vs water or static air mattress – all grades of ulcer[12]												
3 (Andersen 1982; Price 1999;; Sideranko 1992)	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	very serious[7]	none	13/226 (5.8%)	12/232 (5.2%)	RR 1.31 (0.51 to 3.35)	16 more per 1000 (from 25 fewer to 122 more)	⊕OOO VERY LOW	Critical
								5%		15 more per 1000 (from 25 fewer to 117 more)		
Pressure ulcer incidence – Alternating pressure setting on mattress (DUO 2) vs continuous low pressure mattress setting on mattress (DUO 2) – all grades of ulcer[12]												
1Cavicchioli (2007)	randomised trials	serious[4]	no serious inconsistency	no serious indirectness	very serious[8]	none	2/69 (2.9%)	1/71 (1.4%)	RR 2.06 (0.19 to 22.18)	15 more per 1000 (from 11 fewer to 298 more)	⊕OOO VERY LOW	Critical
								1.4%		15 more per 1000 (from 11 fewer to 297 more)		
Pressure ulcer incidence – Alternating pressure air mattress (ALPHA-X-CELL) vs visco-elastic foam mattress (TEMPUR) – all grades of ulcer[12]												
1Vanderwee (2005)	randomised trials	very serious[5]	no serious inconsistency	no serious indirectness	very serious[7]	none	34/222 (15.3%)	35/225 (15.6%)	RR 0.98 (0.64 to 1.52)	3 fewer per 1000 (from 56 fewer to 81 more)	⊕OOO VERY LOW	Critical
								15.6%		3 fewer		

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Alternating-pressure (AP)	Constant low-pressure	Relative (95% CI)	Absolute		
										per 1000 (from 56 fewer to 81 more)		
Pressure ulcer incidence – Alternating pressure mattress (NIMBUS 3) vs dry flotation mattress overlay (ROHO) – all grades of ulcer[12]												
1Malbrain (2010)	randomised trials	very serious[9]	no serious inconsistency	no serious indirectness	very serious[7]	none	2/8 (25%)	2/8 (25%)	RR 1 (0.18 to 5.46)	0 fewer per 1000 (from 205 fewer to 1000 more)	⊕OOO VERY LOW	Critical
								0%		-		
Pressure ulcer incidence – Alternating pressure mattress vs Silicore – patients not singularly with chronic neurological conditions – all grades of ulcer[12]												
2 (Stapleton 1986; Whitney 1984)	randomised trials	very serious[2]	no serious inconsistency	no serious indirectness	very serious[7]	none	16/57 (28.1%)	32/94 (34%)	RR 0.89 (0.54 to 1.47)	37 fewer per 1000 (from 157 fewer to 160 more)	⊕OOO VERY LOW	Critical
								30.7%		34 fewer per 1000 (from 141 fewer to 144 more)		
Pressure ulcer incidence – Alternating pressure mattress vs Silicore overlay – patients with chronic neurological conditions – all grades of ulcer[12]												
2 (Conine 1990; Daechsel 1985)	randomised trials	very serious[2]	no serious inconsistency	no serious indirectness	serious[6]	none	43/88 (48.9%)	49/92 (53.3%)	RR 0.92 (0.7 to 1.22)	43 fewer per 1000 (from 160 fewer to 117 more)	⊕OOO VERY LOW	Critical
								42.1%		34 fewer per 1000 (from 126 fewer to 93 more)		
Pressure ulcer incidence – grade 2+ ulcers[12]												
6 (Cavicchioli 2007;	randomised	very	no serious	no serious	serious[6]	none	45/394	70/432	RR 0.80	34 fewer	⊕OOO	Critical

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Alternating-pressure (AP)	Constant low-pressure	Relative (95% CI)	Absolute		
Stapleton 1986; Gebhardt, 1996; Price, 1999; Vanderwee,2005; Malbrain 2010)	trials	serious[2]	inconsistency	indirectness			(11.4%)	(16.9%)	(0.58 to 1.11)	per 1000 (from 71 fewer to 19 more)	VERY LOW	
								14%		28 fewer per 1000 (from 59 fewer to 15 more)		
Drop out due to discomfort – Alternating pressure overlay vs Silicore overlay												
1Conine (1990)	randomised trials	very serious[2]	no serious inconsistency	no serious indirectness	very serious[7]	none	19/93 (20.4%)	17/94 (18.1%)	RR 1.13 (0.63 to 2.03)	24 more per 1000 (from 67 fewer to 186 more)	⊕OOO VERY LOW	Critical
								0%		-		
Comfort rating at 14 days dynamic flotation mattress (NIMBUS 2) and alternating pressure overlay cushion vs low pressure inflatable mattress (REPOSE SYSTEM) and cushion												
1Price (1999)	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	very serious[7]	none	26	24	-	MD 7 lower (19.01 lower to 5.01 higher)	⊕OOO VERY LOW	Critical
Length of stay in hospital – Alternating pressure setting on mattress (DUO 2) vs continuous low pressure setting on mattress (DUO 2)												
1Caviccioli (2007)	randomised trials	very serious[5]	no serious inconsistency	no serious indirectness	no serious	very serious[10]	-	-	-	See footnote[10]	⊕OOO VERY LOW	Important

1 No adequate sequence generation, allocation concealment and unclear blinding. Higher drop out than event rate for incidence of pressure ulcers (Gebhardt 1996)
2 Unclear sequence generation (Conine 1990, Daeschel 1985, Stapleton 1986, Whitney 1984). Unclear allocation concealment (Conine 1990, Daeschel 1985, Stapleton 1986). Unclear blinding (Daeschel 1985, Stapleton 1986, Whitney 1984). Unclear addressing of incomplete outcome data (Daeschel, 1985). Unclear baseline differences (Daeschel 1985, Whitney 1984).
3 Unclear sequence generation (Anderson 1982, Sideranko 1992). Unclear allocation concealment (Anderson 1982, Price 1999, Sideranko 1992). Unclear blinding (Anderson 1982, Sideranko 1992) and no blinding (Price 1999). Unclear addressing of incomplete outcome data (Anderson 1982, Price 1999, Sideranko 1992). Higher drop out than event rate for incidence of all grades of pressure ulcers and comfort rating at 14 days. (Price 1999)
4 Unclear sequence generation, allocation concealment. Differences between groups at baseline. Cavicchioli (2007).

5 Unclear blinding and addressing of incomplete outcome data. Vanderwee (2005).
6 Confidence interval crossed one MID.
7 Confidence interval crossed both MIDs.
8 Confidence interval crossed both MIDs and limited number of events.
9 Baseline difference; allocation concealment unclear; single blinding.(Malbrain, 2010)
10 There was no data presented, but the authors state that there was no difference in length of stay related to pressure ulcer development among high-risk patients placed on the intervention or control mattresses.
11 Conine (1990) and Daeschel (1985) included patients with chronic neurological conditions, which we identified as a group to be stratified. However the Cochrane review included these studies together and in a subgroup test, no subgroup differences were found so the results are presented together. The results of those with and without chronic neurological conditions are also presented separately.
12 Conine (1990) and Daechsel (1985) used Exton-Smith scale; Stapleton (1986) adapted the grading system from Kenedi et al (1976) bed sore biomechanics study, where category A= superficial/blister, category B = a break in skin (no crater) and category C= a break in skin (with crater) and category D= blackened tissue; Whitney (1984) used a system where stage 0 = no redness or skin breakdown; stage 1= skin redness, fades in 15 minutes or less; stage II inflammation of the skin, fading time exceeds 15 minutes, less than one hour; stage III= inflammation of the skin fading time exceeds one hour; stage IV= skin break with redness of surrounding skin, redness fades longer than one hour; Gebhardt (1996) used a grading system by Bliss (1966) grade 1= persistent erythema; grade 2= epidermal loss; grade 3= blue-black discoloration or cavity extending to dermis ; grade 4=cavity to subcutaneous tissue or deeper; Andersen (1982) used bullae, black necrosis and skin defects as evidence of pressure sores; Price (1999) used the Hofman 1994 scale where 0=normal skin, 1= persistent erythema of the skin; 2= blister formation; 3= superficial subcutaneous necrosis; 4= deep subcutaneous necrosis; Sideranko (1992) did not report grading system; Vanderwee (2005) did not report grading system but grade 1 was non-blanchable erythema or NBE; Malbrain (2010) used EPUAP and Cavicchioli (2007) used EPUAP 2007.

Table 15 – Alternating pressure and Constant Low pressure in Intensive Care Unit/post Intensive Care Unit (factorial design) for pressure ulcer prevention

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	AP and CLP in ICU/post ICU (factorial design)	Control	Relative (95% CI)	Absolute		
Pressure ulcer incidence – Standard mattress in ICU/Standard foam mattress post-ICU vs alternating pressure mattress (NIMBUS) in ICU/Standard foam mattress post-ICU												
1Laurent (1998)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	4/80 (5%)	10/80 (12.5%)	RR 0.4 (0.13 to 1.22)	75 fewer per 1000 (from 109 fewer to 28 more)	⊕OOO VERY LOW	Critical
								12.5%		75 fewer per 1000 (from 109 fewer to 28 more)		
Pressure ulcer incidence – Standard mattress in ICU/Standard foam mattress post-ICU vs standard ICU/constant low pressure mattress (TEMPUR) post-ICU												
1Laurent (1998)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	14/80 (17.5%)	11/75 (14.7%)	RR 1.19 (0.58 to 2.46)	28 more per 1000 (from 62 fewer to 214 more)	⊕OOO VERY LOW	Critical
								14.7%		28 more per 1000 (from 62 fewer to 215 more)		
Pressure ulcer incidence – Alternating pressure (NIMBUS) ICU/SFM post-ICU vs standard ICU/constant low pressure mattress (TEMPUR) post-ICU												
1Laurent (1998)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	10/80 (12.5%)	11/75 (14.7%)	RR 0.85 (0.38 to 1.89)	22 fewer per 1000 (from 91 fewer to 131 more)	⊕OOO VERY LOW	Critical
								14.7%		22 fewer per 1000 (from 91 fewer to 131 more)		
Pressure ulcer incidence – Standard ICU/Standard foam mattress post-ICU vs Alternating pressure mattress (NIMBUS) ICU/Constant low pressure mattress (TEMPUR)CLP post-ICU												
1Laurent (1998)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	14/80 (17.5%)	10/77 (13%)	RR 1.35 (0.64 to 2.85)	45 more per 1000 (from 47 fewer to 240 more)	⊕OOO VERY LOW	Critical

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	AP and CLP in ICU/post ICU (factorial design)	Control	Relative (95% CI)	Absolute		
								13%		46 more per 1000 (from 47 fewer to 240 more)		
Pressure ulcer incidence – – Alternating pressure mattress (NIMBUS) ICU/SFM post-ICU vs Alternating pressure mattress (NIMBUS) ICU/constant low pressure mattress (TEMPUR) post-ICU												
1Laurent (1998)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	10/80 (12.5%)	10/77 (13%)	RR 0.96 (0.42 to 2.18)	5 fewer per 1000 (from 75 fewer to 153 more)	⊕OOO VERY LOW	Critical
								13%		5 fewer per 1000 (from 75 fewer to 153 more)		
Pressure ulcer incidence – Standard ICU/constant low pressure mattress (TEMPUR) post-ICU vs alternating pressure mattress (NIMBUS) ICU/constant low pressure mattress (TEMP UR) post-ICU												
1Laurent (1998)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	11/75 (14.7%)	10/77 (13%)	RR 1.13 (0.51 to 2.5)	17 more per 1000 (from 64 fewer to 195 more)	⊕OOO VERY LOW	Critical
								13%		17 more per 1000 (from 64 fewer to 195 more)		

1 Unclear sequence generation, allocation concealment and no blinding. Laurent (1998).
2 Confidence interval crossed one MID.
3 Confidence interval crossed both MIDs.

Comparisons between different alternating-pressure devices

Table 16 – Comparisons between alternating-pressure devices for pressure ulcer prevention

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Comparisons between alternating-pressure devices	Control	Relative (95% CI)	Absolute		
Pressure ulcer incidence – Alternating-pressure mattress (TRINOVA)vs control – ulcers of all grades[12]												
Taylor (1999)	randomised trials	very serious[4]	no serious inconsistency	no serious indirectness	very serious[5]	none	0/22 (0%)	2/22 (9.1%)	RR 0.2 (0.01 to 3.94)	73 fewer per 1000 (from 90 fewer to 267 more)	⊕OOO VERY LOW	Critical
								9.1%		73 fewer per 1000 (from 90 fewer to 268 more)		
Pressure ulcer incidence – alternating low pressure air mattress with multi-stage inflation and deflation of air cells vs standard (CLINACTIV, HILLROM) alternating low pressure air mattress with single-stage inflation and deflation of air cells – ulcers of all grades[12]												
1Demarre (2012)	randomised trials	Very serious[8]	no serious inconsistency	no serious indirectness	Serious[2]	none	68/298 (22.8%)	56/312 (17.9%)	RR 1.27 (0.93 to 1.74)	48 more per 1000 (from 13 fewer to 133 more)	⊕OOO VERY LOW	Critical
								18%		49 more per 1000 (from 13 fewer to 133 more)		
Pressure ulcer incidence – alternating-pressure mattress with two layers of air cells (PEGASUS AIRWAVE SYSTEM) vs alternating-pressure large cell ripple mattress – grade 2+ ulcers[12]												
1Exton-Smith (1982)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	5/31 (16.1%)	12/31 (38.7%)	RR 0.42 (0.17 to 1.04)	225 fewer per 1000 (from 321 fewer to 15 more)	⊕OOO VERY LOW	Critical
								38.7%		224 fewer per 1000 (from 321 fewer to 15 more)		
Pressure ulcer incidence – alternating-pressure mattress (PEGASUS AIRWAVE SYSTEM) vs alternating-pressure mattress (PEGASUS CAREWAVE SYSTEM) – grade 2+ ulcers[12]												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Comparisons between alternating-pressure devices	Control	Relative (95% CI)	Absolute		
1 Hampton (1997)	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/36 (0%)	0/39 (0%)	-	-	⊕⊕OO LOW	Critical
								0%		-		
Pressure ulcer incidence – alternating-pressure mattress (TRINOVA)Trinova vs control – grade 2+ ulcers[12]												
1 Taylor (1999)	randomised trials	very serious[4]	no serious inconsistency	no serious indirectness	very serious[5]	none	0/22 (0%)	2/22 (9.1%)	RR 0.2 (0.01 to 3.94)	73 fewer per 1000 (from 90 fewer to 267 more)	⊕OOO VERY LOW	Critical
								9.1%		73 fewer per 1000 (from 90 fewer to 268 more)		
Pressure ulcer incidence – Alternating pressure overlay vs Alternating pressure mattress – grade 2+ ulcers[12]												
1Nixon (2006)	randomised trials	Very serious[6]	no serious inconsistency	no serious indirectness	serious[2]	none	106/989 (10.7%)	101/982 (10.3%)	RR 1.04 (0.81 to 1.35)	4 more per 1000 (from 20 fewer to 36 more)	⊕OOO VERY LOW	Critical
								10.3%		4 more per 1000 (from 20 fewer to 36 more)		
Pressure ulcer incidence – – alternating pressure bed (THERAPULSE) vs alternating pressure mattress (HILL-ROM DUO) – grade 2+ ulcers[12]												
1Theaker (2005)	randomised trials	very serious[7]	no serious inconsistency	no serious indirectness	very serious[5]	none	3/30 (10%)	6/32 (18.8%)	RR 0.53 (0.15 to 1.94)	88 fewer per 1000 (from 159 fewer to 176 more)	⊕OOO VERY LOW	Critical
								18.8%		88 fewer per 1000 (from 160 fewer to 177 more)		
Pressure ulcer incidence – alternating low pressure air mattress with multi-stage inflation and deflation of air cells vs standard (CLINACTIV, HILLROM) alternating low pressure air mattress with single-stage inflation and deflation of air cells – grade 2+ ulcers[12]												
1Demarre (2012)	randomised trials	Very serious[8]	no serious inconsistency	no serious indirectness	very serious[5]	none	17/298 (5.7%)	18/312 (5.8%)	RR 0.99 (0.52 to	1 fewer per 1000 (from	⊕OOO	Critical

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Comparisons between alternating-pressure devices	Control	Relative (95% CI)	Absolute		
									1.88)	28 fewer to 51 more)	VERY LOW	
								0%		-		
Withdrawal due to discomfort- alternating low pressure air mattress with multi-stage inflation and deflation of air cells vs standard (CLINACTIV, HILLROM) alternating low pressure air mattress with single-stage inflation and deflation of air cells												
1Demarre (2012)	randomised trials	Very serious[8]	no serious inconsistency	no serious indirectness	very serious[5]	none	11/298 (3.7%)	17/312 (5.4%)	RR 0.68 (0.32 to 1.42)	17 fewer per 1000 (from 37 fewer to 23 more)	⊕OOO VERY LOW	Critical
								0%		-		
Comfort alternating-pressure mattress (TRINOVA)Trinova vs control												
1Taylor (1996)	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	very serious[9]	N=18	-	-	-	⊕OOO VERY LOW	Critical
Length of stay in hospital (days) – who did develop a pressure sore – alternating pressure bed (THERAPULSE) vs alternating pressure mattress (DUP)												
1 Theaker (2005)	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	very serious[10]	26 (range 23-37.3)	24 (range 13-59)	-	-	⊕OOO VERY LOW	Important
Length of stay in hospital (days) – who did not develop a pressure sore – alternating pressure bed (THERAPULSE) vs alternating pressure mattress (DUP)												
1 Theaker (2005)	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	very serious[10]	18 (range 5-127)	20 (range 5-49)	-	-	⊕OOO VERY LOW	Important
Time to develop new pressure ulcer (days) – alternating low pressure air mattress with multi-stage inflation and deflation of air cells vs standard (CLINACTIV, HILLROM) alternating low pressure air mattress with single-stage inflation and deflation of air cells												
1Demarre (2012)	randomised trials	serious[8]	no serious inconsistency	no serious indirectness	no serious imprecision	very serious[10]	5.0 (IQR 3.0-8.5)	8.0 days (IQR 3.0-8.5)	P=0.182[11]	-	⊕OOO VERY LOW	Important

1 Inadequate sequence generation. Unclear allocation concealment, blinding and addressing of incomplete outcome data (Exton -Smith 1982).
2 Confidence interval crossed one MID.
3 Unclear sequence generation, allocation concealment, blinding, addressing incomplete outcome data, baseline differences (Hampton 1997).
4 Unclear sequence generation, blinding, addressing incomplete outcome data. Selective reporting (Taylor 1999).
5 Confidence interval crossed both MIDs.
6 No blinding . High drop out in both groups. (Nixon 2006).

7 Unclear sequence generation and addressing incomplete outcome data (Theaker 2005).
8 No blinding of outcome assessors. High drop-out in both groups.(Demarre 2012)
9 Only comfort data for the intervention studied. 18/22 patients completed the comfort questionnaire, 11/18 (61.1%) described the mattress as being comfortable. Most 10/18 (55.5%) found the mattress to be acceptable; overall opinion was that the mattress was unacceptable 5/18.
10 Not enough data to analyse in Revman.
11 Mann-Whitney U-test=113, p=0.182.
12 Taylor (1999) no grading system reported but both sores were superficial one was non-blanching erythema and one was a superficial break in the skin. Demarre (2012) used EPUAP 1999 grading system; Exton-Smith (1982) unclear grading system but included grades 3 and 4 which were superficial or deep sores; Hampton (1997) did not report the grading system; Nixon (2006) used EPUAP 2004 and NPUAP 1999; Theaker (2005) used the Lowthian scale.

Low-air-loss (LAL) beds

Three studies evaluated the use of low-air-loss beds. Such devices provide a flow of air that assists in controlling the microclimate of the patient's skin (NPUAP 2007).

Table 17 – Low Air Loss vs standard bed for pressure ulcer prevention

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Low Air Loss	Standard bed	Relative (95% CI)	Absolute		
Pressure ulcer incidence – – low-air-loss bed (KINAIR) vs static air mattress overlay (EHOB WAFFLE) – all grades of ulcers[5]												
1 Cobb (1997)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	Serious[2]	none	6/62 (9.7%)	12/61 (19.7%)	RR 0.49 (0.2 to 1.23)	100 fewer per 1000 (from 157 fewer to 45 more)	⊕OOO VERY LOW	Critical
								19.7%		100 fewer per 1000 (from 158 fewer to 45 more)		
Pressure ulcer incidence – low-air-loss bed (KINAIR/CLENSICAIR) vs static air mattress overlay (EHOB WAFFLE) or standard ICU bed or standard care (standard bed or foam, air, alternating-pressure mattresses) – grade 2+ ulcers[5]												
3 Bennett (1998) Cobb (1997) Inman (1993)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	20/153 (13.1%)	41/166 (24.7%)	-	247 fewer per 1000 (from 247 fewer to 247 fewer)	⊕⊕OO LOW	Critical
								19.7%		197 fewer per 1000 (from 197 fewer to 197 fewer)		
Pressure incidence – – low-air-loss bed (KINAIR) vs static air mattress overlay (EHOB WAFFLE) or standard ICU bed – grade 2+ ulcers[5]												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Low Air Loss	Standard bed	Relative (95% CI)	Absolute		
2 Cobb (1997) Inman (1993)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	9/111 (8.1%)	36/110 (32.7%)	RR 0.25 (0.13 to 0.49)	245 fewer per 1000 (from 167 fewer to 285 fewer)	⊕⊕OO LOW	Critical
								34.5%		259 fewer per 1000 (from 176 fewer to 300 fewer)		
Comfort – low air loss hydrotherapy (CLENSICAIR) vs standard care (standard bed or foam, air , alternating -pressure mattresses)												
1 Bennett (1998)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	very low[3]	N=10	-	-	See footnote[4]	⊕OOO VERY LOW	Critical
Patient acceptability – low air loss hydrotherapy (CLENSICAIR) vs standard care (standard bed or foam, air , alternating -pressure mattresses)												
1 Bennett (1998)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	very low[4]	-	-	-	See footnote[5]	⊕OOO VERY LOW	Critical

1 Unclear sequence generation (Cobb 1997, Inman 1993) and allocation concealment (Bennett 1998, Inman 1993). Unclear blinding (Cobb 1997, Inman 1993, Bennett 1998). No addressing of incomplete outcome data (Inman 1993). Differences at baseline (Cobb 1997).
2 Confidence interval crossed one MID point.
3 Data on comfort only from intervention group and only 10/42 patients completed the questionnaire. 5/10 thought it was comfortable, 4/10 thought it was uncomfortable.
4 It should be noted that there were more dropouts overall from the treatment than the control group 24/48 (35%) vs 2/58 (3%) (p=0.0001). Six subjects receiving low airloss hydrotherapy exited the study on the first day because either a patient or family member complained about the bed. This was due to being wet, cold or uncomfortable on the specialty bed. Two subjects were removed by the research investigators or nurses as a result of hypothermia within the first 24 hours of enrolment.
5 Bennett (1998) used NPUAP 1989; Cobb (1997) used NPUAP 1989 and Shea 1975; Inman (1993) used Shea 1975.

7.4.1.3. Other support surfaces – operating room

Operating room mattresses (indentation load deflection) versus usual care

Table 18 – Indentation load deflection (IDL) (25%) operating room foam mattress (density 1.3 cubic feet, IDL 30lb) vs operating room usual care (padding as required, including gel pads, foam mattresses, ring cushions (donuts) etc) for pressure ulcer prevention

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	ILD operating room mattress	Usual care	Relative (95% CI)	Absolute		
Incidence of pressure ulcers – all grades of pressure ulcer												
1Schultz (1999)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	55/206 (26.7%)	34/207 (16.4%)	RR 1.63 (1.11 to 2.38)	103 more per 1000 (from 18 more to 227 more)	⊕⊕OO LOW	Critical
								16.4%		103 more per 1000 (from 18 more to 226 more)		
Incidence of pressure ulcers – grade 2 + pressure ulcers												
1Schultz (1999)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	6/206 (2.9%)	3/207 (1.4%)	RR 2.01 (0.51 to 7.93)	15 more per 1000 (from 7 fewer to 100 more)	⊕OOO VERY LOW	Critical
								1.5%		15 more per 1000 (from 7 fewer to 104 more)		
Patient acceptability – postoperative skin changes												
1Schultz (1999)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious	very serious[4]	-	-	P=0.0111	See footnote[5]	⊕OOO VERY LOW	Critical

1 No allocation concealment.
2 Confidence interval crossed one MID point.
3 Confidence interval crossed both MID points.
4 No details given for number of patients in each arm for postoperative skin changes.
5 Patients on the experimental mattress (IDL) were significantly more likely to have skin changes than those on the usual care operating room table, no further details were given.

Operating table overlay versus no overlay

Table 19 – Operating table overlay vs no overlay for pressure ulcer prevention

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Operating table overlay	No overlay	Relative (95% CI)	Absolute		
Pressure ulcer incidence – Viscoelastic polymer pad vs no overlay[6]												
1Nixon (1998)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	22/205 (10.7%)	43/211 (20.4%)	RR 0.53 (0.33 to 0.85)	96 fewer per 1000 (from 31 fewer to 137 fewer)	⊕⊕OO LOW	Critical
								20.4%		96 fewer per 1000 (from 31 fewer to 137 fewer)		
Pressure ulcer incidence – Viscoelastic foam overlay vs no overlay[6]												
1Feuchtinger (2006)	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	very serious[4]	none	13/85 (15.3%)	9/90 (10%)	RR 1.53 (0.69 to 3.39)	53 more per 1000 (from 31 fewer to 239 more)	⊕OOO VERY LOW	Critical
								10%		53 more per 1000 (from 31 fewer to 239 more)		
Pressure ulcer incidence – Viscoelastic foam overlay vs no overlay – grade 2+ ulcers[6]												
1Feuchtinger (2006)	randomised trials	very serious[3]	no serious inconsistency	no serious indirectness	very serious[5]	none	2/85 (2.4%)	1/90 (1.1%)	RR 2.12 (0.2 to 22.93)	12 more per 1000 (from 9 fewer to 244 more)	⊕OOO VERY LOW	Critical
								1.1%		12 more per 1000 (from 9 fewer to 241 more)		

1 Difference at baseline. Standard mattress group had a longer length of operation, longer pre-operative stay and more time in hypotensive state than the dry polymer pad group (Nixon 1998).
2 Confidence interval crossed one MID.
3 Unclear sequence generation, allocation concealment and addressing of incomplete outcome data (Feuchtinger 2006).
4 Confidence interval crossed both MIDs.

5 Confidence interval crossed both MID points and limited number of events.
6 Nixon (1998) used the Torrance 1983 grading system; Feuchtinger (2006)used EPUAP 2005 grading system.

Face pillows in operating room

Table20 – Disposable polyurethane foam prone head positioner (OSI) vs neoprene air filled bladder (dry flotation) device (ROHO)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	OSI face pillow	ROHO face pillow	Relative (95% CI)	Absolute		
Incidence of pressure ulcers – all grades of ulcer[4]												
1Grisell (2008)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	10/22 (45.5%)	0/22 (0%)	Peto OR 12.55 (3.11to 50.57)	-	⊕OOO VERY LOW	Critical
								0%		-		
Incidence of pressure ulcers – grades 2+ ulcers[4]												
1Grisell (2008)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	Very serious[2,3]	none	2/22 (9.1%)	0/22 (0%)	Peto OR 7.75 (0.47 to 128.03)	-	⊕OOO VERY LOW	Critical
								0%		-		

1 Grisell (2008): No details of baseline data. No blinding. higher drop-out than event rate. 2 Limited number of events. 3 Confidence interval crossed both MID points. 4 NPUAP grading system.

Table 21 – Disposable polyurethane foam prone head positioner (OSI)vs prone view protective helmet system with a disposable polyurethane foam prone head positioner (DUPACO)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	OSI face pillow	Dupaco face pillow	Relative (95% CI)	Absolute		
Incidence of pressure ulcers – all grades of ulcer[4]												
1Grisell (2008)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	10/22 (45.5%)	0/22 (0%)	Peto OR 12.55 (3.11 to 50.57)	-	⊕OOO VERY LOW	Critical
								0%		-		
Incidence of pressure ulcers – grades 2+ ulcer[4]												
1Grisell (2008)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	Very serious[2,3]	none	2/22 (9.1%)	0/22 (0%)	Peto OR 7.75 (0.47 to 128.03)	-	⊕OOO VERY LOW	Critical
								0%		-		

1 Grisell (2008): No details of baseline data. No blinding.higher drop-out than event rate.
2 Limited number of events. 3 Confidence interval crossed both MID points. 4 NPUAP grading system.

Table 22 – Neoprene air filled bladder (dry flotation) device (ROHO)vs prone view protective helmet system with a disposable polyurethane fo am prone head positioner (DUPACO)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	ROHO face pillow	Dupaco face pillow	Relative (95% CI)	Absolute		
Incidence of pressure ulcers – all grades of ulcers[2]												
1Grisell (2008)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/22 (0%)	0/22 (0%)	not pooled	not pooled	⊕⊕OO LOW	Critical
								0%		not pooled		
Incidence of pressure ulcers – grades 2+ ulcers[2]												
1Grisell (2008)	randomised trials	Very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/22 (0%)	0/22 (0%)	not pooled	not pooled	⊕⊕OO LOW	Critical
								0%		not pooled		

1 Grisell (2008): No details of baseline data. No blinding.Higher drop-out than event rate.
2 NPUAP grading system.

Other mattresses intra- and post-operatively

Table 23 – Multi-cell pulsating dynamic mattress system (MICROPULSE) vs standard mattress for surgical patients for pressure ulcer prevention

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Micropulse System for surgical patients	Usual care (gel pad in operating room and a replacement mattress postoperatively)	Relative (95% CI)	Absolute		
Pressure ulcer incidence – all grades of ulcer[4]												
2 Aronovitch (1999) Russell (2000)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	3/188 (1.6%)	14/180 (7.8%)	RR 0.21 (0.06 to 0.7)	61 fewer per 1000 (from 23 fewer to 73 fewer)	⊕⊕OO LOW	Critical
								7.9%		62 fewer per 1000 (from 24 fewer to 74 fewer)		
Pressure ulcer incidence – grade 2+ ulcers[4]												
1 Aronovitch (1999);	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	Serious[3]	none	0/90 (0%)	6/80 (7.5%)	RR 0.07 (0 to 1.2)	70 fewer per 1000 (from 75 fewer to 15 more)	⊕OOO VERY LOW	Critical
								7.5%		70 fewer per 1000 (from 75 fewer to 15 more)		
Length of stay in hospital												
1 Aronovitch (1999)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	very serious[2]	-	-	-	See footnote[2]	⊕OOO VERY LOW	Important

1 Unclear sequence generation (quasi-randomised), allocation concealment and blinding and higher drop out than event rate(Aronovitch 1999). The conventional management group were at higher risk at baseline (Knoll score) Unclear sequence generation method , no blinding and higher drop out than event rate (Russell 2000).
2 Data given only for those who developed ulcers – 6/8 who developed ulcers had a length of stay longer than average for the specific diagnosis. Average length of stay for those developing ulcers was 14 days, which was6.7 days longer than the hospital's average of 7.3 days for this Diagnosis Related Group. The authors state that this represents and increase in length of stay of 92%.

3 Confidence interval crossed one MID point.
4 Aronovitch (1999)used NPUAP and WOCN and Russell (2000) used NPUAP 1997.

Table 24 – Visco-elastic foam (TEMPUR-PEDIC) A&E overlay and ward mattress vs standard A&E overlay and ward mattress

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Accident and emergency overlay and ward mattress	Control	Relative (95% CI)	Absolute		
Proportion with incidence of pressure ulcers – grade 2+ ulcers[3]												
1Gunningberg (2000)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious imprecision[2]	none	4/48 (8.3%)	8/53 (15.1%)	RR 0.55 (0.18 to 1.72)	68 fewer per 1000 (from 124 fewer to 109 more)	⊕OOO VERY LOW	Critical
								15.1%		68 fewer per 1000 (from 124 fewer to 109 more)		
Proportion with incidence of pressure ulcers – all grades of ulcers[3]												
1Gunningberg (2000)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious imprecision[2]	none	12/48 (25%)	17/53 (32.1%)	RR 0.78 (0.42 to 1.46)	71 fewer per 1000 (from 186 fewer to 148 more	⊕OOO VERY LOW	Critical
								32.1%		71 fewer per 1000 (from 186 fewer to 148 more)		

1 No details of allocation concealment.
2 Confidence interval crossed both MID points.
3 EPUAP 1999 grading system.

7.4.1.4. Profiling beds

Table 25 – Profiling bed with a pressure-reducing foam mattress vs flat-based bed with a pressure-reducing mattress

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Profiling bed	Flat-based bed	Relative (95% CI)	Absolute		
Proportion with incidence of pressure ulcers – all grades of ulcer[2]												
1 Keogh (2001)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/35 (0%)	0/35 (0%)	-	-	⊕⊕OO LOW	Critical
								0%		-		

1 Unclear blinding, unclear addressing of incomplete outcome data and higher drop out than event rate.
2 EPUAP 1991 grading system.

7.4.1.5. Seat cushions: comparison between different cushions

Table 26 – Seat cushions for pressure ulcer prevention

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Seat cushions	Control	Relative (95% CI)	Absolute		
Pressure ulcer incidence – Slab foam cushion v Bespoke contoured foam cushion [6]												
2 Conine (1993) Lim (1988)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	104/151 (68.9%)	102/149 (68.5%)	RR 1.01 (0.86 to 1.17)	7 more per 1000 (from 96 fewer to 116 more)	⊕⊕OO LOW	Critical
								68.8%		7 more per 1000 (from 96 fewer to 117 more)		
Pressure ulcer incidence – Gel Cushion with foam base (JAY) v **Foam** cushion [6]												
1Conine (1994)	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	serious[3]	none	17/68 (25%)	30/73 (41.1%)	RR 0.61 (0.37 to 1)	160 fewer per 1000 (from 259 fewer to 0 more)	⊕⊕OO LOW	Critical
								41.1%		160 fewer per 1000 (from 259		

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Seat cushions	Control	Relative (95% CI)	Absolute		
										fewer to 0 more)		
Pressure ulcer incidence – Pressure reducing cushion (not specified – chosen by nurse based on patient)v Standard 3inch convoluted foam cushion (EGGRATE)[6]												
1Geyer (2001)	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	very serious[4]	none	6/15 (40%)	10/17 (58.8%)	RR 0.68 (0.33 to 1.42)	188 fewer per 1000 (from 394 fewer to 247 more)	⊕OOO VERY LOW	Critical
								58.8%		188 fewer per 1000 (from 394 fewer to 247 more)		
pressure ulcer incidence – skin protection cushion vs segmented foam cushion – sitting related ischial tuberosities[6]												
1Brienza (2010)	randomised trials	Very serious[5]	no serious inconsistency	no serious indirectness	serious[3]	none	1/113 (0.88%)	8/119 (6.7%)	RR 0.13 (0.02 to 1.04)	58 fewer per 1000 (from 66 fewer to 3 more)	⊕OOO VERY LOW	Critical
								0%		-		
pressure ulcer incidence – skin protection cushion vs segmented foam cushion – combined ischial tuberosities and sacral/coccyx[6]												
1Brienza (2010)	randomised trials	Very serious[5]	no serious inconsistency	no serious indirectness	serious[3]	none	12/113 (10.6%)	21/119 (17.6%)	RR 0.60 (0.31 to 1.17)	71 fewer per 1000 (from 122 fewer to 30 more)	⊕OOO VERY LOW	Critical
								0%		-		
Patient acceptability – withdrawal due to discomfort – Gel Cushion with foam base (JAY) vs Foam cushion												
1Conine (1994)	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	very serious[4]	none	1/83 (1.2%)	6/80 (7.5%)	RR 0.16 (0.02 to 1.30)	63 fewer per 1000 (from 73 fewer to 22 more)	⊕OOO VERY LOW	Critical
								0%		-		

1 Unclear sequence generation, allocation concealment and blinding (Conine 1993, Lim 1988).
2 Unclear sequence generation and allocation concealment (Conine 1994).
3 Confidence interval crossed one MID.
4 Confidence interval crossed both MIDs.
5 Baseline differences. The study could not control for other support surfaces.
6 Conine (1993) and (1994) used Exton Smith 1982; Lim (1988) used NPUAP 1989; Geyer (2001) used NPUAP 1992; Brienza (2010) us ed NPUAP 2001.

7.4.2. Forest plots

Constant low-pressure supports (CLP) vs standard foam mattresses (SFM)

Figure 2 – Pressure ulcer incidence – grades 2+ ulcers

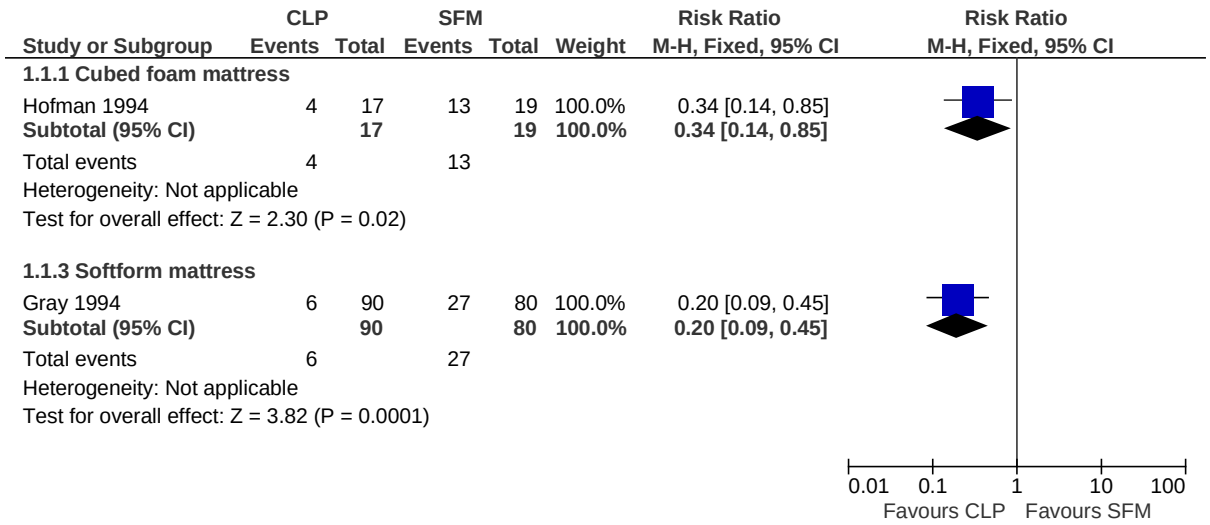


Figure 3 – Pressure ulcer incidence – all grades of ulcer

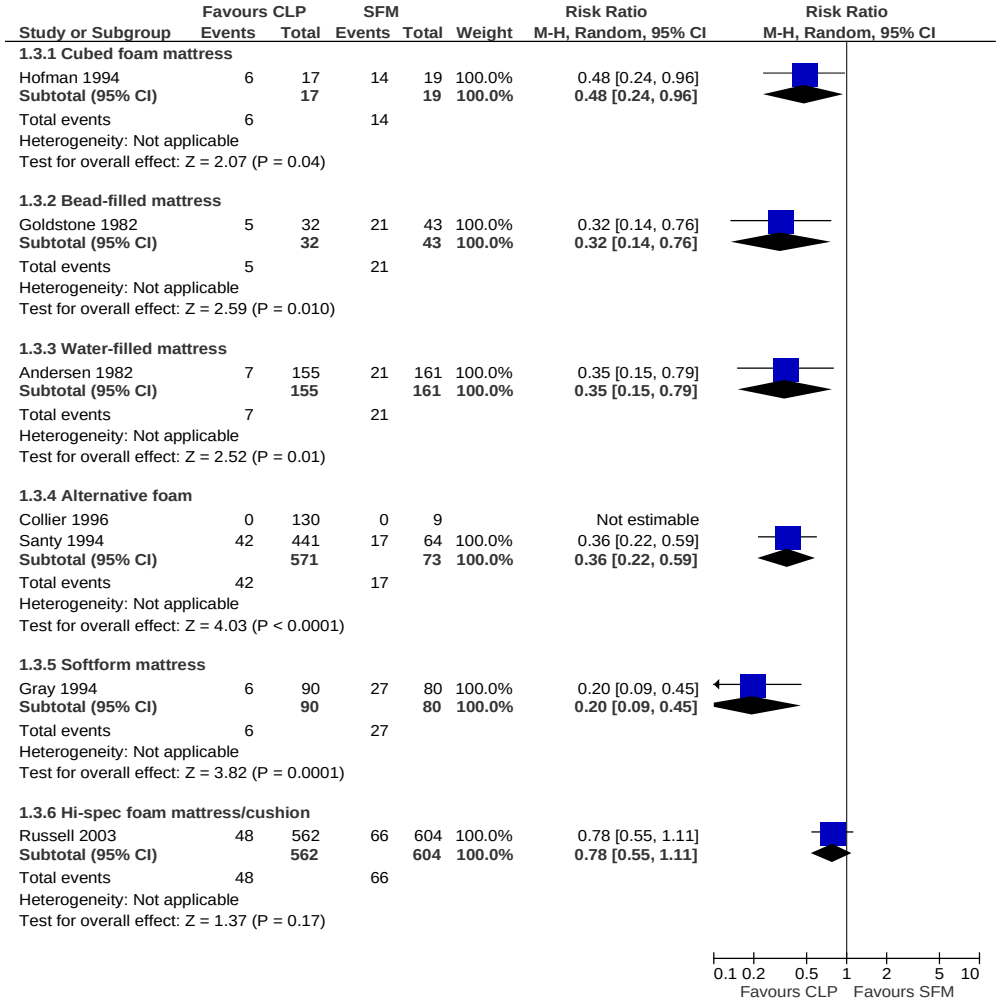


Figure 4 – Patient acceptability – very uncomfortable

Study or Subgroup	Softform mattress Events	Total	Std Foam Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Gray 1994	0	90	0	80		Not estimable
Total (95% CI)		**90**		**80**		**Not estimable**
Total events	0		0			

Heterogeneity: Not applicable
Test for overall effect: Not applicable

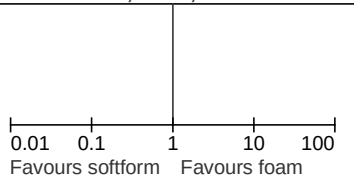


Figure 5 – Patient acceptability – uncomfortable

Study or Subgroup	Softform mattress Events	Total	Std Foam Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Gray 1994	0	90	2	80	100.0%	0.12 [0.01, 1.91]
Total (95% CI)		**90**		**80**	**100.0%**	**0.12 [0.01, 1.91]**
Total events	0		2			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.50 (P = 0.13)

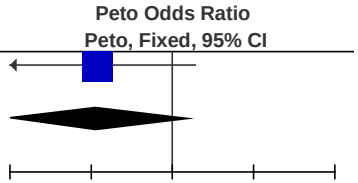


Figure 6 – Patient acceptability – adequate

Study or Subgroup	Softform Events	Total	Std Foam Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Gray 1994	6	90	44	80	100.0%	0.12 [0.05, 0.27]
Total (95% CI)		**90**		**80**	**100.0%**	**0.12 [0.05, 0.27]**
Total events	6		44			

Heterogeneity: Not applicable
Test for overall effect: Z = 5.18 (P < 0.00001)

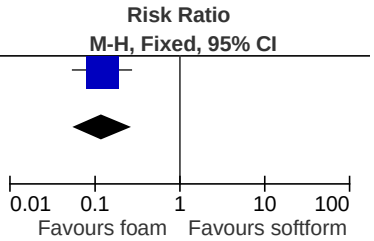


Figure 7 – Patient acceptability – comfortable

Study or Subgroup	Softform mattress Events	Total	Std Foam Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Gray 1994	62	90	26	80	100.0%	2.12 [1.50, 2.99]
Total (95% CI)		**90**		**80**	**100.0%**	**2.12 [1.50, 2.99]**
Total events	62		26			

Heterogeneity: Not applicable
Test for overall effect: Z = 4.27 (P < 0.0001)

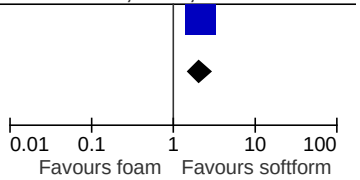


Figure 8 – Patient acceptability – very comfortable

Study or Subgroup	Softform mattress Events	Total	Std Foam Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Gray 1994	11	90	0	80	100.0%	7.45 [2.20, 25.24]
Total (95% CI)		**90**		**80**	**100.0%**	**7.45 [2.20, 25.24]**
Total events	11		0			

Heterogeneity: Not applicable
Test for overall effect: Z = 3.22 (P = 0.001)

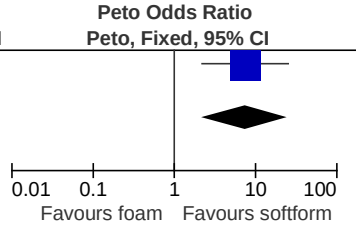
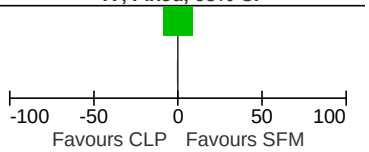


Figure 9 – Patient acceptability – comfort

Study or Subgroup	CLP Mean	SD	Total	SFM Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Russell 2003	2.33	0.98	323	2.46	1.01	383	100.0%	-0.13 [-0.28, 0.02]
Total (95% CI)			**323**			**383**	**100.0%**	**-0.13 [-0.28, 0.02]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.73 (P = 0.08)



7.4.3. Alternative foam mattress vs standard foam mattress

Figure 10 – Pressure ulcer incidence – all grades of ulcer (studies pooled)

Study or Subgroup	Alternative Foam Events	Alternative Foam Total	Std Foam Events	Std Foam Total	Weight	Risk Ratio M-H, Random, 95% CI
2.1.1 Various alternatives (pooled)						
Collier 1996	0	130	0	9		Not estimable
Gray 1994	6	90	27	80	19.9%	0.20 [0.09, 0.45]
Hofman 1994	6	17	14	19	22.7%	0.48 [0.24, 0.96]
Russell 2003	48	562	66	604	30.3%	0.78 [0.55, 1.11]
Santy 1994	42	441	17	64	27.2%	0.36 [0.22, 0.59]
Subtotal (95% CI)		**1240**		**776**	**100.0%**	**0.43 [0.24, 0.76]**
Total events	102		124			
Heterogeneity: Tau² = 0.25; Chi² = 12.50, df = 3 (P = 0.006); I² = 76%						
Test for overall effect: Z = 2.89 (P = 0.004)						
Total (95% CI)		**1240**		**776**	**100.0%**	**0.43 [0.24, 0.76]**
Total events	102		124			
Heterogeneity: Tau² = 0.25; Chi² = 12.50, df = 3 (P = 0.006); I² = 76%						
Test for overall effect: Z = 2.89 (P = 0.004)						
Test for subgroup differences: Not applicable						

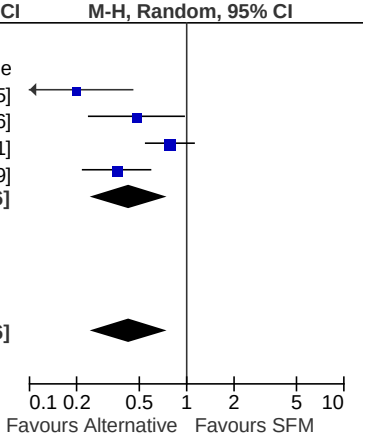
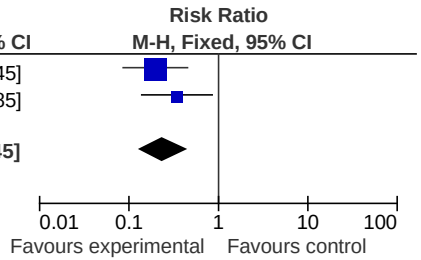


Figure 11 – Pressure ulcer incidence – grades 2+ ulcers (studies pooled)

Study or Subgroup	Experimental Events	Experimental Total	Std Foam Events	Std Foam Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Gray 1994	6	90	27	80	70.0%	0.20 [0.09, 0.45]
Hofman 1994	4	17	13	19	30.0%	0.34 [0.14, 0.85]
Total (95% CI)		**107**		**99**	**100.0%**	**0.24 [0.13, 0.45]**
Total events	10		40			
Heterogeneity: Chi² = 0.80, df = 1 (P = 0.37); I² = 0%						
Test for overall effect: Z = 4.50 (P < 0.00001)						



Comparisons between alternative foam supports

Figure 11 – Pressure ulcer incidence – all grades of ulcer

Study or Subgroup	Foam 1 Events	Foam 1 Total	Foam 2 Events	Foam 2 Total	Risk Ratio M-H, Fixed, 95% CI
3.1.1 Alternative foam vs standard foam					
Santy 1994	42	441	17	64	0.36 [0.22, 0.59]
3.1.2 Maxifloat foam mattress vs Iris foam overlay					
Vyhlidal 1997	5	20	12	20	0.42 [0.18, 0.96]
3.1.3 Solid foam vs convoluted foam					
Kemp 1993	12	39	21	45	0.66 [0.37, 1.16]
3.1.4 Transfoam mattress vs Transfoamwave mattress					
Gray 1998	1	50	1	50	1.00 [0.06, 15.55]

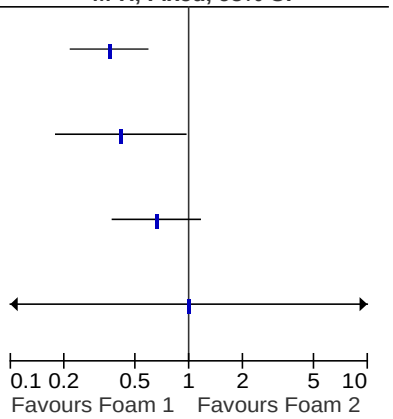
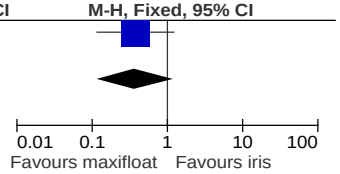


Figure 12 – Pressure ulcer incidence – grades 2+ ulcers

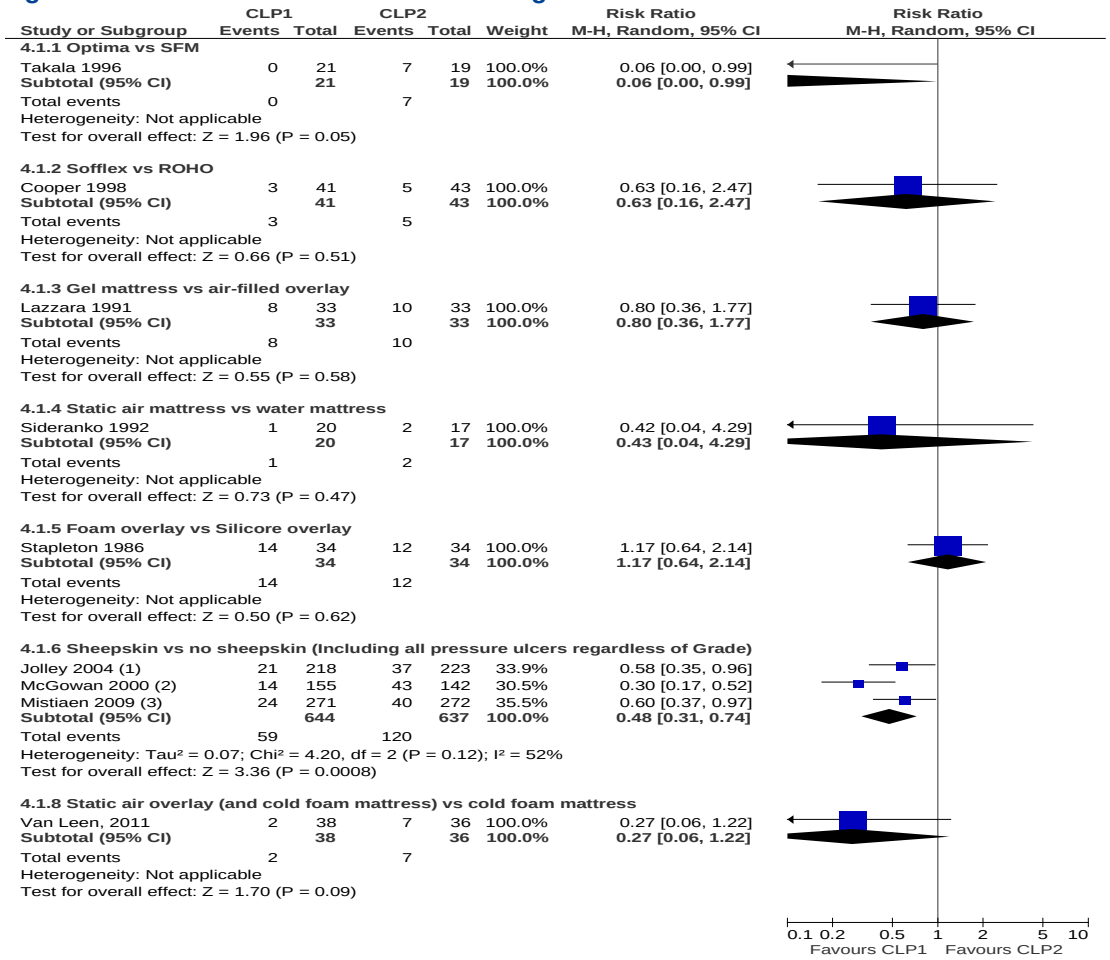
Study or Subgroup	Maxifloat foam overlay Events	Maxifloat foam overlay Total	Iris foam overlay Events	Iris foam overlay Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Vyhlidal 1997	3	20	8	20	100.0%	0.38 [0.12, 1.21]
Total (95% CI)		**20**		**20**	**100.0%**	**0.38 [0.12, 1.21]**
Total events	3		8			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.64 (P = 0.10)



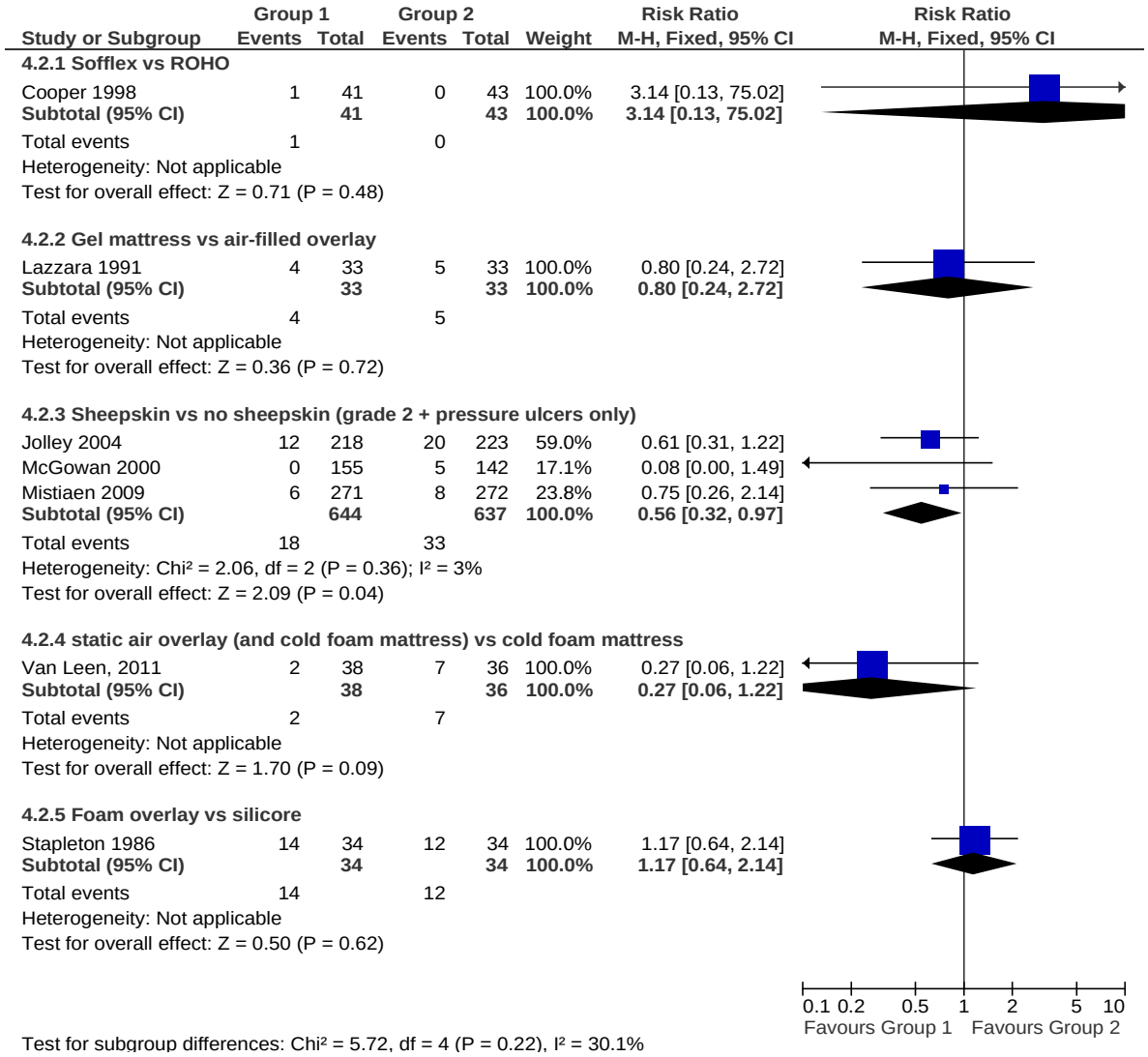
Comparisons between CLP supports

Figure 13 – Pressure ulcer incidence – all grades of ulcer



(1) This study evaluates all patients with pressure ulcers regardless of grade
(2) This study evaluates all patients with pressure ulcers regardless of grade
(3) This study evaluates all patients with pressure ulcers regardless of grade

Figure 14 – Pressure ulcer incidence – grade 2+ ulcers



Test for subgroup differences: Chi² = 5.72, df = 4 (P = 0.22), I² = 30.1%

Figure 15 – Patient acceptability – very uncomfortable

Study or Subgroup	SOFFLEX Events	SOFFLEX Total	ROHO Events	ROHO Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Cooper 1998	0	41	0	43		Not estimable
Total (95% CI)		**41**		**43**		**Not estimable**
Total events	0		0			

Heterogeneity: Not applicable
Test for overall effect: Not applicable

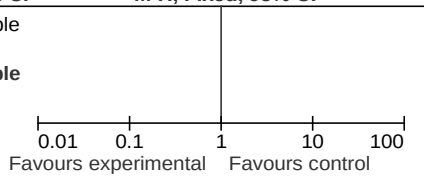


Figure 16 – Patient acceptability – uncomfortable

Study or Subgroup	SOFFLEX Events	SOFFLEX Total	ROHO Events	ROHO Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Cooper 1998	0	41	5	43	100.0%	0.13 [0.02, 0.77]
Total (95% CI)		**41**		**43**	**100.0%**	**0.13 [0.02, 0.77]**
Total events	0		5			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.24 (P = 0.03)

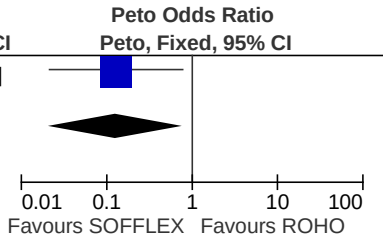


Figure 17 – Patient acceptability – adequate

Study or Subgroup	SOFFLEX Events	SOFFLEX Total	ROHO Events	ROHO Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Cooper 1998	4	41	4	43	100.0%	1.05 [0.28, 3.92]
Total (95% CI)		**41**		**43**	**100.0%**	**1.05 [0.28, 3.92]**
Total events	4		4			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.07 (P = 0.94)

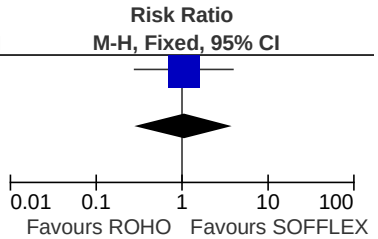


Figure 18 – Patient acceptability – comfortable

Study or Subgroup	SOFFLEX Events	SOFFLEX Total	ROHO Events	ROHO Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Cooper 1998	24	41	24	43	100.0%	1.05 [0.72, 1.52]
Total (95% CI)		**41**		**43**	**100.0%**	**1.05 [0.72, 1.52]**
Total events	24		24			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.25 (P = 0.80)

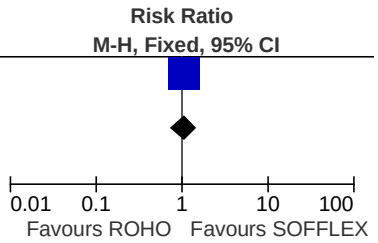
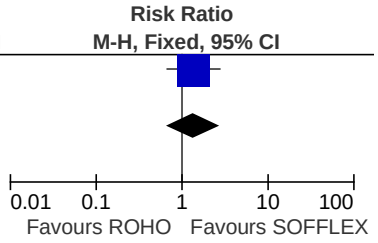


Figure 19 – Patient acceptability – very comfortable

Study or Subgroup	SOFFLEX Events	SOFFLEX Total	ROHO Events	ROHO Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Cooper 1998	13	41	10	43	100.0%	1.36 [0.67, 2.76]
Total (95% CI)		**41**		**43**	**100.0%**	**1.36 [0.67, 2.76]**
Total events	13		10			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.86 (P = 0.39)



Alternating-pressure vs standard foam mattress

Figure 20 – Pressure ulcer incidence – all grades of ulcer

Study or Subgroup	Alternating Pressure Events	Alternating Pressure Total	SFM Events	SFM Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Andersen 1982	7	166	21	161	61.4%	0.32 [0.14, 0.74]
Sanada 2003	6	55	10	27	38.6%	0.29 [0.12, 0.73]
Total (95% CI)		**221**		**188**	**100.0%**	**0.31 [0.17, 0.58]**
Total events	13		31			

Heterogeneity: Chi² = 0.02, df = 1 (P = 0.88); I² = 0%
Test for overall effect: Z = 3.69 (P = 0.0002)

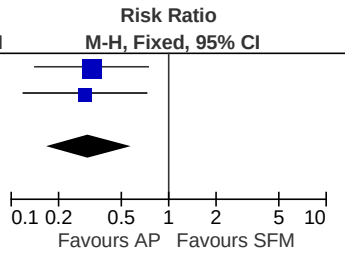
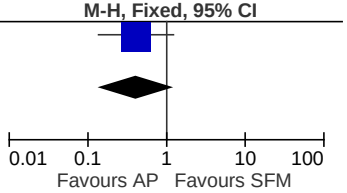


Figure 21 – Pressure ulcer incidence – grades 2+ ulcers

	Alternating Pressure		SFM			Risk Ratio	Risk Ratio
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**M-H, Fixed, 95% CI**	**M-H, Fixed, 95% CI**
Sanada 2003	5	55	6	27	100.0%	0.41 [0.14, 1.22]	
Total (95% CI)		**55**		**27**	**100.0%**	**0.41 [0.14, 1.22]**	
Total events	5		6				
Heterogeneity: Not applicable							
Test for overall effect: Z = 1.60 (P = 0.11)							



7.4.4. Alternating-pressure vs constant low-pressure

Figure 22 – Pressure ulcer incidence – all grades of ulcer and condition

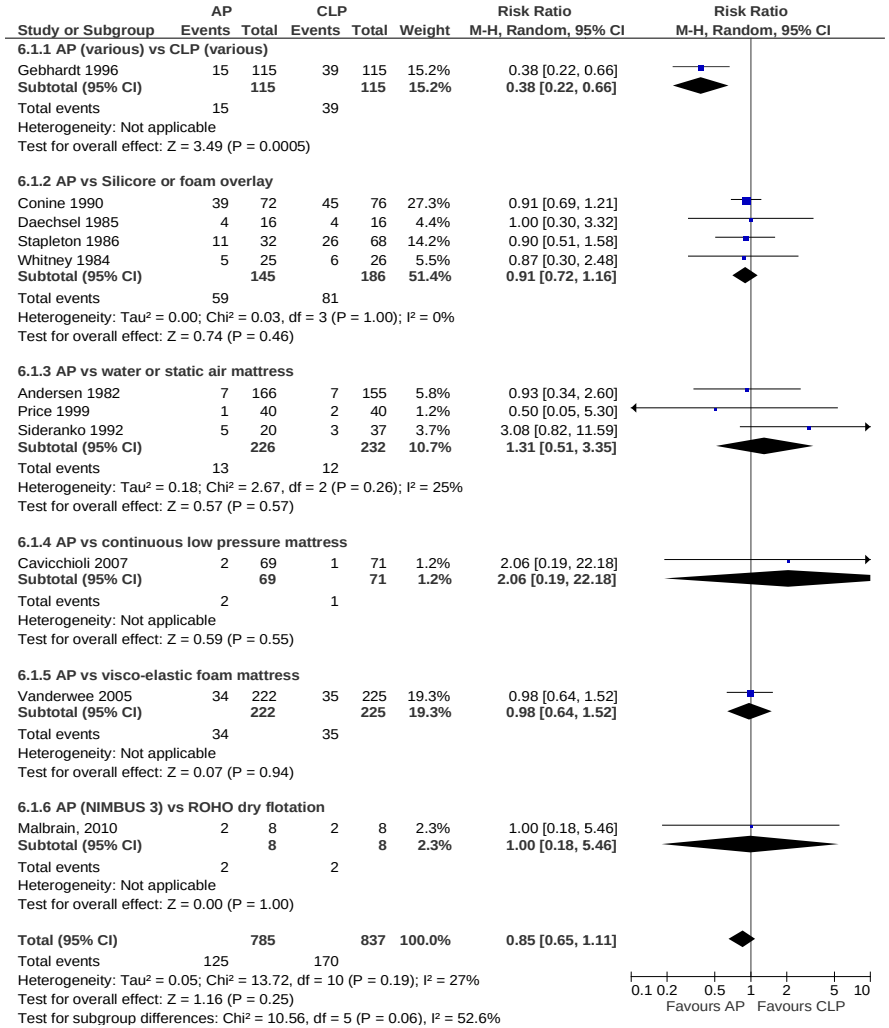


Figure 23 – Pressure ulcer incidence – with and without neurological conditions

Study or Subgroup	AP Events	AP Total	Silicore or foam Events	Silicore or foam Total	Weight	Risk Ratio M-H, Fixed, 95% CI
6.2.1 AP vs Silicore or foam overlay - not neurological condition						
Stapleton 1986	11	32	26	68	23.7%	0.90 [0.51, 1.58]
Whitney 1984	5	25	6	26	8.4%	0.87 [0.30, 2.48]
Subtotal (95% CI)		**57**		**94**	**32.0%**	**0.89 [0.54, 1.47]**
Total events	16		32			
Heterogeneity: Chi² = 0.00, df = 1 (P = 0.95); I² = 0%						
Test for overall effect: Z = 0.45 (P = 0.65)						
6.2.2 AP vs Silicore or foam overlay - neurological condition						
Conine 1990	39	72	45	76	62.3%	0.91 [0.69, 1.21]
Daechsel 1985	4	16	4	16	5.7%	1.00 [0.30, 3.32]
Subtotal (95% CI)		**88**		**92**	**68.0%**	**0.92 [0.70, 1.22]**
Total events	43		49			
Heterogeneity: Chi² = 0.02, df = 1 (P = 0.89); I² = 0%						
Test for overall effect: Z = 0.57 (P = 0.57)						
Total (95% CI)		**145**		**186**	**100.0%**	**0.91 [0.71, 1.17]**
Total events	59		81			
Heterogeneity: Chi² = 0.03, df = 3 (P = 1.00); I² = 0%						
Test for overall effect: Z = 0.73 (P = 0.47)						
Test for subgroup differences: Chi² = 0.01, df = 1 (P = 0.91), I² = 0%						

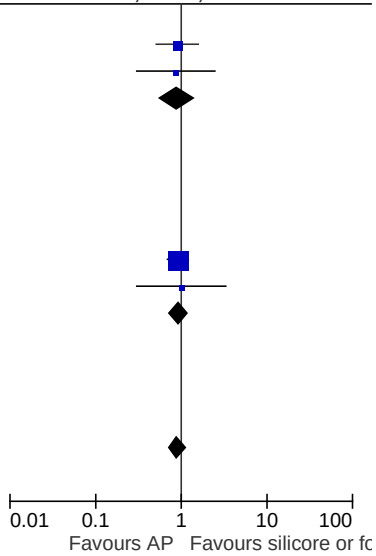


Figure 24 – Pressure ulcer incidence – grade 2+ ulcers

Study or Subgroup	AP Events	AP Total	CLP Events	CLP Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Cavicchioli 2007	1	69	1	71	1.5%	1.03 [0.07, 16.13]
Gebhardt 1996	0	23	8	20	14.0%	0.05 [0.00, 0.84]
Malbrain, 2010	0	8	1	8	2.3%	0.33 [0.02, 7.14]
Price 1999	1	40	2	40	3.1%	0.50 [0.05, 5.30]
Stapleton 1986	11	32	26	68	25.6%	0.90 [0.51, 1.58]
Vanderwee 2005	34	222	35	225	53.5%	0.98 [0.64, 1.52]
Total (95% CI)		**394**		**432**	**100.0%**	**0.80 [0.58, 1.11]**
Total events	47		73			
Heterogeneity: Chi² = 5.22, df = 5 (P = 0.39); I² = 4%						
Test for overall effect: Z = 1.31 (P = 0.19)						

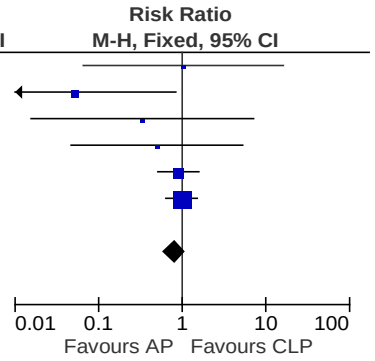


Figure 25 – Drop-out due to discomfort

Study or Subgroup	AP Events	AP Total	CLP Events	CLP Total	Weight	Risk Ratio M-H, Fixed, 95% CI
6.4.1 AP vs Silicore						
Conine 1990	19	93	17	94	100.0%	1.13 [0.63, 2.03]
Subtotal (95% CI)		**93**		**94**	**100.0%**	**1.13 [0.63, 2.03]**
Total events	19		17			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.41 (P = 0.68)						
Total (95% CI)		**93**		**94**	**100.0%**	**1.13 [0.63, 2.03]**
Total events	19		17			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.41 (P = 0.68)						
Test for subgroup differences: Not applicable						

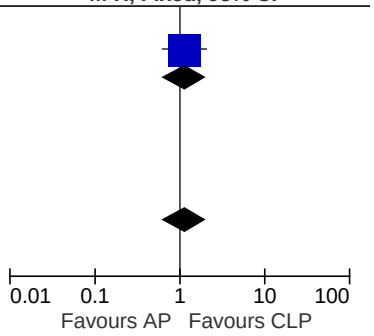
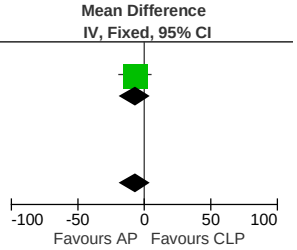


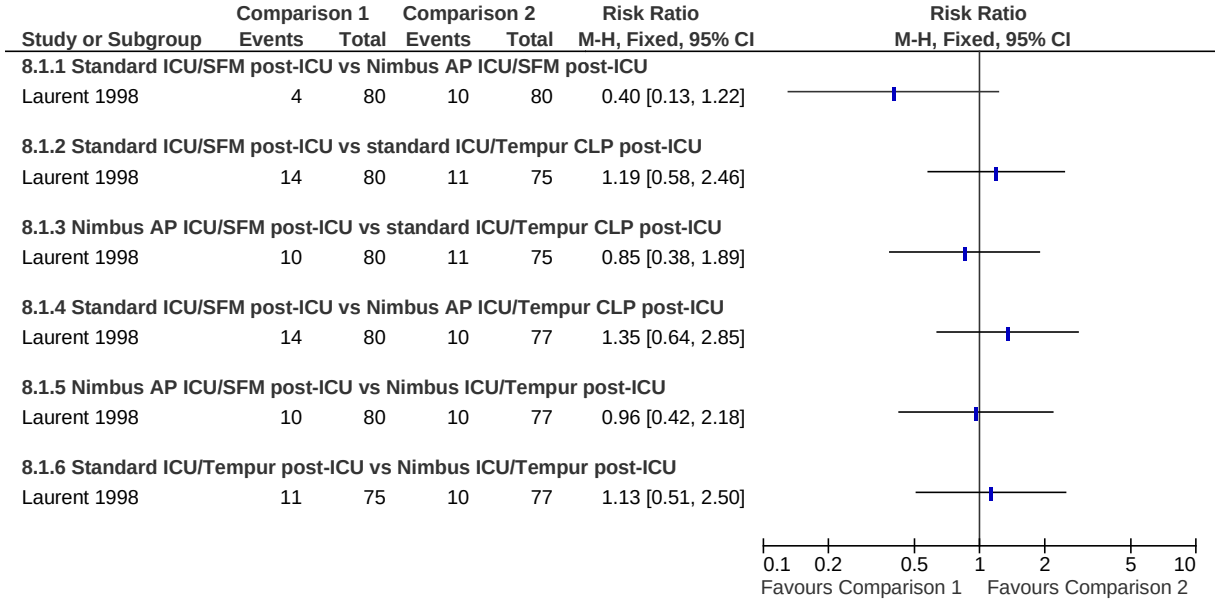
Figure 26 – Comfort rating at 14 days

Study or Subgroup	AP Mean	AP SD	AP Total	CLP Mean	CLP SD	CLP Total	Weight	Mean Difference IV, Fixed, 95% CI
6.5.1 dynamic flotation mattress and alternating-pressure cushion vs low-pressure inflatable mattress and cushion								
Price 1999	60	25	26	67	18	24	100.0%	-7.00 [-19.01, 5.01]
Subtotal (95% CI)			**26**			**24**	**100.0%**	**-7.00 [-19.01, 5.01]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.14 (P = 0.25)								
Total (95% CI)			**26**			**24**	**100.0%**	**-7.00 [-19.01, 5.01]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.14 (P = 0.25)								
Test for subgroup differences: Not applicable								



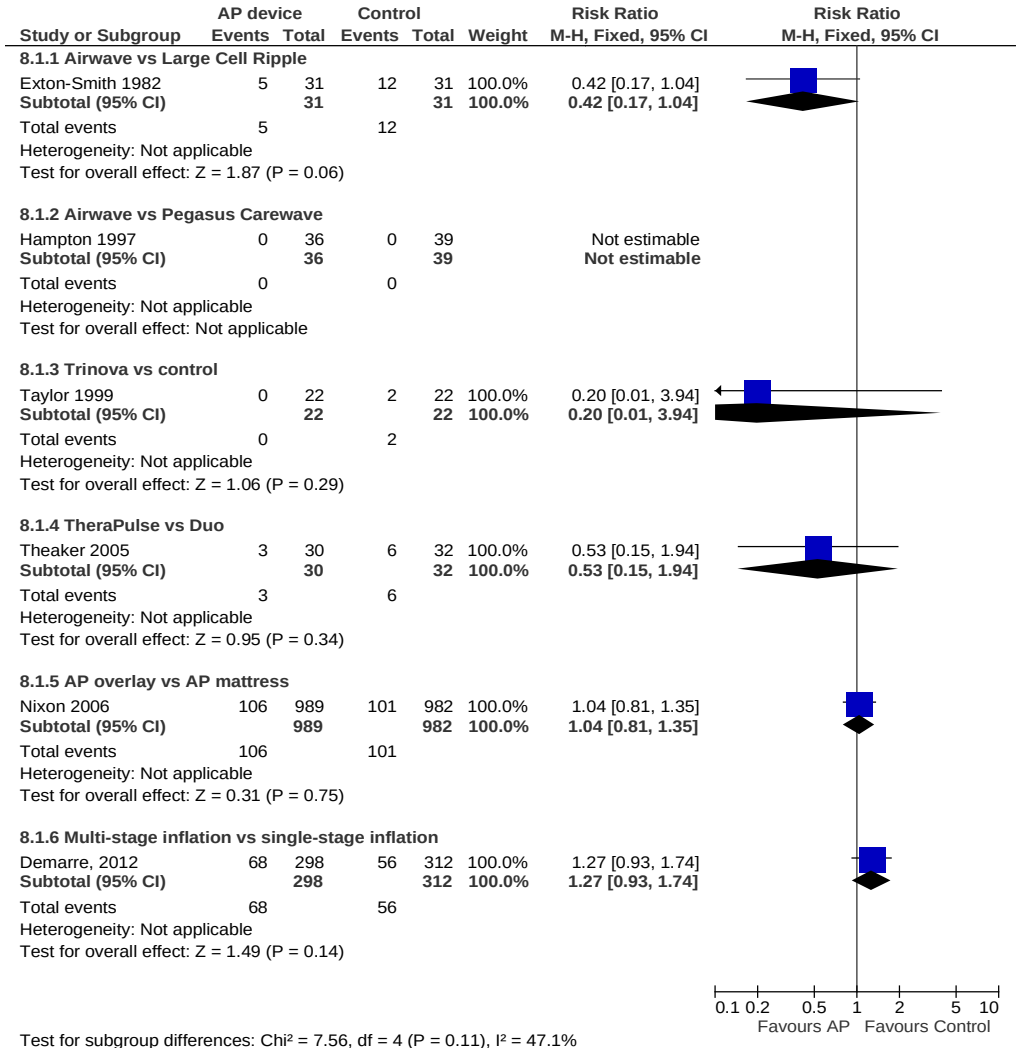
Alternating-pressure and constant low-pressure in ICU/post-ICU

Figure 27 – Pressure ulcer incidence – all grades of ulcer



Comparisons between alternating-pressure devices

Figure 28 – Pressure ulcer incidence – all grades of ulcer



Test for subgroup differences: Chi² = 7.56, df = 4 (P = 0.11), I² = 47.1%

Figure 29 – Pressure ulcer incidence – grade 2+ ulcers

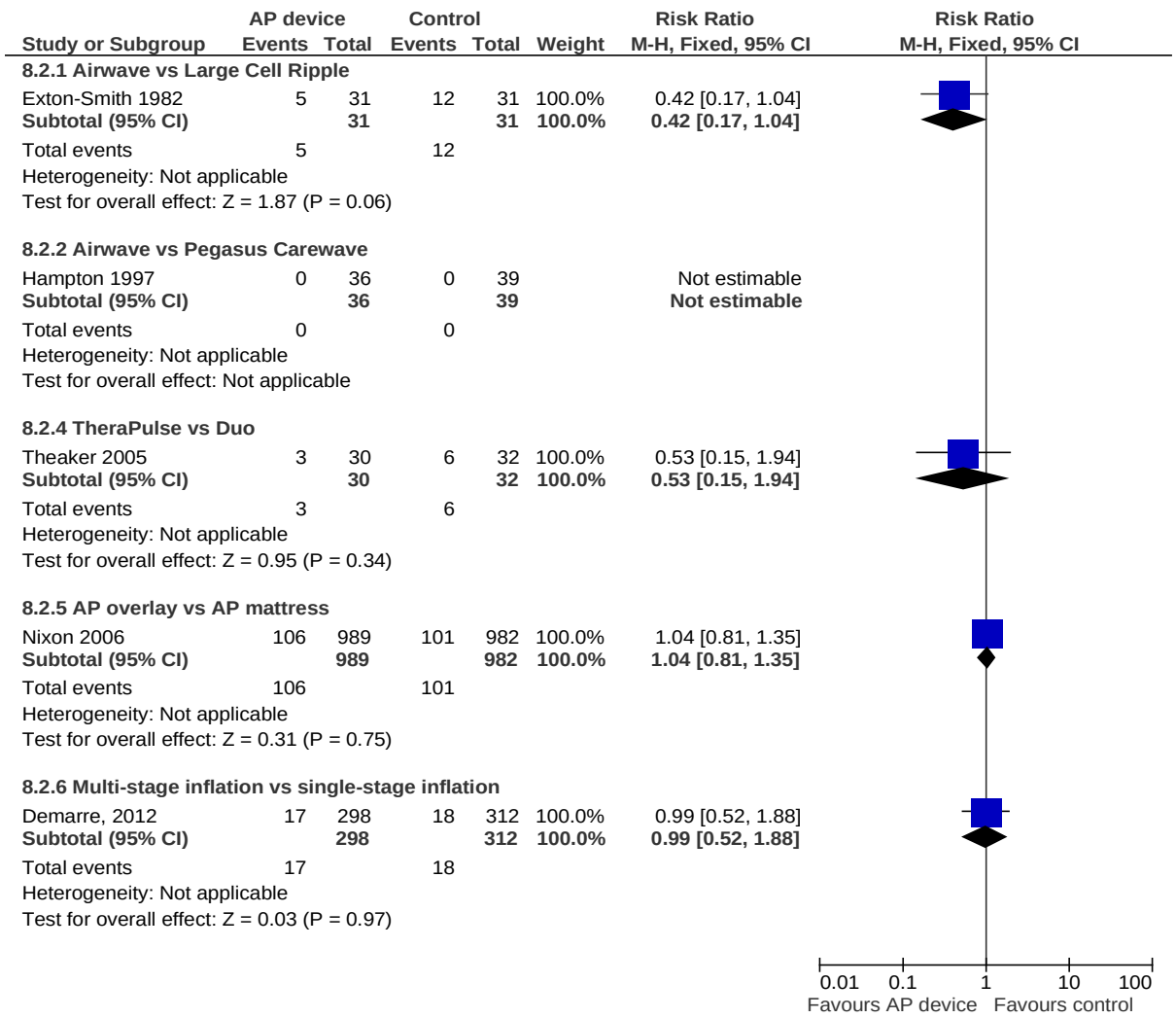
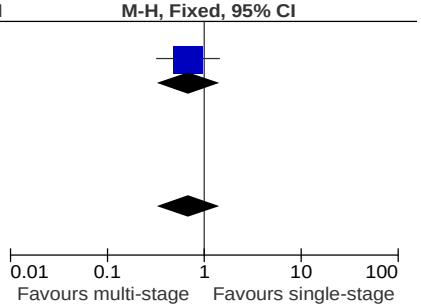


Figure 30 – Withdrawal due to discomfort

Study or Subgroup	multi-stage Events	Total	single-stage Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
8.3.6 Multi-stage inflation vs single-stage inflation						
Demarre, 2012	11	298	17	312	100.0%	0.68 [0.32, 1.42]
Subtotal (95% CI)		**298**		**312**	**100.0%**	**0.68 [0.32, 1.42]**
Total events	11		17			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.03 (P = 0.30)						
Total (95% CI)		**298**		**312**	**100.0%**	**0.68 [0.32, 1.42]**
Total events	11		17			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.03 (P = 0.30)						
Test for subgroup differences: Not applicable						



Low-air-loss vs standard bed

Figure 31 – Pressure ulcer incidence – all grades of ulcer

Study or Subgroup	Low air loss Events	Total	Standard Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Cobb 1997	6	62	12	61	100.0%	0.49 [0.20, 1.23]
Total (95% CI)		**62**		**61**	**100.0%**	**0.49 [0.20, 1.23]**
Total events	6		12			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.52 (P = 0.13)						

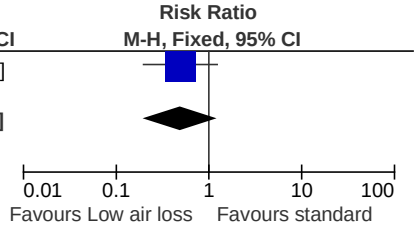


Figure 32 – Pressure ulcer incidence – grade 2+ ulcers

Study or Subgroup	Low Air Loss Events	Total	Standard ICU bed Events	Total	Risk Ratio M-H, Fixed, 95% CI
Bennett 1998	8	42	4	56	2.67 [0.86, 8.27]
Cobb 1997	6	62	12	61	0.49 [0.20, 1.23]
Inman 1993	6	49	25	49	0.24 [0.11, 0.53]

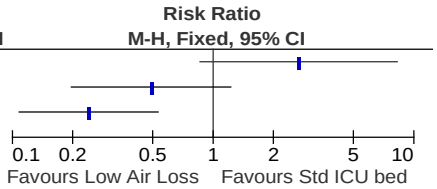
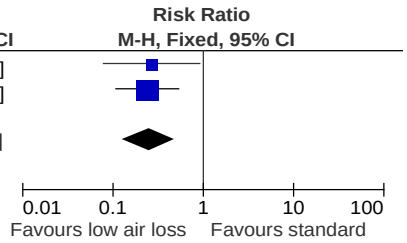


Figure 33 – Pressure ulcer incidence – grade 2+ ulcers (pooled)

Study or Subgroup	Low air loss Events	Total	Standard bed Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Cobb 1997	3	62	11	61	30.7%	0.27 [0.08, 0.91]
Inman 1993	6	49	25	49	69.3%	0.24 [0.11, 0.53]
Total (95% CI)		**111**		**110**	**100.0%**	**0.25 [0.13, 0.49]**
Total events	9		36			

Heterogeneity: Chi² = 0.02, df = 1 (P = 0.88); I² = 0%
Test for overall effect: Z = 4.07 (P < 0.0001)



Operating table overlay vs no overlay

Figure 34 – Pressure ulcer incidence – all grades of ulcer

Study or Subgroup	Overlay Events	Total	No Overlay Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
13.1.1 Viscoelastic polymer pad vs no overlay						
Nixon 1998	22	205	43	211	100.0%	0.53 [0.33, 0.85]
Subtotal (95% CI)		**205**		**211**	**100.0%**	**0.53 [0.33, 0.85]**
Total events	22		43			
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.64 (P = 0.008)						
13.1.2 Viscoelastic foam overlay vs no overlay						
Feuchtinger 2006	13	85	9	90	100.0%	1.53 [0.69, 3.39]
Subtotal (95% CI)		**85**		**90**	**100.0%**	**1.53 [0.69, 3.39]**
Total events	13		9			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.05 (P = 0.30)						

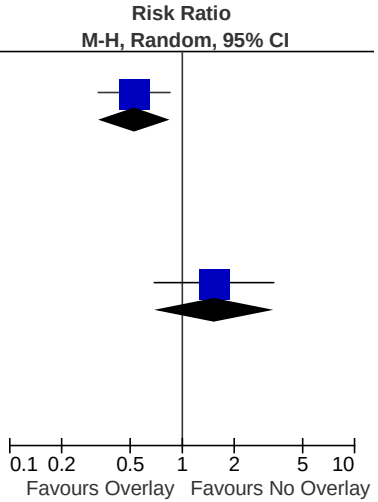
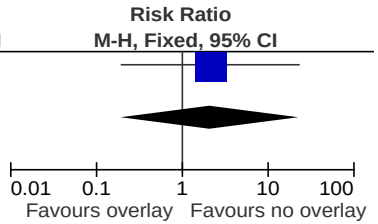


Figure 35 – Pressure ulcer incidence – grades 2+ ulcers

Study or Subgroup	Overlay Events	Overlay Total	No Overlay Events	No Overlay Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Feuchtinger 2006	2	85	1	90	100.0%	2.12 [0.20, 22.93]
Total (95% CI)		**85**		**90**	**100.0%**	**2.12 [0.20, 22.93]**
Total events	2		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.62 (P = 0.54)



Indentation load deflection operating room foam mattress vs operating room usual care

Figure 36 – Pressure ulcer incidence – all grades of ulcer

Study or Subgroup	IDL Events	IDL Total	Usual care Events	Usual care Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Schultz 1999	55	206	34	207	100.0%	1.63 [1.11, 2.38]
Total (95% CI)		**206**		**207**	**100.0%**	**1.63 [1.11, 2.38]**
Total events	55		34			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.50 (P = 0.01)

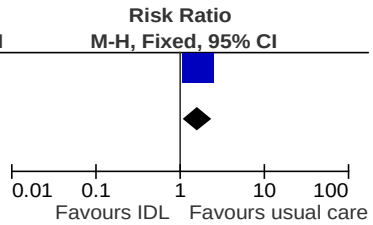
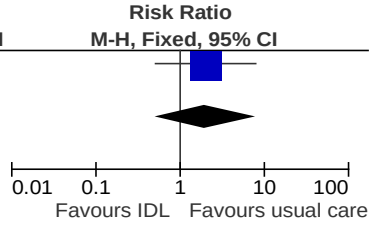


Figure 37 – Pressure ulcer incidence – grade 2+ ulcers

Study or Subgroup	IDL Events	IDL Total	Usual care Events	Usual care Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Schultz 1999	6	206	3	207	100.0%	2.01 [0.51, 7.93]
Total (95% CI)		**206**		**207**	**100.0%**	**2.01 [0.51, 7.93]**
Total events	6		3			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.00 (P = 0.32)



Micropulse system for surgical patients

Figure 38 – Pressure ulcer incidence – all grades of ulcer

	Micropulse System		Std Care			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI
Aronovitch 1999	1	90	7	80	51.7%	0.13 [0.02, 1.01]	
Russell 2000	2	98	7	100	48.3%	0.29 [0.06, 1.37]	
Total (95% CI)		**188**		**180**	**100.0%**	**0.21 [0.06, 0.70]**	
Total events	3		14				

Heterogeneity: Chi² = 0.40, df = 1 (P = 0.53); I² = 0%
Test for overall effect: Z = 2.53 (P = 0.01)

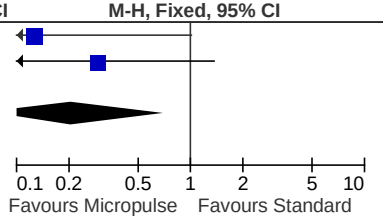
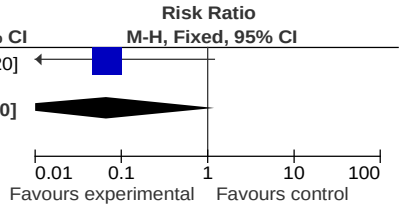


Figure 39 – Pressure ulcer incidence – grade 2+ ulcer

	Micropulse System		Std Care			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI
Aronovitch 1999	0	90	6	80	100.0%	0.07 [0.00, 1.20]	
Total (95% CI)		**90**		**80**	**100.0%**	**0.07 [0.00, 1.20]**	
Total events	0		6				

Heterogeneity: Not applicable
Test for overall effect: Z = 1.84 (P = 0.07)



Visco-elastic A&E overlay and ward mattress vs standard A&E overlay and ward mattress

Figure 40 – Pressure ulcer incidence – grade 2+ ulcers

	Visco-elastic foam		Standard			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI
Gunningberg 2000	4	48	8	53	100.0%	0.55 [0.18, 1.72]	
Total (95% CI)		**48**		**53**	**100.0%**	**0.55 [0.18, 1.72]**	
Total events	4		8				

Heterogeneity: Not applicable
Test for overall effect: Z = 1.03 (P = 0.30)

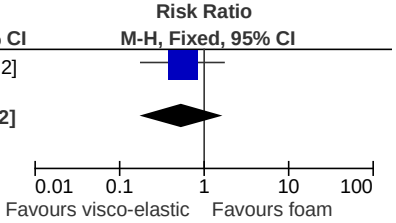
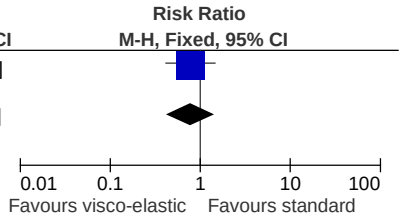


Figure 41 – Pressure ulcer incidence – all grades of ulcer

Study or Subgroup	Visco-elastic foam Events	Total	Standard Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Gunningberg 2000	12	48	17	53	100.0%	0.78 [0.42, 1.46]
Total (95% CI)		**48**		**53**	**100.0%**	**0.78 [0.42, 1.46]**
Total events	12		17			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.78 (P = 0.44)

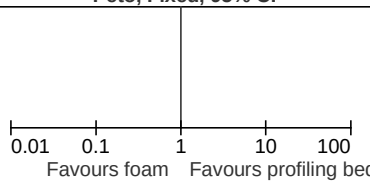


Profiling bed vs flat-based bed

Figure 42 – Pressure ulcer incidence – all grades of ulcer

Study or Subgroup	Profiling bed Events	Total	Foam mattress Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Keogh 2001	0	35	0	35		Not estimable
Total (95% CI)		**35**		**35**		**Not estimable**
Total events	0		0			

Heterogeneity: Not applicable
Test for overall effect: Not applicable



Seat cushions

Figure 43 – Pressure ulcer incidence – all grades of ulcer

Study or Subgroup	Cushion 1 Events	Total	Cushion 2 Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
17.1.1 Slab foam v Bespoke contoured foam						
Conine 1993	85	125	84	123	82.5%	1.00 [0.84, 1.18]
Lim 1988	19	26	18	26	17.5%	1.06 [0.75, 1.49]
Subtotal (95% CI)		**151**		**149**	**100.0%**	**1.01 [0.86, 1.17]**
Total events	104		102			
Heterogeneity: Chi² = 0.09, df = 1 (P = 0.77); I² = 0%						
Test for overall effect: Z = 0.08 (P = 0.94)						
17.1.2 Jay Gel Cushion v Foam						
Conine 1994	17	68	30	73	100.0%	0.61 [0.37, 1.00]
Subtotal (95% CI)		**68**		**73**	**100.0%**	**0.61 [0.37, 1.00]**
Total events	17		30			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.97 (P = 0.05)						
17.1.3 Pressure reducing cushion v Standard foam cushion						
Geyer 2001	6	15	10	17	100.0%	0.68 [0.33, 1.42]
Subtotal (95% CI)		**15**		**17**	**100.0%**	**0.68 [0.33, 1.42]**
Total events	6		10			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.03 (P = 0.30)						
17.1.4 Skin protection cushion vs segmented foam cushion - sitting-acquired pressure ulcer - ischial tuberosities ulcers						
Brienza, 2010	1	113	8	119	100.0%	0.13 [0.02, 1.04]
Subtotal (95% CI)		**113**		**119**	**100.0%**	**0.13 [0.02, 1.04]**
Total events	1		8			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.93 (P = 0.05)						
17.1.5 Skin protection cushion vs segmented foam cushion - combined ischial tuberosities and sacral/coccyx pressure ulcers						
Brienza, 2010	12	113	21	119	100.0%	0.60 [0.31, 1.17]
Subtotal (95% CI)		**113**		**119**	**100.0%**	**0.60 [0.31, 1.17]**
Total events	12		21			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.51 (P = 0.13)						

Test for subgroup differences: Chi² = 9.65, df = 4 (P = 0.05), I² = 58.5%

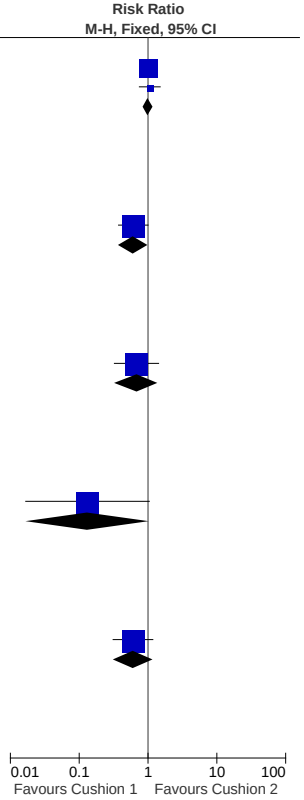
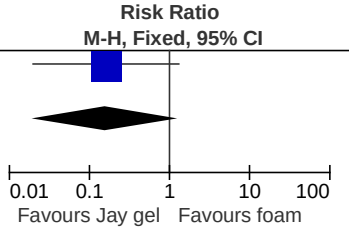


Figure 44 – Withdrawal due to discomfort

Study or Subgroup	Jay gel cushion Events	Total	Foam cushion Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Conine 1994	1	83	6	80	100.0%	0.16 [0.02, 1.30]
Total (95% CI)		**83**		**80**	**100.0%**	**0.16 [0.02, 1.30]**
Total events	1		6			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.71 (P = 0.09)



Face pillows

Figure 45 – Incidence of pressure ulcers – all grades of ulcer

Study or Subgroup	OSI face pillow Events	Total	ROHO face pillow Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Grisell, 2008	10	22	0	22	100.0%	12.55 [3.11, 50.57]
Total (95% CI)		**22**		**22**	**100.0%**	**12.55 [3.11, 50.57]**
Total events	10		0			

Heterogeneity: Not applicable
Test for overall effect: Z = 3.56 (P = 0.0004)

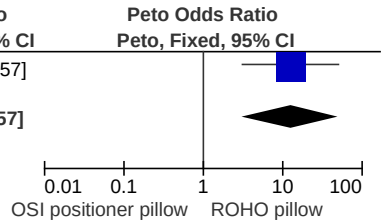


Figure 46 – Incidence of pressure ulcers – grade 2+ ulcers

Study or Subgroup	OSI face pillow Events	Total	ROHO face pillow Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Grisell, 2008	2	22	0	22	100.0%	7.75 [0.47, 128.03]
Total (95% CI)		**22**		**22**	**100.0%**	**7.75 [0.47, 128.03]**
Total events	2		0			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.43 (P = 0.15)

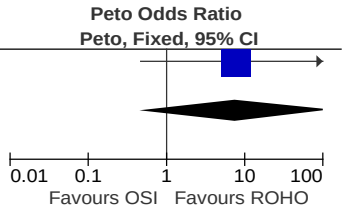


Figure 47 – Incidence of pressure ulcers – all grades of ulcer

Study or Subgroup	OSI face pillow Events	Total	Dupaco face pillow Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Grisell, 2008	10	22	0	22	100.0%	12.55 [3.11, 50.57]
Total (95% CI)		**22**		**22**	**100.0%**	**12.55 [3.11, 50.57]**
Total events	10		0			

Heterogeneity: Not applicable
Test for overall effect: Z = 3.56 (P = 0.0004)

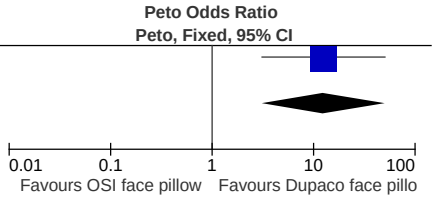


Figure 48 – Incidence of pressure ulcers – grade 2+ ulcers

Study or Subgroup	OSI face pillow Events	Total	Dupaco face pillow Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Grisell, 2008	2	22	0	22	100.0%	7.75 [0.47, 128.03]
Total (95% CI)		**22**		**22**	**100.0%**	**7.75 [0.47, 128.03]**
Total events	2		0			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.43 (P = 0.15)

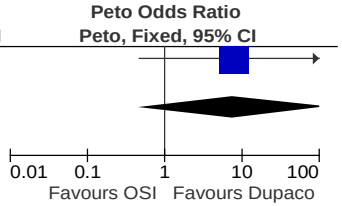


Figure 49 – Incidence of pressure ulcers – all grades of ulcer

Study or Subgroup	ROHO face pillow Events	Total	Dupaco face pillow Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Grisell, 2008	0	22	0	22		Not estimable
Total (95% CI)		**22**		**22**		**Not estimable**
Total events	0		0			

Heterogeneity: Not applicable
Test for overall effect: Not applicable

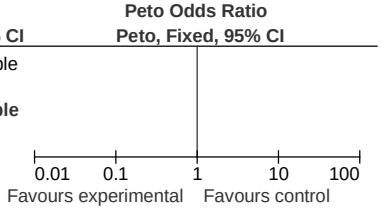
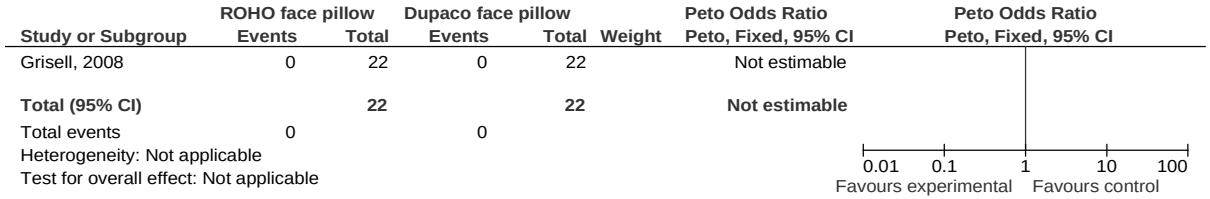


Figure 50 – Incidence of pressure ulcers – grade 2+ ulcers



7.4.5. Clinical evidence tables

Table 26 – MCINNES2011

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Quality assessment	Comments
Author and year: **McInnes 2011** Title: **Support surfaces for pressure ulcers prevention (Review)** Journal: **Cochrane Database of Systematic Reviews 2011, Issue 4.**	**N of studies:** 53 **Inclusion criteria:** **Population:** people receiving health care who were thought at risk of developing pressure ulcers, in any settings. Patients could have existing pressure ulcers but only the incidence of new pressure ulcers was looked at. **Studies:** RCTs and quasi-randomised trials comparing support surfaces and measured the incidence of new pressure ulcers. **Exclusion criteria:** see	• Low-tech CLP support surfaces: • Standard foam mattresses • Alternative foam mattresses/overlays (eg convoluted foam, cubed foam) • Gel-filled mattresses/overlays • Fibre-filled mattresses/overlays • Air-filled mattresses/overlays • Water-filled mattresses/overlays • Bead-filled mattresses/overlays • Sheepskins • High-tech support	**Primary outcomes:** incidence of pressure ulcers Grades of new pressure ulcers **Secondary outcomes:** cost of the devices; patient comfort; durability/longevity of the devices; acceptability of the devices for healthcare staff; quality of life	Does the review address an appropriate question relevant to the guideline review question? yes Does the review collect the type of studies you consider relevant to the guideline review question? yes Was the literature search sufficiently rigorous to identify all relevant studies? yes Was study quality assessed reported? yes Was an adequate description of the methodology used and included, and the methods used are appropriate to the question? yes	**Quality grade:** very low risk of bias

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Quality assessment	Comments
	above. **Population:** Studies: only reporting subjective measures of outcome; only reported proxy measures such as interface pressure. **Details of studies included:** 27 studies included participants without pre-existing pressure ulcers; 8 included patients with grade 1 or above pressure ulcers; 4 did not specify the grading of the pre-existing ulcers and one included people with grade 4 pressure ulcers only. 12 studies the baseline skin status was unclear. Five studies evaluated different operating table surfaces; 9 evaluated different surfaces in intensive care units; 8 confined evaluation to orthopaedic patients; one involved both A&E and ward setting; five were in extended care	surfaces: • AP mattresses/overlays • Air-fluidised beds • Low-air-loss beds • Other support surfaces • Turning beds/frames • Operating table overlays • Wheelchair cushions • Limb protectors			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Quality assessment	Comments
	facilities; 3 were in nursing homes, 7 involved two or more different hospital wards; 15 did not specify the study setting. 11 trials evaluated cushions, 4 evaluated sheepskins, 4 looked at turning beds/tables; 16 examined overlays and 2 looked at mattress; 3 evaluated foam surfaces, 2 evaluated waffle surfaces. Many studies had multiple interventions. Many studies had a small sample size and only 20 reported a priori sample size calculation.				

Table 27 – BRIENZA2010

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Brienza 2010** Title: **A randomized clinical trial on preventing pressure ulcers with wheelchair seat cushions** Journal: **J Am Geriatr Soc (2010) December; 58 (12), 2308-2314.** Sequence generation: **1:1 randomisation scheme prepared by a research team member who was independent to those who had contact with participants. Randomised blocks of varying length used.** Allocation concealment: **adequate, see above.** Blinding: **not possible due to the differences in configuration and weight of the**	**Patient group:** Elderly, nursing home population who used wheelchairs as primary means of seating and mobility and were at-risk for developing pressure ulcers. **All patients** **Randomised N:** 232 (222 received intervention) **Completed N:** 190 **Drop-outs:** 42 Age: 86.7 (s.d 7.6 years) Ethnicity: 92.2% white. Gender: 84.9% female. **Group 1 (SPC)** **Randomised N:** 113 **Completed N:** 86 **Dropouts:** 27 (6 did not receive intervention, 5 voluntarily withdrew, 16 other) **Age:**86.8 (s.d 7.4) **Gender (f):**91 (80.5%)	**Group 1:** skin protection cushion (SPC) **Group 2:** segmented foam cushion (SFC) Treatment started with seating assessment by occupational therapist trained in seating and mobility. SPC group had a commercially available cushion with an incontinence cover. Selected from a group of three designed to improve tissue tolerance by reducing peak pressures near bony prominences, accommodating orthopaedic deformities through immersion, enveloping small irregularities at the seating interface without causing high pressure gradients, and dissipating heat and moisture. Solid seat inserts were provided. Multiple SPC group cushions were needed to allow for cushion selection based upon specific clinical conditions. Clinical judgment	**Outcome 1:** Incidence of a sitting-acquired pressure ulcer – ischial tuberosities ulcers	**Group 1 (SPC): 1/113 (0.9%)** **Group 2 (SFC): 8/119 (6.7%)** **P<0.04** Stage 1 ulcers (n=1), stage 2 (n=7), and unstageable (n=1)	**Funding:** not reported **Limitations:** baseline differences. The study could not control for other support surfaces. **Additional outcomes:** N/A Notes: a pilot study was conducted prior to the clinical trial to assist in developing methods and to determine appropriate sample size. The authors state that the RCT could have lowered the risk level as the wheelchair fit and function was monitored and
			Outcome 2: Incidence of combined ischial tuberosities and sacral/coccyx pressure ulcers:	**Group 1 (SPC):** 12/113 (10.6%) **Group 2 (SFC):** 21/119 (17.6%) 33 participants had 38 IT and sacral /coccyx pressure ulcers. Stage 1 (n=6), stage 2 (n=29), stage 3 (n=2), unstageable (n=1). P: NS	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
cushions, outcome assessors were masked. Addressing incomplete outcome data: **missing data was due to voluntary withdrawal death or other – examples given. ITT analysis used. Missing data covered with flow diagram.** Statistical analysis: **Rate of pressure ulcers ITT analysis. Kaplan-Meier used to estimate the cumulative incidence of pressure ulcers, with the log-rank statistic used to assess differences by treatment group.** Baseline differences: **no statistically significant differences except ambulation. Slightly fewer males in the SFC group (10.9%) than the SPC group (19.5%).**	**ethnicity (white):**103 (91.2%) **BMI:**24.6 (s.d 4.4) **Total Braden score:**15.4 (s.d 1.4) **Incontinent:97 (90.7%)** **Ambulation:** 0 feet: 67 (62.6%); </= 10 feet: 14 (13.1%), >10 feet: 26 (24.3%) **Could not walk unassisted:** 62.6% **Could walk 3 meters or less**:13.1% **Could walk 3 meters or more:** 24.3% **Group 2 (SFC)** **Randomised N:** 119 **Completed N:** 94 **Dropouts:** 25 (4 did not receive intervention, 6 voluntary withdrawn, 14 other, 1 discharged). **Age:**86.6 (s.d 7.8) **Gender (f):**106 (89.1) **ethnicity (white):*111 (93.3%)*** **BMI:**25.0 (s.d 5.2)	and expertise of the team was used to select a particular SPC cushion based on its compatibility with the subject's clinical needs and preferences. SFC group received a 7.6cm thick, segmented foam cushion fitted with an incontinence cover, and solid seat insert. This cushion was chosen as the control because it is representative of a large number of cushions currently used in nursing homes. Both groups: interface pressure measurement data was used to monitor the effects of adjustments made to the wheelchair. Each participant received a new, properly fitted wheelchair. Two models were used. One chair (Guardian Escort was used and floor to seat height is fixed at 51 cm, adjustments are possible, but not easily accomplished. Subjects needing an alternate seat-to-floor height			adjusted regularly. Pressure mapping used to assist in selection of skin protection wheel chair cushions.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Study power/sample size: **power calculation done 90% power required a sample size of 234.** Setting: **12 nursing homes (profit and nonprofit) in the Greater Pittsburgh Area. 180 licensed beds.** Length of study: **6 months.** Assessment of PUs: **Sitting-acquired pressure ulcer was those occurring primarily over the ischial tuberosities while sacral ulcers primarily result from excessive loading in bed.** **Weekly skin and risk assessments (Braden Score) were performed by a research nurse masked to the treatment assignment. Assessments continued until first**	**Total Braden score:**15.5 (s.d 1.5) **Incontinent:**97 (85.8%) **Ambulation:** 0 feet: 86 (76.1%), </=10 feet: 5 (4.4%); > 10 feet 22 (19.5%) **Could not walk unassisted:** 76.1% **Could walk 3 meters or less:** 4.4% **Could walk more than 3 meters:** 19.5% **Inclusion criteria:** LTC resident 65 years of age or older; Braden score of </=18 (at risk for developing pressure ulcers; combined Braden Activity and Mobility Subscale score </=5; absence of ischial area pressure ulcers; tolerance for daily wheelchair sitting time >/=6 hours; and ability to accommodate seating and positioning needs with the wheelchair selected for use in this study.	were given a Breezy Ultra 4 wheelchair. The difference between groups for different wheelchair was non-significant. Wheelchairs and cushions were checked weekly be the seating specialist and repaired or adjusted as needed.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
incidence of a pressure ulcer, discharge from the facility, voluntary withdrawal from the study, death, or the study end date 6 months from the initiation of the seating intervention. Multiple ulcers: N/A	**Exclusion criteria:** Body weight exceeding 113kg (exceeds wheelchair weight capacity); hip width exceeding 51cm (exceeds wheelchair width capacity); wheelchair seating requirements for head support, seat depth >46cm, or accommodation of severe orthopaedic deformities of the pelvis, lower extremities or back that exceed the capability of the study wheelchairs; and current use of any cushioning material(s) other than the SFC or equivalent, or a lower quality cushion.				

Table 28 – DEMARRE2012

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Demarre 2012** Title: **Multi-stage versus single-stage inflation and deflation cycle for alternating low pressure air mattresses to prevent pressure ulcers in hospitalised patients: a randomised-controlled clinical trial** Journal: **International Journal of Nursing Studies, 47 (2012), 416-426.** Type of study: **multi-centre RCT** Sequence generation: **randomised on 1:1 ratio by simple randomisation. The sequence was based on computer-generated list of random numbers.** Allocation concealment: **Nurses contacted researcher and received a number for type of allocated**	**Patient group:** hospitalised patients. The wards were neurology (n=6), rehabilitation (n=3), cardiology (n=2), dermatology (n=1), pneumology (n=1), oncology (n=1) and chronic care (n=1) or a combination of different types of medical conditions (n=2). **All patients** **Randomised N:** 610 **Completed N:** 307 **Drop-outs:** 303 **Group 1** **Randomised N:** 298 **Completed N:** 152 **Dropouts:** 146 (PU category II-IV (n=17), losses to follow-up because of: technical problems (n=3), discomfort (n=11), reason not	**Group 1:** ALPAM with multi-stage inflation and deflation of the air cells. The inflation curve of the air cell was identical to the deflation curve of t air cell. The head zone contained 3 air cells with a continuous low pressure, the heel zone contained 7 cells with a continuous ultra low pressure and the back and sacrum zone contained 10 alternating low pressure cells. A sensor at the sacral zone measured the applied pressure of the body on the mattress. The device consisted of a mattress and a control unit. Cycle times for inflation and deflation were between 10 and 12 minutes. The air cell width was 10cm. **Group 2:** standard ALPAM. An ALPAM with a standard single-stage, steep inflation and deflation of the air cells. All air cells were alternating, the cycle time was 10 minutes and the air cell width was 10cm. An external manual control unit was used	**Outcome 1:** Cumulative incidence of pressure ulcer grade II-IV (% developing a new pressure ulcer): **Outcome 2:** Non-blanchable erythema (pressure Grade 1) **Outcome 3:** excluding pressure ulcers (Grade II-IV) occurring in the first 3 days after admission in the study (which could have been caused by tissue damage prior to start of study) **Outcome 4:** Ti to develop a pressure ulcer (median time)	**Group 1:17/298 (**5.7%) **Group 2: 18/312 (**5.8%) P=0.97 **Group 1:** 51/298 (17.1%) **Group 2:** 38/312 (12.2%) P=0.08 **Group 1:** (3.4%) **Group 2:** (4.2%) P=0.61 Binary logistic regression analysis: OR 1.17 (95% CI 0.553-2.455), x2 = 0.16, df=1, p=0.687) **Group 1:** 5.0 days (IQR 3.0-8.5) **Group 2:** 8.0 days (IQR 3.0-8.5) Mann-Whitney U-test = 113, p=0.182.	**Funding:** Financially sponsored by Ghent University as part of a PhD study. Authors state that the mattresses and cushions were provided by Hill-Rom but they did not influence the study. **Limitations:** No blinding of outcome assessors. High drop-out in both groups. Both groups had some patients with patients who had grade I ulcers already (15.4%). **Additional outcomes:** Incidence of grade II, grade III, Grade IV,

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
mattress (first on computer generated list). Blinding: **blinding not possible due to differences in external control unit of the mattresses studied. No information was given to the nurses regarding the differences in mattresses. Outcome assessors not blinded.** Addressing incomplete outcome data: **flow chart with detailed reasons for drop-out given. High drop-out (in both groups). ITT analysis used.** Statistical analysis: **data presented in %s and means if normally distributed data and medians of not normally distributed. T-tests used in normally distributed continuous data. Mann-Whitney u-tests for non-normally distributed**	defined (n=3), transfer to another ward (n=15), discharge to home (n=40), death (n=15), discharge to another institution (n=42)) **Group 2** **Randomised N:** 312 **Completed N:** 155 **Dropouts:** 157 (PU category II-IV (n=18), losses to follow-up because of: technical problems (n=3), discomfort (n=16), reason not defined (n=5), transfer to another ward (n=22), discharge to home (n=41), death (n=14), discharge to another institution (n=37), withdrawal of consent (n=1)) **Inclusion criteria:** at risk for pressure ulcer development according to the Braden scale. **Exclusion criteria:** having a pressure ulcer	to adjust the mattress to the patient's weight. Both mattresses were covered with an identical mattress cover. No standard repositioning protocol was used in bed. An identical seating protocol was used in both groups. All patients were seated on a static air cushion. The control unit was disconnected during transport of the patient, resulting in an inflated mattress for 2 hours without alternating air cells.	**Outcome 5:** acceptability of the devices – number who withdrew due to discomfort	**Group 1:** 11/298 **Group 2:** 17/312	incontinence-associated dermatitis. Incidence for various areas – pelvic area (sacral; hip); heel area (heel, ankle); other. Probability to remain pressure free.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
continuous data. Chi-square and Fisher's exact tests for categorical variables. Baseline differences: **no significant differences** Study power/sample size: **powered for 600 patients (300 in each group).** Setting: **25 wards from 5 Belgian hospitals.** Length of study: **14 days follow-up** Assessment of PUs: **pressure ulcers classified by EPUAP classification system. Skin assessment daily by nurses. Transparent plastic disc method used to observe non-blanchable erythema (Grade 1).** Multiple ulcers: **N/A**	Grade II-IV on admission; the expected admission time in the hospital was < 3 days; aged < 18 years; there was a 'do not resuscitate code' specifying ending all therapeutic interventions; weight was less than 30kg or more than 160kg (mattress specification); Informed consent could not be obtained from patient or his/her legal representative.				

Table 29 – VANLEEN2011

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Van Leen (2011)** Title: **Pressure relief, cold foam or static air? A single center, prospective, controlled randomized clinical trial in a Dutch nursing home** Journal: **Journal of Tissue Viability (2011), 20,30-34.** Type of study: **single centre RCT.** Sequence generation: **numbered envelopes** Allocation concealment: **numbered envelopes** Blinding: **not reported.** Addressing incomplete outcome data: **ITT analysis used. State that those who died did not develop pressure ulcers.** Statistical analysis: **using SPSS 15.0. No further details.**	**Patient group:** nursing home residents **All patients** **Randomised N:** 83 **Completed N:** 74 **Drop-outs:** 5 died during study in group 1 and 4 died during study in group 2, none of the patients who died developed a pressure ulcer during their participation. **Group 1** **Randomised N:** 42 **Completed N:** 38 **Dropouts:** 4 (died) **Age (mean, s.d):** 81.1 (8.37) Gender (females): 33 Norton 5-8 at start of study: 26 (61.9%) Norton 9-12 at start of study: 16 (38.1%) Diagnoses Dementia: 31 (73.8%) CVA: 8 (19%)	**Group 1:** combination of a standard 15cm cold foam mattress with a static air overlay **Group 2:** a standard 15cm cold foam mattress All patients: when out of bed, sitting on a static air pillow following the institutional PUPP. At night, nobody received repositioning conforming to this PU protocol. No repositioning was allowed before development of a grade 2 pressure ulcer.	**Outcome 1:** development of grade 2, 3 and 4 pressure ulcers (EPUAP classification) at the heel or in the sacral/hip region. **Incidence of pressure ulcers:**	**Group 1:** 2/42 ITT (4.8%) **Group 2:** 7/41 ITT (17.1%) P=0.088 (Fisher's exact test) (95% CI 1.3% to 25.9%)	**Funding:** no funding. **Limitations:** Ethical issues of not using repositioning. Limited details of sequence generation and allocation concealment. No details of blinding of outcome assessors. Small study. **Additional outcomes:** incidence of pressure ulcers in groups at Norton scale risk 5-8 and 9-12, for Grade 2,3 and 4 ulcers The authors protocol is contrary to national guidelines for pressure ulcer
			Outcome 2: Incidence of Grade 2 ulcers:	**Group 1:** 0/42 **Group 2:** 1/41	
			Outcome 3: Incidence of Grade 3 ulcers:	**Group 1:** 1/42 **Group 2:** 5/41	
			Outcome 4: Incidence of Grade 4 ulcers	**Group 1:** 0/42 **Group 2:** 0/41	
			Outcome 5:		

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Baseline differences: **there were more patients in the intervention group with a very low Norton score (more pressure ulcer prone patients).** Study power/sample size: **power of 80% required 38 patients in each group** Setting: **Nursing home, De Naaldhorst, the Netherlands.** Length of study: **patients were followed for a period of 6 months.** Assessment of PUs: **not reported.** **Risk of pressure ulcers assessed by Norton scale.** Multiple ulcers: **not reported.**	Rheumatoid arthritis: 1 (2.4%) Encephalopathy: 0 m. Parkinson: 1 (2.4%) Diabetes: 0 Arthrosis: 0 Hip fracture: 1 (2.4%) COPD: 0 **Group 2** **Randomised N:** 41 **Completed N:** 36 **Dropouts:** 5 (died) **Age (mean, s.d):** 83.1 (7.86) Gender (females): 34 (82.9%) Norton 5-8 at start of study: 22 (53.7%) Norton 9-12 at start of study: 19 (46.3%) Diagnoses: Dementia: 31 (75.6%) CVA: 4 (9.8%) Rheumatoid arthritis: 0 Encephalopathy: 1 (2.4%) m. Parkinson: 1 (2.4%) Diabetes: 1 (2.4%)				prevention regarding repositioning for 2 reasons: interference in sleep and the higher workload for nursing staff and the accompanying higher costs.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	Arthrosis: 1 (2.4%) Hip fracture: 1 (2.4%) COPD: 1 (2.4%) **Inclusion criteria:** age >65, Norton score between 5-12; informed consent of patients or representatives in case of mental disorders. **Exclusion criteria:** a pressure ulcer in the previous 6 months				

Table 30 – GRISELL2008

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Grisell (2008)** Title: **Face tissue Pressure in Prone Positioning: a comparison of three face pillows while in the prone position for spinal surgery.** Journal: **SPINE, 33 (26), 2938-2941.** **Type of study prospective randomised trial.**	**Patient group:** elective surgery patients – thoracic, lumbar or thora-columbar spinal surgery that required prone positioning **All patients** **Randomised N:** 66 **Completed N:** 66 **Drop-outs:** 0	3 different types of face pillows that are used for prone positioning in the operating room: **Group 1:** a neoprene air filled bladder (dry flotation) device by ROHO **Group 2:** the OSI (orthopaedic systemc inc) (disposable polyurethane foam prone head positioner) **Group 3:** the Prone View Protective Helmet system (a	**Outcome 1:** incidence of pressure ulcers **Outcome 2:** incidence of stage 1 pressure ulcers **Outcome 3:** incidence of stage 2 pressure ulcers	**Group 1:** 0/22 **Group 2:** 10/22 **Group 3:** 0/22 **Group 1:** 0/22 **Group 2:** 8/22 **Group 3:** 0/22 **Group 1:** 0/22 **Group 2:** 8/22 **Group 3:** 0/22	**Funding:** Not reported. **Limitations:** Aimed at tissue interface pressures rather than incidence of pressure ulcers. No details of allocation concealment or blinding of outcome

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Sequence generation: **randomisation list mentioned and was consulted for assignment of positioner before start of surgery. Randomisation list was generated using website www.randomization.com – which uses randomly permutated blocks to assign each subject to a pillow.** Allocation concealment: **no details** Blinding: **the patient was unaware of their assigned positioner type at all times. No details of other blinding.** Addressing incomplete outcome data: **all patients completed the study.** Statistical analysis: **Nonparamateric statistical methods used because of small sample sizes. Mann-Whitney U was used to analyse measures of**	**Group 1** **Randomised N:** 22 **Completed N:** 22 **Dropouts:** 0 **Group 2** **Randomised N:** 22 **Completed N:** 22 **Dropouts:** 0 **Group 2** **Randomised N:** 22 **Completed N:** 22 **Dropouts:** 0 **Inclusion criteria:** aged 18 to 65 years (inclusive); presenting to the operating room for elective thoracic, lumbar, or thora-columbar spinal surgery that required prone positioning were included. **Exclusion criteria:** patients with any facial skin ailment or lesion (rash, abrasion	disposable polyurethane foam head positioner) All patients: positioned prone on a Jackson table using standard positioning. A low profile pressure sensor was positioned between the subject's forehead and the pillow and between the subject's chin and the pillow. Procedures lasted from 1 to 12 hours.			assessors. Small sample size. No details of population characteristics and baseline differences. Did not stratify by age, gender, surgery type, surgery location or surgery length (other than the requirement that surgery last at least 1 hour) **Additional outcomes:** tissue interface pressure Studies main aims were regarding tissue pressures. No statistics were used to evaluate the lengths of procedures but the authors state that the average time for the

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
central tendency and variability of the tissue pressures measured. The Friedman analysis was used to evaluate and assess the differences across time at each of the time variables measured. Baseline differences: **no details** Study power/sample size: **80% power required 20 patients in each group.** Setting: **surgery** Length of study: **no details except range of surgery times.** Assessment of PUs: **Authors say any pressure ulcers seen were staged according to the NPUAP staging system.** Multiple ulcers: **there were multiple ulcers but gave details of number of patients.**	infection, redness, inflammation, bruising); history of increased intraocular pressure or glaucoma; patients presented for emergent spinal surgery; patients for surgery that included any cervical level; patients whose major language was not English.				procedures on each of the positioners was similar.

Table 31 – MISTIAEN2010E

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Mistiaen (2010)** Title: **The effectiveness of the Australian Medical Sheepskin for the prevention of pressure ulcers in somatic nursing home patients: A prospective multicenter randomized-controlled trial (ISRCTN17553857)** Journal: **Wound Rep Reg (2010), 18, 572-579.** Type of study: **multicenter prospective RCT** Sequence generation: **Randomisation scheme created in SPSS by assigning the intervention to a random sample of around 50% in a list of 1,500 numbers and assigning the control group to the rest Randomisation was done on admission day or at least within 48 hours after admission.** Allocation concealment: **Adequate. The sequence generation was then**	**Patient group:** nursing home patients **All patients** **Randomised N:** 588 **Completed N:** 543 **Drop-outs:** 45 **Group 1** **Randomised N:** 295 **Completed N:** 271 **Dropouts:** 24 Gender (female %): 71% Age mean (range): 78 (26-97) Barthel score mean: 9.9 Patients with risk on pressure ulcer % (Braden score </=20): 70 Patients with risk on pressure ulcer % (Braden score	**Group 1:** All usual care and the application of the Australian Medical Sheepskin (AMS) (hi-temp, urine resistant, size XXL) as an overlay on top of the standard mattress in the area of the buttocks. An extra AMS at the bottom of the bed and in the (wheel) chair was also permitted. The application of the AMS started no later than 48 hours after admission. The AMS was then applied during the first 30 days after admission or until a patient died or was discharged, whichever came first. All other usual pressure ulcer preventive interventions such as mobilisation and repositioning could be added as co-interventions as far as were usual care in the nursing homes. All other nursing care could be continued as usual (including incontinence materials) **Group 2:** Control group received usual care only,	**Outcome 1:** incidence of sacral pressure ulcers in the first 30 days after admission **Outcome 2:** incidence of pressure ulcers on other areas **Outcome 4:** comfort of the sheepskin as experienced by the patients (self-developed seven-time questionnaire with a five-point rating answer structure) – softness, itching, smell, warmth, tickling, comfort, if would recommend to other patients; additional comments	**Group 1:** 24/271 (8.9%) ACA **Group 2:** 40/272 (14.7%) ACA Two-sided x^2, p=0.035 **Group 1:** 16.4% **Group 2:** 15.1% X^2, p=0.69 (209 filled out questionnaire) Too warm: one third Recommend AMS to other patients: 52%, no judgement 26%, would not recommend 22%. Compliance to AMS: Group 1: 1/3 of patients in the sheepskin group discontinued the use of the MAS, mostly within the first week and mainly because they found it too warm. The sheepskin was almost never applied under the heels or in the chair. In the control group, 1.7% of the observable days was	**Funding:** grant from the Efficacy Research Program, round 2007, of the Netherlands Organisation for Health Research and Development. **Limitations:** no blinding . Unclear addressing of incomplete outcome data. **Additional outcomes:** onset day of pressure ulcers; usual care components by intervention group (table given). No significant differences in usual care component.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
blinded on a paper list numbered 1 through 1,500 by a secretary not further involved in the project. The admitting nurse called the principal investigator who then disclosed the allocation from the blinded list to the nurse, who then disclosed to patient. Blinding: **Not possible to blind if someone is in the experimental group or not, only the patient allocation itself was blinded to all parties involved. Checking was done to see that allocated intervention was correctly applied.** Addressing incomplete outcome data: **ITT analysis was used. Main reason for not obtaining outcome data was primarily nurses forgetting to send the forms or discarded by accident when a patient died or was discharged home or transferred to another institution or lost in the mail.**	</=18): 47 BMI mean: 24.6 **Group 2** **Randomised N:** 293 **Completed N:** 272 **Dropouts:** 21 Gender (female %): 67% Age mean (range): 78 (27-98) Barthel score mean: 9.4 Patients with risk on pressure ulcer % (Braden score </=20): 71 Patients with risk on pressure ulcer % (Braden score </=18): 47 BMI mean: 25.6 **Inclusion criteria:** patients newly admitted for a primarily somatic reason, adult (aged	including all the pressure-reducing interventions and other preventive actions, normally taken in the participating nursing homes. The application, in any form, of the AMS was forbidden in this group during the first 30 days after admission. In both groups: the regular/usual mattresses were applied (differed from institution to institution and even ward to ward). Wound care specialists were allowed to start with a special pressure-reducing mattress for a patient during the observation period when they considered this necessary and was required to be noted on the daily observation form.		spent with an AMS, this occurred in the beginning of the study period, because it was then not entirely clear to the nurses when they were allowed to give an AMS to the patients.	
			Mean onset day of pressure ulcers (days after admission):	**Group 1:** 12 **Group 2:** 9	
			Outcome 5: ease of use of the sheepskin as experienced by the care personnel (measured by group interviews with ward nurses on three occasions)	Nurses did not encounter difficulties in using AMS in daily practice, but it did make it slightly more difficult to change bed linen in bed-ridden patients. Also the dirty sheepskins needed separate linen bags caused some inconvenience.	
			Outcome 6: quality of life (visual analog scale 0=worst health status ever 100=the best that could be imagined) mean	**Group 1:** 62.1 **Group 2:** 61.3 Student's t test p=0.71 Mean quality of life for patients without sacral pressure ulcers:	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Characteristics of lost to follow-up patients vs analysed patients were given (no statistically significant differences) Statistical analysis: **primary outcome (incidence) was conducted with multilevel binary logistic regression analysis.** Baseline differences: **No difference for gender, age, Braden score, Barthel score and BMI or medical diagnosis or prior surgery in month before admission. no significant differences between nursing homes in the proportion of patients that were randomised to the intervention or control group.** Study power/sample size: **80% power 750 (2x375) required.** Setting: **8 nursing homes (23 nursing wards), the Netherlands.** Length of study: **observations continued**	18 years and older), expected stay >1 week **Exclusion criteria:** pressure ulcers on the sacrum at admission, having darkly pigmented skin (because of difficulty in diagnosing grade 1 pressure ulcer), and known allergy to wool; admitted for a primarily psycho-geriatric reason.			**Group 1:** 63 **Group 2:** 53 Student's t test, p=0.003	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
until day 30 after admission Assessment of PUs: **daily skin observations, used EPUAP grading system. Used photographic series of the various pressure ulcer grades as well as transparent disks that nurses pressed against erythema by hand to see whether the area blanched under pressure. If uncertain they called a specialised nurse. All cases of pressure ulcers were reported to a wound care specialist who checked the observation, gave care instructions and monitored the progress of the ulcer.** **Risk assessment: Braden scale.** Multiple ulcers: **N/A**					

Table 32 – MALBRAIN2010

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Malbrain 2010** Title: **A pilot randomised controlled trial comparing reactive air and active alternating pressure mattresses in the prevention and treatment of pressure ulcers among medical ICU patients** Journal: **Journal of Tissue Viability (2010), 19, 7-15** Sequence generation: **envelopes shuffled.** Allocation concealment: **envelopes were identical, shuffled and placed in a box but no mention of opaque.** Blinding: **single blinded** Addressing incomplete outcome data: **adequate** Statistical analysis: **T-test and Fisher's exact test.** Baseline differences:	**Patient group:** patients in ICU with high pressure ulcer risk (Norton score</=8 requiring mechanical ventilation for at least 5 days, with either intact skin or pressure ulcers **All patients** **Randomised N:** 16 **Completed N:** 15 **Drop-outs:** one death but know that developed a sacral persistent erythema (category 1) immediately prior to death. **Group 1** **Randomised N:** 8 **Completed N:** 8 **Dropouts:** 0 **Age (years):** 71.5 (s.d 11.8) **Sex F/M:** 3/5 **BMI (kg/m2):** 22.1 (s.d 2.7) **Pre-albumin (mg/dl):**	Group 1: ROHO dry floatation mattress overlay Group 2: the NIMBUS 3 active alternating pressure mattress Both groups were given standard treatment according to Belgian consensus protocol. Repositioning every 2 hours from semi-Fowler to the right/left lateral 30 degrees position. Two-way stretch sheet and a low friction slide sheet used for repositioning. Pillow between calves and interface, which is standard protocol in Belgium. Additional nutritional support. All had indwelling urinary catheters. Skin was inspected daily and documented.	**Outcome 1: incidence of pressure ulcers (all grades)**	**Group 1:** 2/8 (25%) **Group 2:** 2/8 (25%)	**Funding:** no details **Limitations:** very small sample size; unclear allocation concealment. Single blinded. Baseline differences. **Additional outcomes:** healing of ulcers. Notes:

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
statistically significant difference in age and per-albumin. Study power/sample size: **power calculation not given but very small sample size.** Setting: ICU, **Belgium** Length of study: **not reported but average given for both groups as 15 (s.d 14) in the NIMBUS group and 12.2 (s.d 5.5) in the ROHO group** Assessment of PUs: **PUSH tool** Multiple ulcers: **all were recorded.**	20.3 (s.d 12.4**)** **Norton score:** 7 (s.d 0) **APACHE II score:** 20.4 (s.d 7.5) **SOFA score:** 11.4 (s.d 3.2) **CRP day 1 (mg/dl):** 10.1 (s.d 14.1) **% Semi-Fowler position:** 58.1 (s.d 7.5) **% lateral decubitus:** 41 (s.d 17.2) **Group 2** **Randomised N:** 8 **Completed N:** 7 **Dropouts:** 1 died **Age (years):** 56.9 (s.d 16.3) **Sex F/M:** 5/3 **BMI (kg/m2):** 24.2 (s.d 6.5) **Pre-albumin (mg/dl):** 6.7 (s.d 3.6) **Norton score:** 7.4 (s.d 1.1) **APACHE II score:** 22.8 (s.d 4.6) **SOFA score:** 11.8 (s.d 2.7)				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	CRP day 1 (mg/dl): 10.3 (s.d 8.2) **% Semi-Fowler position:** 54.9 (s.d 11.8) **% lateral decubitus:** 37.1 (s.d 11.2) **Inclusion criteria:** patients in ICU with high pressure ulcer risk (Norton score</=8 requiring mechanical ventilation for at least 5 days, with either intact skin or pressure ulcers **Exclusion criteria:** if consent refused or if at time admitted not at least one of the mattresses available.				

8. HEEL ULCER PREVENTION (DEVICES)

8.1. Review protocol

Table 1 – Protocol review

Protocol	Heel prevention (devices)
Review question	What are the most clinically effective pressure re-distributing devices for the prevention of heel pressure ulcers?
Population	Individuals of all ages in all settings
Intervention	**Heel-specific devices:** • Air-filled booties • Foam foot protectors • Gel foot protectors • Pillows and other aids • Splints or other medical devices • Sheepskins for heels (synthetic and natural) • Pressure Relief Ankle Foot Orthosis • As prevention strategies
Comparison	• Each other • No intervention
Outcomes	**Critical outcomes for decision-making:** • Proportion of participants developing new pressure ulcers (dichotomous outcome)(describe different categories of ulcer) **Important outcomes:** • Patient acceptability • Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital or NHS care (continuous data) • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised

Protocol	Heel prevention (devices)
	o Short-form health survey (SF36) o Manchester Short Assessment of Quality of Life o EQ-5D o WHO-QOL BREF o Cardiff HRQoL tool o HUI o Pressure ulcer quality of life (Gorecki)
Study design	• High quality systematic reviews of RCTs and/or RCTs only. • Cochrane reviews will be included if they match our inclusion criteria and have appropriate assumptions for missing data such as available case analysis or ITT (with the appropriate assumptions) • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies with outcomes that do not involve pressure ulcers • Abstracts unless no RCTs are found • Non-English language papers
The search strategy	**The databases to be searched are:** • Medline, Embase, Cinahl, the Cochrane Library. • All years. • Studies will be restricted to English language only
Review strategy	**How will individual PICO characteristics be combined across studies in a meta-analysis (for intervention reviews)** • Population – any population will be combined for meta-analysis except for different strata • Intervention – Different categories of device will not be combined for meta-analysis • Comparison – any comparison which fits the inclusion criteria will be meta-analysed • Outcomes – single side effects will be meta-analysed separately from other side effects • Study design – randomised and quasi-randomised studies will be meta-analysed together. Blinded and unblinded studies will be meta-analysed together. Crossover trials will be meta-analysed together with parallel trials • Unit of analysis – patients, clusters (hospital wards), individual pressure ulcers – for those where patients are the unit of analysis and the patient has multiple ulcers it should be the first pressure ulcer occurring (describe different

Protocol	Heel prevention (devices)
	categories of ulcer) • Minimum duration of treatment = no minimum. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use available case analysis for dealing with missing data if there is a 10% differential or higher between the groups or if the missing data is higher than the event rate, if cannot work out the available case analysis will take the author's data.. • MIDs: 0.75 to 1.25 for dichotomous variables and 0.5 x standard deviation for continuous variables.
Analysis	**Strata:** The following groups will be considered separately as strata if data are present: • Children (neonates, infants, children) and adults • People with neurological impairment or spinal cord damage or injury • People with sensory impairment • Bariatric patients (BMI >40) **Subgroups:** The following groups will be considered separately as subgroups if data are present and there is inconsistency: • Different categories of pressure ulcer (from category 2 upwards where outcomes are reported separately) • Adjunctive therapies
Other terms	Support surfaces, pressure relieving, pressure reducing, pressure preventing
Notes	Where have said 'describe' or 'descriptive' this will be noted in the summary table.

8.2. Search strategy

8.2.1. Search filters

Table 2 – Search filters in OVID Medline

Search strategy	Heel ulcer prevention		Results
Date	27th Mar 2012		
Database	Medline-Ovid		
Search strategy (part I – Protection devices)	1	letter/	761962
	2	editorial/	307832
	3	news/	150655
	4	exp historical article/	303553
	5	Anecdotes as Topic/	4270
	6	comment/	502495
	7	case report/	1566420
	8	(letter or comment*).ti.	83724
	9	or/1-8	3056534
	10	randomized controlled trial/ or random*.ti,ab.	681405
	11	9 not 10	3041380
	12	animals/ not humans/	3612470
	13	exp Animals, Laboratory/	669993
	14	exp Animal Experimentation/	5302
	15	exp Models, Animal/	368581
	16	exp Rodentia/	2474809
	17	(rat or rats or mouse or mice).ti.	1037887
	18	or/11-17	7181325
	19	pressure ulcer/	8951
	20	decubit*.ti,ab.	3879
	21	(pressure adj (sore* or ulcer* or damage)).ti,ab.	6110
	22	(bedsore* or bed-sore*).ti,ab.	502

Search strategy	Heel ulcer prevention		Results
	23	(incontinen* adj2 dermatitis).ti,ab.	53
	24	((moist* or friction or shear) adj2 (sore* or ulcer* or damage or wound* or injur* or lesion*)).ti,ab.	632
	25	or/19-24	13575
	26	limit 25 to english language	10837
	27	(seat* or chair* or wheelchair* or pillow*).ti,ab.	36666
	28	wheelchairs/	3185
	29	(bed or beds).ti,ab.	70275
	30	(cutfoam or padding or sheepskin* or sheep-skin* or gels).ti,ab.	35899
	31	(alternat* adj2 pressure).ti,ab.	279
	32	shoes/	4352
	33	exp orthotic devices/	8586
	34	(orthotic adj2 (device* or therap* or treat*)).ti,ab.	512
	35	(shoe* or boot* or footwear or foot-wear).ti,ab.	15002
	36	(orthos* or insole).ti,ab.	13416
	37	((contact or walk*) adj2 cast*).ti,ab.	341
	38	(aircast* or scotchcast*).ti,ab.	102
	39	((foot or feet or heel*) adj2 (pressure or protect* or device*)).ti,ab.	1022
	40	((foot or feet or heel* or leg*) adj2 trough*).ti,ab.	5
	41	(heel* adj2 (lift* or splint* or float* or glove* or suspen* or elevat*)).ti,ab.	160
	42	or/27-41	178049
	43	26 and 42	1575
	44	43 not 18	1400
	45	randomized controlled trial.pt.	325596
	46	controlled clinical trial.pt.	83986
	47	randomi#ed.ab.	289033
	48	placebo.ab.	135372
	49	drug therapy.fs.	1524063
	50	randomly.ab.	177256

Search strategy	Heel ulcer prevention		Results
	51	trial.ab.	249935
	52	groups.ab.	1158597
	53	or/45-52	2925297
	54	Clinical Trials as topic.sh.	159527
	55	trial.ti.	103737
	56	or/45-48,50,54-55	797665
	57	Meta-Analysis/	33150
	58	Meta-Analysis as Topic/	12045
	59	(meta analy* or metanaly* or metaanaly*).ti,ab.	43213
	60	((systematic* or evidence*) adj2 (review* or overview*)).ti,ab.	51468
	61	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.	20401
	62	(search strategy or search criteria or systematic search or study selection or data extraction).ab.	21932
	63	(search* adj4 literature).ab.	20026
	64	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.	63574
	65	cochrane.jw.	8354
	66	or/57-65	148230
	67	56 or 66	903308
	68	44 and 67	207
Part II (support surfaces)	1	pressure ulcer/	8894
	2	decubit*.ti,ab.	3865
	3	(pressure adj (sore* or ulcer* or damage)).ti,ab.	6062
	4	(bedsore* or bed-sore*).ti,ab.	501
	5	(incontinen* adj2 dermatitis).ti,ab.	50
	6	((moist* or friction or shear) adj2 (sore* or ulcer* or damage or wound* or injur* or lesion*)).ti,ab.	622
	7	or/1-6	13487
	8	limit 7 to english language	10757
	9	randomized controlled trial.pt.	322734

Search strategy	Heel ulcer prevention		Results
	10	controlled clinical trial.pt.	83763
	11	randomi#ed.ab.	285035
	12	placebo.ab.	134079
	13	drug therapy.fs.	1512984
	14	randomly.ab.	175416
	15	trial.ab.	246425
	16	groups.ab.	1148425
	17	or/9-16	2901023
	18	Clinical Trials as topic.sh.	158570
	19	trial.ti.	102055
	20	or/9-12,14,18-19	789946
	21	letter/	752856
	22	editorial/	302491
	23	news/	143966
	24	exp historical article/	302413
	25	Anecdotes as Topic/	4185
	26	comment/	493095
	27	case report/	1558286
	28	(letter or comment*).ti.	83156
	29	or/21-28	3025178
	30	randomized controlled trial/ or random*.ti,ab.	674026
	31	29 not 30	3010191
	32	animals/ not humans/	3594930
	33	exp Animals, Laboratory/	665788
	34	exp Animal Experimentation/	5218
	35	exp Models, Animal/	365269
	36	exp Rodentia/	2460341
	37	(rat or rats or mouse or mice).ti.	1032770

Search strategy	Heel ulcer prevention		Results
	38	or/31-37	7127677
	39	Meta-Analysis/	32205
	40	Meta-Analysis as Topic/	11873
	41	(meta analy* or metanaly* or metaanaly*).ti,ab.	42057
	42	((systematic* or evidence*) adj2 (review* or overview*)).ti,ab.	50096
	43	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.	19856
	44	(search strategy or search criteria or systematic search or study selection or data extraction).ab.	21391
	45	(search* adj4 literature).ab.	19634
	46	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.	61940
	47	cochrane.jw.	7944
	48	or/39-47	145126
	49	20 or 48	893674
	50	49 not 38	782841
	51	8 and 50	995
	52	exp beds/	3372
	53	(mattress* or cushion* or foam or transfoam or overlay* or pad or pads or gel).ti,ab.	250061
	54	(pressure adj2 (device* or support* or constant)).ti,ab.	6845
	55	(static adj air).ti,ab.	72
	56	(air adj (suspension or bag*)).ti,ab.	439
	57	(pressure adj2 (relie* or reduc* or alleviat* or redistribut* or re-distribut* or alternat*)).ti,ab.	16888
	58	water suspension*.ti,ab.	280
	59	(elevation adj2 device*).ti,ab.	10
	60	(clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or foot waffle or silicore or pegasus or cairwave).ti,ab.	448
	61	((turn* or tilt*) adj2 (bed* or frame*)).ti,ab.	454
	62	(kinetic adj (therapy or table*)).ti,ab.	77
	63	net bed*.ti,ab.	9
	64	(positioning or repositioning or re-positioning).ti,ab.	

Search strategy	Heel ulcer prevention		Results
	65	or/52-64	33140
	66	(seat* or chair* or wheelchair* or pillow*).ti,ab.	309311
	67	wheelchairs/	36394
	68	65 or 66 or 67	3172
	69	51 and 68	344756
	70	limit 69 to yr="2010 -Current"	323
			49

Table 3 – Search filters in Embase

Search strategy	Heel ulcer prevention		Results
Date	27th Mar 2012		
Database	Embase-OVID		
Search strategy (part I – Protection devices)	1	decubitus/	12517
	2	decubit*.ti,ab.	4766
	3	(pressure adj (sore* or ulcer* or damage)).ti,ab.	7117
	4	(bedsore* or bed-sore*).ti,ab.	659
	5	((moist* or friction or shear) adj2 (sore* or ulcer* or damage or wound* or injur* or lesion*)).ti,ab.	767
	6	(incontinen* adj2 dermatitis).ti,ab.	56
	7	or/1-6	17007
	8	limit 7 to english language	13126
	9	(seat* or chair* or wheelchair* or pillow*).ti,ab.	41012
	10	exp wheelchair/	5086
	11	(bed or beds).ti,ab.	89020
	12	(cutfoam or padding or sheepskin* or sheep-skin* or gels).ti,ab.	35692
	13	(alternat* adj2 pressure).ti,ab.	299
	14	orthopedic shoe/	193
	15	shoe/	5740

Search strategy	Heel ulcer prevention		Results
	16	orthotics/	2943
	17	(orthotic adj2 (device* or therap* or treat*)).ti,ab.	614
	18	(shoe* or boot* or footwear or foot-wear).ti,ab.	18106
	19	(orthos* or insole).ti,ab.	16100
	20	((contact or walk*) adj2 cast*).ti,ab.	396
	21	(aircast* or scotchcast*).ti,ab.	127
	22	((foot or feet or heel*) adj2 (pressure or protect* or device*)).ti,ab.	1219
	23	((foot or feet or heel* or leg*) adj2 trough*).ti,ab.	5
	24	(heel* adj2 (lift* or splint* or float* or glove* or suspen* or elevat*)).ti,ab.	178
	25	or/9-24	203234
	26	8 and 25	1719
	27	random*.ti,ab.	717655
	28	factorial*.ti,ab.	18594
	29	(crossover* or cross over*).ti,ab.	60412
	30	((doubl$ or singl$) adj blind$).ti,ab.	137024
	31	(assign* or allocat* or volunteer* or placebo*).ti,ab.	553050
	32	crossover procedure/	33588
	33	double blind procedure/	108289
	34	single blind procedure/	15735
	35	randomized controlled trial/	320112
	36	or/27-35	1186128
	37	letter.pt. or letter/	778574
	38	note.pt.	514042
	39	editorial.pt.	401605
	40	case report/ or case study/	1831335
	41	(letter or comment*).ti.	135434
	42	or/37-41	3393890
	43	randomized controlled trial/ or random*.ti,ab.	801083

Search strategy	Heel ulcer prevention		Results
	44	42 not 43	3367763
	45	animal/ not human/	1323451
	46	nonhuman/	3824666
	47	exp Animal Experiment/	1504918
	48	exp experimental animal/	410580
	49	animal model/	633405
	50	exp Rodent/	2532293
	51	(rat or rats or mouse or mice).ti.	1107552
	52	or/44-51	8891638
	53	systematic review/	48857
	54	meta-analysis/	62389
	55	(meta analy* or metanaly* or metaanaly*).ti,ab.	55834
	56	((systematic or evidence) adj2 (review* or overview*)).ti,ab.	59625
	57	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.	24583
	58	(search strategy or search criteria or systematic search or study selection or data extraction).ab.	26269
	59	(search* adj4 literature).ab.	24389
	60	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.	75972
	61	((pool* or combined) adj2 (data or trials or studies or results)).ab.	31350
	62	cochrane.jw.	11048
	63	or/53-62	224468
	64	36 or 63	1344623
	65	26 and 64	300
	66	65 not 52	290
Part II (support surfaces)	1	random*.ti,ab.	711167
	2	factorial*.ti,ab.	18452
	3	(crossover* or cross over*).ti,ab.	60004
	4	((doubl$ or singl$) adj blind$).ti,ab.	136181

Search strategy	Heel ulcer prevention		Results
	5	(assign* or allocat* or volunteer* or placebo*).ti,ab.	549213
	6	crossover procedure/	33346
	7	double blind procedure/	107813
	8	single blind procedure/	15595
	9	randomized controlled trial/	318508
	10	or/1-9	1177104
	11	letter.pt. or letter/	775094
	12	note.pt.	511290
	13	editorial.pt.	399508
	14	case report/ or case study/	1825147
	15	(letter or comment*).ti.	134926
	16	or/11-15	3380104
	17	randomized controlled trial/ or random*.ti,ab.	794389
	18	16 not 17	3354078
	19	animal/ not human/	1321445
	20	nonhuman/	3806953
	21	exp Animal Experiment/	1498332
	22	exp experimental animal/	408085
	23	animal model/	629106
	24	exp Rodent/	2520889
	25	(rat or rats or mouse or mice).ti.	1103508
	26	or/18-25	8855378
	27	systematic review/	48030
	28	meta-analysis/	61737
	29	(meta analy* or metanaly* or metaanaly*).ti,ab.	54972
	30	((systematic or evidence) adj2 (review* or overview*)).ti,ab.	58719
	31	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.	24411
	32	(search strategy or search criteria or systematic search or study selection or data extraction).ab.	26081

Search strategy	Heel ulcer prevention	Results
	33 (search* adj4 literature).ab.	24044
	34 (medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.	75039
	35 ((pool* or combined) adj2 (data or trials or studies or results)).ab.	31034
	36 cochrane.jw.	11048
	37 or/27-36	222072
	38 decubitus/	12420
	39 decubit*.ti,ab.	4747
	40 (pressure adj (sore* or ulcer* or damage)).ti,ab.	7047
	41 (bedsore* or bed-sore*).ti,ab.	655
	42 ((moist* or friction or shear) adj2 (sore* or ulcer* or damage or wound* or injur* or lesion*)).ti,ab.	759
	43 (incontinen* adj2 dermatitis).ti,ab.	53
	44 or/38-43	16890
	45 limit 44 to english language	13015
	46 (10 or 37) not 26	1103384
	47 45 and 46	1435
	48 (mattress* or cushion* or foam or transfoam or overlay* or pad or pads or gel).ti,ab.	265218
	49 (pressure adj2 (device* or support* or constant)).ti,ab.	7910
	50 (static adj air).ti,ab.	100
	51 (air adj (suspension or bag*)).ti,ab.	513
	52 (pressure adj2 (relie* or reduc* or alleviat* or redistribut* or re-distribut* or alternat*)).ti,ab.	20059
	53 water suspension*.ti,ab.	370
	54 (elevation adj2 device*).ti,ab.	13
	55 (clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or foot waffle or silicore or pegasus or cairwave).ti,ab.	525
	56 ((turn* or tilt*) adj2 (bed* or frame*)).ti,ab.	525
	57 (kinetic adj (therapy or table*)).ti,ab.	100
	58 net bed*.ti,ab.	9
	59 (positioning or repositioning or re-positioning).ti,ab.	

Search strategy	Heel ulcer prevention		Results
	60	(seat* or chair* or wheelchair* or pillow*).ti,ab.	38650
	61	exp bed/	40750
	62	exp wheelchair/	7588
	63	or/48-62	5032
	64	47 and 63	378050
	65	limit 64 to yr="2010 -Current"	427
			69

Table 4 – Search filters in CINAHL

Search strategy	Heel ulcer prevention		Results
Date	27th Mar 2012		
Database	CINAHL		
Search strategy (part I – Protection devices)	S25	S22 NOT S23 Limiters – English Language; Exclude MEDLINE records	455
	S24	S22 NOT S23	1485
	S23	PT anecdote or PT audiovisual or PT bibliography or PT biography or PT book or PT book review or PT brief item or PT cartoon or PT commentary or PT computer program or PT editorial or PT games or PT glossary or PT historical material or PT interview or PT letter or PT listservs or PT masters thesis or PT obituary or PT pamphlet or PT pamphlet chapter or PT pictorial or PT poetry or PT proceedings or PT "questions and answers" or PT response or PT software or PT teaching materials or PT website	
	S22	S7 and S21	1001377
	S21	S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20	2467
	S20	heel* AND (lift* OR splint* OR float* OR glove* OR suspen* OR elevat*)	42142
	S19	(foot or feet or heel* or leg*) and trough*	178
	S18	(foot OR feet OR heel*) AND (pressure OR protect* OR device*)	22
	S17	contact N2 cast* OR walk* N2 cast*	3452
	S16	orthotic N2 treat* OR orthotic N2 therap* OR orthotic N2 device*	152
	S15	alternat* N2 pressure	233
	S14	bed or beds or cutfoam or padding or sheepskin* or sheep-skin* or gels or shoe* or boot* or footwear or foot-wear or	131

Search strategy	Heel ulcer prevention		Results
	orthos* or insole or aircast* or scotchcast*		26061
	S13	(MH "Orthopedic Footwear")	94
	S12	(MH "Seating")	633
	S11	(MH "Orthoses+")	5830
	S10	(MH "Shoes+")	2320
	S9	seat* or chair* or wheelchair* or pillow*	13034
	S8	(MH "Wheelchairs+")	2982
	S7	S1 or S2 or S3 or S4 or S5 or S6	9652
	S6	((moist* or friction or shear) and (sore* or ulcer* or damage or wound* or injur* or lesion*))	1377
	S5	incontinen* n2 dermatitis	70
	S4	bedsore* OR bed-sore*	155
	S3	pressure n1 sore* OR pressure n1 ulcer* OR pressure n1 damage*	8313
	S2	decubit*	476
	S1	(MH "Pressure Ulcer")	7543
Part II (support surfaces)	S26	S7 and S24 Limiters – Published Date from: 20101201-20121231; English Language; Exclude MEDLINE records	133
	S25	S7 and S24	3354
	S24	S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23	48691
	S23	seat* or chair* or wheelchair* or pillow*	12957
	S22	positioning or repositioning or re-positioning	7537
	S21	net bed*	4
	S20	kinetic and (therapy or table*)	370
	S19	(turn* or tilt*) and (bed* or frame*)	1366
	S18	clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or foot waffle or silicore or pegasus or cairwave	57
	S17	elevation N2 device*	6
	S16	water suspension*	0
	S15	pressure and (relie* or reduc* or alleviat* or redistribut* or re-distribut* or alternat*)	14412
	S14	air suspension or air bag*	131

Search strategy	Heel ulcer prevention		Results
	S13	static air	12
	S12	pressure and (device* or support* or constant)	8690
	S11	mattress* or cushion* or foam or transfoam or overlay* or pad or pads or gel	9244
	S10	(MH "Wheelchairs+")	2956
	S9	(MH "Pillows and Cushions")	456
	S8	(MH "Beds and Mattresses+")	2576
	S7	S1 or S2 or S3 or S4 or S5 or S6	9607
	S6	((moist* or friction or shear) and (sore* or ulcer* or damage or wound* or injur* or lesion*))	1368
	S5	incontinen* n2 dermatitis	69
	S4	bedsore* OR bed-sore*	155
	S3	pressure n1 sore* OR pressure n1 ulcer* OR pressure n1 damage*	8277
	S2	decubit*	474
	S1	(MH "Pressure Ulcer")	7513

Table 5 – Search filters in Cochrane

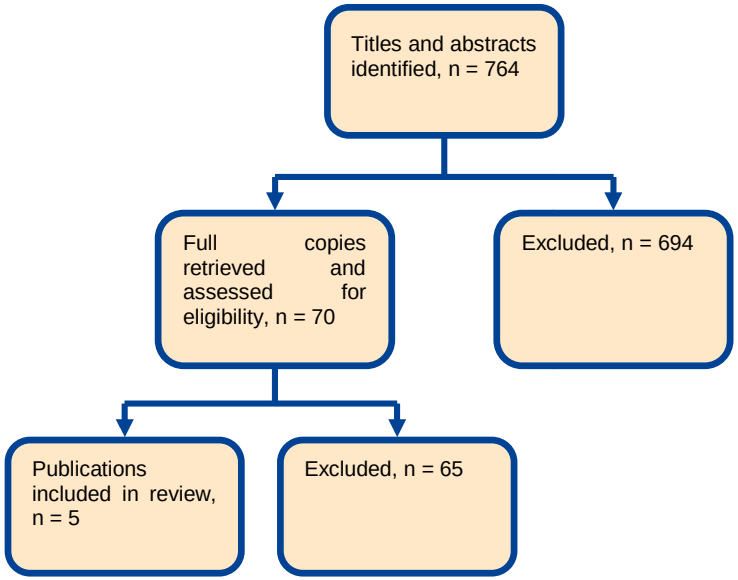
Search strategy	Heel ulcer prevention		Results
Date	27th Mar 2012		
Database	Cochrane (- CDSR [3/2012]; DARE; Central [3/2012]; NHS EED; HTA)		
Search strategy (part I – Protection devices)	#1	MeSH descriptor Pressure Ulcer explode all trees	487
	#2	decubit*:ti,ab,kw	349
	#3	(pressure near/2 (sore* or ulcer* or damage)):ti,ab,kw	829
	#4	(bedsore* or bed-sore*):ti,ab,kw	33
	#5	(incontinen* near/2 dermatitis):ti,ab,kw	10
	#6	((moist* or friction or shear) near/2 (sore* or ulcer* or damage or wound* or injur* or lesion*)):ti,ab,kw	63
	#7	(#1 OR #2 OR #3 OR #4 OR #5 OR #6)	1171
	#8	(seat* or chair* or wheelchair* or pillow*):ti,ab,kw	2687
	#9	MeSH descriptor Wheelchairs explode all trees	128

Search strategy	Heel ulcer prevention		Results
	#10	MeSH descriptor Shoes explode all trees	234
	#11	MeSH descriptor Orthotic Devices explode all trees	713
	#12	(bed or beds or cutfoam or padding or sheepskin* or sheep-skin* or gels or shoe* or boot* or footwear or foot-wear or orthos* or insole or aircast* or scotchcast*):ti,ab,kw	12750
	#13	(alternat* near/2 pressure):ti,ab,kw	44
	#14	(orthotic near/2 (device* or therap* or treat*)):ti,ab,kw	450
	#15	((contact or walk*) near/2 cast*):ti,ab,kw	53
	#16	((foot or feet or heel*) near/2 (pressure or protect* or device*)):ti,ab,kw	146
	#17	((foot or feet or heel* or leg*) near/2 trough*):ti,ab,kw	1
	#18	(heel* near/2 (lift* or splint* or float* or glove* or suspen* or elevat*)):ti,ab,kw	24
	#19	(#8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18)	15727
	#20	(#7 AND #19)	
Part II (support surfaces)	#1	MeSH descriptor Pressure Ulcer explode all trees	481
	#2	decubit*:ti,ab,kw	348
	#3	(pressure near/2 (sore* or ulcer* or damage)):ti,ab,kw	821
	#4	(bedsore* or bed-sore*):ti,ab,kw	32
	#5	(incontinen* near/2 dermatitis):ti,ab,kw	10
	#6	((moist* or friction or shear) near/2 (sore* or ulcer* or damage or wound* or injur* or lesion*)):ti,ab,kw	63
	#7	(#1 OR #2 OR #3 OR #4 OR #5 OR #6)	1161
	#8	MeSH descriptor Beds explode all trees	243
	#9	MeSH descriptor Wheelchairs explode all trees	127
	#10	(mattress* or cushion* or foam or transfoam or overlay* or pad or pads or gel):ti,ab,kw	7516
	#11	(pressure NEAR/2 (device* or support* or constant)):ti,ab,kw	800
	#12	(static NEAR/2 air):ti,ab,kw	4
	#13	(air NEAR/2 (suspension or bag*)):ti,ab,kw	8
	#14	(pressure NEAR/2 (relie* or reduc* or alleviat* or redistribut* or re-distribut* or alternat*)):ti,ab,kw	3643
	#15	water suspension*:ti,ab,kw	118
	#16	(elevation NEAR/2 device*):ti,ab,kw	5

Search strategy	Heel ulcer prevention	Results
	#17 (clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or foot waffle or silicore or pegasus or cairwave):ti,ab,kw	53
	#18 ((turn* or tilt*) NEAR/2 (bed* or frame*)):ti,ab,kw	47
	#19 ((turn* or tilt*) NEAR/2 (bed* or frame*)):ti,ab,kw	47
	#20 net bed*:ti,ab,kw	289
	#21 (positioning or repositioning or re-positioning):ti,ab,kw	8906
	#22 (seat* or chair* or wheelchair* or pillow*):ti,ab,kw	2653
	#23 (#8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22)	22993
	#24 (#7 AND #23)	498
	#25 (#24), from 2010 to 2012	48

8.2.2. Selection of articles

Figure 1 – Flow diagram of clinical article selection for what is the clinical and cost-effectiveness of pressure-redistributing devices for the prevention of heel ulcers? review



8.2.3. Excluded clinical studies

Reference	Reason for exclusion
ANON1993	Ordered for devices for prevention review
ARONOVITCH1998	Ordered for devices for prevention review
BALES2012	Literature review
BERTHE2007	Ordered for devices for prevention review
BHATNAGAR1997	Commentary
BRIENZA2010	Ordered for devices for prevention review
BROWN2000	Ordered for devices for prevention review
CHALONER2000	Ordered for devices for prevention review
CHENEWORTH1994	Literature review
DEFLOOR2000B	Not our outcomes
DEKEYSER1994	Not our outcomes
DEMARRE2012	Ordered for devices for prevention review
DONNELLY2011	Ordered for devices for prevention review
EKSTEEN2006	Not an RCT
EVANS2009	Not an RCT/abstract not freely available
EVANS2009A	Abstract
EWING1964	Cochrane excluded as it was considered too small and suffering from risk of bias to the extent that its results could not be regarded as valid. Does not mention pressure ulcers but 'reddening of skin of heels and ankles'.
FAWCETT2004	Abstract
FERRELL1993	Ordered for devices for prevention review; economic study
FINNEGAN2008	Not our outcomes
GIL-AGUDO2009	Not our outcomes
GONZALEZ DELLA VALLE2001	Not our outcomes
GOOSSENS2008	Not our outcomes
GRAY2000	Ordered for devices for prevention review
GRINDLEY1996	Not our outcomes
GRISELL2008	Ordered for devices for prevention review
HAMPTON2010	Not an RCT
HEYNEMAN2009	Pooled 2 RCTs (which were included in review)
HUANG2011	Not our outcomes
HUBER2008	Not our outcomes
ISMAIL2001	Ordered for devices for prevention review. But the paper states that 'those who developed pressure sore were not turned at night' unclear if just these patients or all patients.
JAN2011	Not RCT
JESURUM1996	Ordered for devices for prevention review.
JOLLEY2010	Ordered for devices for prevention review
JUNKIN2009	Systematic review

LOCKYERSTEVENS1993	Not an RCT
MACFARLANE2006	Not an RCT
MAKHSOUS2009	Ordered for devices for prevention review
MAYROVITZ2003	Not an RCT
MAYROVITZ2004	Not an RCT
MCINNES2012	Ordered for devices for prevention review
MILNE2011	Abstract not freely available
MISTIAEN2008	Cost-effectiveness study protocol
MISTIAEN2010A	Ordered for devices for prevention review
MISTIAEN2010E	Ordered for devices for prevention review
NICOSIA2007	Meta-analysis which included devices which were not specific to the heel
NIXON2006B	Erratum for study ordered for devices for prevention review
PINZURI1991	Not an RCT
RAFTER2011	Ordered for devices for prevention review
RUSSELL2000	Ordered for devices for prevention review
RUSSELL2000B	Ordered for devices for prevention review
RUSSELL2003	Ordered for devices for prevention review
RUSSELL2003A	Ordered for devices for prevention review
SANTAMARIA2012	Abstract
SCOTT1999	Ordered for devices for prevention review
SILVERTHORN2011	Not pressure ulcers
SIMMS2011	Abstract
STERZI2003	Ordered for devices for prevention review
STONE2011	Abstract
TACCONE2009	Not an RCT
VANLEEN2011	Ordered for devices for prevention review
WILLIAMS1995	Commentary
VUOLO2010	Commentary
ZERNIKE1994	Not our outcomes
ZERNIKE1997	Not our outcomes

8.3. Clinical evidence

Five randomized controlled trials were included in the review. [74, 76, 77, 134, 135]

8.3.1. Summary of included studies

Table 6 – Summary of studies included in the review

Study	Intervention/comparison	Population	Outcomes	Study length
Cadue 2008[74]	Foam body support and standard pressure prevention protocol (half-seated position, water mattress preventive massage 6 times/day) versus standard pressure ulcer protocol (as above)	Patients in an intensive care setting	Number of participants developing non-blanching pressure ulcer or worse on the heel	Maximum follow-up 3 months
Donnelly 2011[134]	Heel elevation (Heelift suspension boot) plus pressure-redistributing support surface versus standard care plus pressure-redistributing surface alone	Post-hip fracture patients	Incidence of heel ulcers (all categories)	12 days
Gilcreast 2005[76]	Bunny boot (fleece) high cushion heel protector vs egg crate heel lift positioner vs foot waffle cushion	Military tertiary-care academic medical centre patients of moderate or high risk of pressure ulcer development, Braden score ≤14	Pressure ulcer incidence	Follow-up period unclear
Tymec 1997[77]	Foot waffle vs hospital pillow under both legs from below knee to the Achilles tendon	Patients in selected nursing units of large hospital; Braden score <1 (risk); intact skin on heels	Number of pressure ulcers developed	unclear
Torra 2009 [135]	Special polyurethane foam hydrocellular dressing for the protection of the heel (Allevyn Heel) vs protective bandage of the heel (Soffban and gauze bandage).	Nursing home patients and home care program patients from primary health care centres.	Number of participants with pressure ulcers	8 weeks

8.3.2. Clinical evidence GRADE-tables

Table 7 – Bunny boot fleece cushion heel protector versus egg crate heel lift positioner for prevention of heel pressure ulcers – ICU, med, surgical ward, cardiology patients

Quality assessment							No of patients		Effect		Quality	Importance of outcome
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Bunny boot	Egg crate	Relative (95% CI)	Absolute		
Incidence of patients with heel ulcers												
1 Gilcreast (2005)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	3/77 (3.9%)	4/87 (4.6%)	RR 0.85 (0.2 to 3.67)	7 fewer per 1000 (from 37 fewer to 123 more)	⊕OOO VERY LOW	Critical outcome
								4.6%		7 fewer per 1000 (from 37 fewer to 123 more)		

1 Inadequate allocation concealment; no blinding; limited details of baseline data; unclear how many patients were randomised to each group and therefore which arms the drop-outs came from but there was 29% of patients who did not have follow-up data.
2 Confidence interval crossed both MID points.

Table 8 – Bunny boot fleece cushion heel protector versus foot waffle air cushion for prevention of heel pressure ulcers – ICU, med, surgical ward, cardiology patients

Quality assessment							No of patients		Effect		Quality	Importance of outcome
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Bunny boot	Foot waffle	Relative (95% CI)	Absolute		
Incidence of patients with heel ulcers												
1 Gilcreast (2005)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	3/77 (3.9%)	5/76 (6.6%)	RR 0.59 (0.15 to 2.39)	27 fewer per 1000 (from 56 fewer to 91 more)	⊕OOO VERY LOW	Critical outcome
								6.6%		27 fewer per 1000 (from 56 fewer to 92 more)		

1 Inadequate allocation concealment; no blinding; limited details of baseline data; unclear how many patients were randomised to each group and therefore which arms the drop-outs came from but there was 29% of patients who did not have follow-up data.
2 Confidence interval crossed both MID points.

Table 9 – Eggcrate heel lift positioner versus foot waffle air cushion for prevention of heel pressure ulcers – ICU, med, surgical ward, cardiology patients

Quality assessment							No of patients		Effect		Quality	Importance of outcome
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Eggcrate	Foot waffle	Relative (95% CI)	Absolute		
Incidence of patients with heel ulcers												
1 Gilcreast (2005)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	4/87 (4.6%)	5/76 (6.6%)	RR 0.7 (0.19 to 2.51)	20 fewer per 1000 (from 53 fewer to 99 more)	⊕OOO VERY LOW	Critical outcome
								6.6%		20 fewer per 1000 (from 53 fewer to 100 more)		

1 Inadequate allocation concealment; no blinding; limited details of baseline data; unclear how many patients were randomised to each group and therefore which arms the drop-outs came from but there was 29% of patients who did not have follow-up data.
2 Confidence interval crossed both MID points.

Table 10 – Foot waffle heel elevation device versus heel elevation pillow for prevention of heel pressure ulcers – patients from selected nursing units at a hospital

Quality assessment							No of patients		Effect		Quality	Importance of outcome
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Foot waffle	Pillow	Relative (95% CI)	Absolute		
Incidence of patients with heel pressure ulcers												
1 Tymec (1997)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	0/26 (0%)	1/26 (3.8%)	Peto OR 0.14 (0 to 6.82)	33 fewer per 1000 (from 38 fewer to 176 more)	⊕OOO VERY LOW	Critical outcome
								3.9%		33 fewer per 1000 (from 39 fewer to 178 more)		
Time to pressure ulcer												
1 Tymec (1997)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	No serious	Very serious[3]	10 days	13 days	-	Log-rank test p=0.036	⊕OOO VERY LOW	Critical outcome

1 unclear allocation concealment, blinding and reporting of incomplete outcome data.
2 Confidence interval crossed both MID points.
3 No standard deviations so could not analyse in Revman.

Table 11 – Eggcrate suspension boot heel elevation device plus pressure-redistributing support surface versus standard care (pressure-redistributing surface alone e.g. cut foam mattress, mattress overlays and alternating pressure mattresses) for prevention of heel pressure ulcers – older patients with fractured hips

Quality assessment							No of patients		Effect		Quality	Importance of outcome
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Heel elevation device	Standard care	Relative (95% CI)	Absolute		
Incidence of patients with heel pressure ulcers												
1 Donnelly (2011)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/120 (0%)	17/119 (14.3%)	Peto OR 0.12 (0.04 to 0.31)	123 fewer per 1000 (from 94 fewer to 136 fewer)	⊕⊕⊕O MODERATE	Critical outcome
								14.3%		123 fewer per 1000 (from 94 fewer to 136 fewer)		
Comfort												
1 Donnelly (2011)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	Very serious[3]	See footnote[2]	See footnote[2]	See footnote[2]	See footnote[2]	⊕OOO VERY LOW	Critical outcome

1 No blinding of patients or health care practitioners. Underpowered.
2 Comfort – Themed analysis of participants' opinions – 32% of subjects felt the boots interfered with sleep and 41% felt that they adversely affected movement in bed, 59% rated them as comfortable overall. Poor concordance reasons were the weight and bulk of the boot (36%), heat (particularly a t night) (31%) and discomfort (24%).
3 Could not analyse in Revman as data not for both arms of the trial.

Table 12 – Foam support surface (Perpendicular foam blocks covered with jersey) plus usual care versus usual care (half-seated position, water mattress preventive massage 6 times/day) for prevention of heel pressure ulcers – ICU patients

Quality assessment							No of patients		Effect		Quality	Importance of outcome
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Foam body support plus usual care	Usual care	Relative (95% CI)	Absolute		
Incidence of patients with heel ulcers (follow-up 3 months) – all grades												
1 Cadue (2008)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	3/35 (8.6%)	19/35 (54.3%)	RR 0.16 (0.05 to 0.49)	456 fewer per 1000 (from 277 fewer to 516 fewer)	⊕⊕⊕O MODERATE	Critical outcome
								54.3%		456 fewer per 1000 (from 277 fewer to 516 fewer)		
Mean time to pressure ulcer												
1 Cadue (2008)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	Very serious[2]	5.6 days	2.8 days	-	P=0.01	⊕OOO VERY LOW	Critical outcome

1 Unclear blinding. No a priori sample size calculation and small sample size. 2 No standard deviations could not analyse data in Revman.

Table 13 – Polyurethane hydrocellular foam dressing versus protective bandage4 – nursing home and home care program patients

Quality assessment							No of patients		Effect		Quality	Importance of outcome
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Polyurethane hydrocellular foam dressing	Protective bandage	Relative (95% CI)	Absolute		
Incidence of patients with heel pressure ulcers												
1Torra (2009)	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	Serious[2]	none	3.3%	44%	RR 13.42 (95% CI 3.3 to 54)	N/A[3]	⊕OOO VERY LOW	Critical outcome

1 Open study. Unclear how many in each group but relative risk reported. No details of allocation concealment and randomisati on method. Unclear addressing of incomplete outcome data. ; 2 Limited number of events. ; 3 Absolute values not available as number of patients in each group not given.
4 The study names it a dressing but from the photos it looks to be a device.

8.3.3. Forest plots

8.3.3.1. Heel pressure-redistributing devices for the prevention of heel pressure ulcers

Figure 2 – Bunny boot vs. egg crate – incidence of heel pressure ulcers

Study or Subgroup	Bunny boot Events	Total	Egg crate Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Gilcreast, 2005	3	77	4	87	100.0%	0.85 [0.20, 3.67]
Total (95% CI)		**77**		**87**	**100.0%**	**0.85 [0.20, 3.67]**
Total events	3		4			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.22 (P = 0.82)

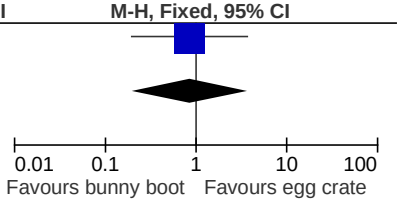


Figure 3 – Bunny boot vs. foot waffle- incidence of heel pressure ulcers

Study or Subgroup	Bunny boot Events	Total	Foot waffle Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Gilcreast, 2005	3	77	5	76	100.0%	0.59 [0.15, 2.39]
Total (95% CI)		**77**		**76**	**100.0%**	**0.59 [0.15, 2.39]**
Total events	3		5			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.74 (P = 0.46)

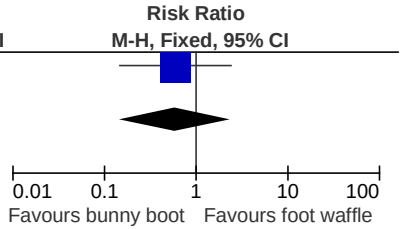


Figure 4 – Egg crate vs. foot waffle- incidence of heel pressure ulcers

Study or Subgroup	Eggcrate Events	Total	Foot waffle Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Gilcreast, 2005	4	87	5	76	100.0%	0.70 [0.19, 2.51]
Total (95% CI)		**87**		**76**	**100.0%**	**0.70 [0.19, 2.51]**
Total events	4		5			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.55 (P = 0.58)

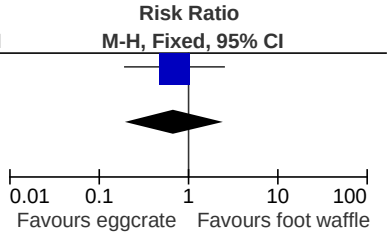


Figure 5 – Foot waffle vs. pillow- incidence of heel pressure ulcers

Study or Subgroup	Foot waffle Events	Total	Pillow Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Tymec, 1997	0	26	1	26	100.0%	0.14 [0.00, 6.82]
Total (95% CI)		**26**		**26**	**100.0%**	**0.14 [0.00, 6.82]**
Total events	0		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.00 (P = 0.32)

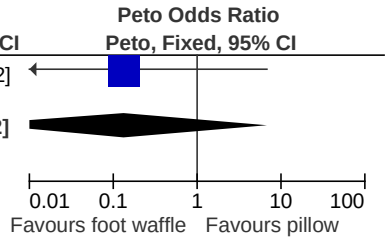


Figure 6 – Heel elevation device vs. standard care- incidence of heel pressure ulcers

Study or Subgroup	Heel elevation device Events	Total	Standard care Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Donnelly, 2011	0	120	17	119	100.0%	0.12 [0.04, 0.31]
Total (95% CI)		**120**		**119**	**100.0%**	**0.12 [0.04, 0.31]**
Total events	0		17			

Heterogeneity: Not applicable
Test for overall effect: Z = 4.29 (P < 0.0001)

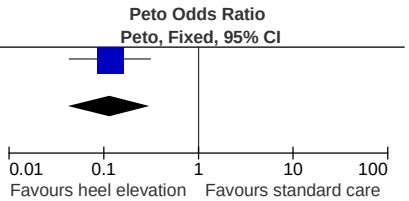


Figure 7- Foam body support vs. usual care- incidence of heel pressure ulcers

Study or Subgroup	Foam body support Events	Total	Usual care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Cadue, 2008	3	35	19	35	100.0%	0.16 [0.05, 0.49]
Total (95% CI)		**35**		**35**	**100.0%**	**0.16 [0.05, 0.49]**
Total events	3		19			

Heterogeneity: Not applicable
Test for overall effect: Z = 3.22 (P = 0.001)

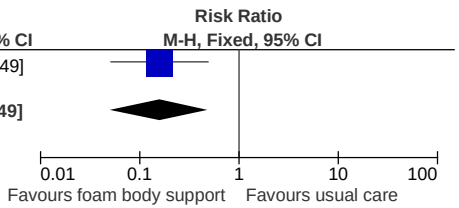
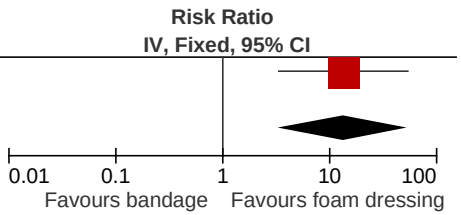


Figure 8 – Protective bandage vs. polyurethane foam hydrocellular dressing

Study or Subgroup	log[Risk Ratio]	SE	Weight	Risk Ratio IV, Fixed, 95% CI
Torra, 2009	2.5967	0.71	100.0%	13.42 [3.34, 53.96]
Total (95% CI)			**100.0%**	**13.42 [3.34, 53.96]**

Heterogeneity: Not applicable
Test for overall effect: Z = 3.66 (P = 0.0003)



8.3.4. Clinical evidence tables

Table 14 – CADUE2008 [foreign language but in support surfaces for prevention Cochrane Review)

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Cadue (2008) **Title: Prevention of heel pressure sores with a foam body-support device. A randomised controlled trial in a medical intensive care unit; 37 (1 suppl. Part 1); 30-60.** **Journal: Presse Medical 2008** **Type of study: RCT** **Sequence generation: 'randomisation table was used to allocate 70 patients into 2 groups'. The two groups were formed randomly by following a randomisation table (yes)** **Allocation concealment: translated as sealed envelope (yes)**	Patient group: patients in intensive care setting All patients Randomised N: 70 Completed N: 70 Group 1 Randomised N: 35 Completed N: 35 Dropouts: 0 Group 2 Randomised N: 35 Completed N: 35 Dropouts: 0 Inclusion criteria: patients in an intensive care setting with a Waterlow Score >10, no existing heel pressure ulcers, >/=18 years or over. Exclusion criteria: not	Group 1: Foam body support and standard pressure prevention protocol (half-seated position, water mattress preventative massage 6 times/day) Group 2: Standard pressure ulcer protocol (see above)	Outcome 1: number of participants developing non-blanching pressure ulcer or worse on the heel	Group 1: 3/35 (8.6%) Group 2: 19/35 (55.4%)	Funding: do not know Limitations: Unclear blinding. No a priori sample size calculation and small sample size. Additional outcomes: * Notes: Abstract, with full paper not available in English. Extraction taken from Cochrane Review on support surfaces in the prevention of pressure ulcers.
			Outcome 2: mean time without any pressure ulcer	Group 1: 5.6 days Group 2: 2.8 days P=0.01	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Blinding: translated to: the physiotherapist and nurse assessed the stage of the lesion daily – but it is not clear if they were blinded (unclear) **Addressing incomplete outcome data: 70 patients were included, 35 in each group. Table presented the principle results and notes that 'n=35' which has been interpreted that data were presented on 35 patients in each group. No mention was found of any withdrawals (yes)** **Analysis: do not know** **Statistical analysis: do not know** **Baseline differences: translated as at inclusion there was no significant difference between the two groups in the**	stated				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
theoretical risk of developing pressure ulcers or any of the main factors known to contribute to the occurrence of bedsores. Study power/sample size: no a priori sample size calculation given Setting: do not know Length of study: maximum follow-up 30 days Categorisation of Pus: Assessment of PUs: do not know Multiple ulcers: N/A					

Table 15 – GILCREAST2005

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Gilcreast (2005) **Title: Research comparing three heel ulcer-prevention devices** **Journal: Journal of wound ostomy and continence nursing, 32 (2), 112-120.** **Type of study: RCT** **Sequence generation: drawing of cards** **Allocation concealment: inadequate (non-numbered envelopes)** **Blinding: no- 1 nurse was performing all research tasks and was not blinded to the device to which the participant was assigned.** **Addressing incomplete outcome data: gives details of why patients were not followed up but unclear which group they were from.**	Patient group: patients moderate or high risk of pressure ulcer development (69% of participants were in ICU) All patients Randomised N: 338 (not clear how distributed among the 3 groups). Completed N: 240 Dropouts: 29% – 53 not included, as did not wear the devices for at least 48 hours; 45 not included as they were non-compliant. Group 1 Randomised N: unclear Completed N: 77 Dropouts: unclear Group 2 Randomised N:	Group 1: Bunny boot (fleece) high cushion heel protector Group 2: Egg crate heel lift positioner Group3: foot waffle The investigators attempted to control for all extraneous variables by monitoring all factors relating to pressure ulcer development.	Outcome 1: incidence of pressure ulcers	Group 1: 3/77 (4%) Group 2: 4/87 (5%) Group 3: 5/76 (7%)	Funding: TriService Nursing Research Program Limitations: Inadequate allocation concealment; no blinding; limited details of baseline data; unclear how many patients were randomised to each group and therefore which arms the drop-outs came from but there were 29% of patients who did not have follow-up data. Additional outcomes: * Notes: *

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Analysis: no ITT analysis. **Statistical analysis: chi-square , analysis of variance and logistic regression analysis** **Baseline differences: limited baseline information presented (unclear). Baseline imbalance in sex.** **Study power/sample size: a priori calculation of 80% power required 550 participants total sample of 338 patients was obtained.** **Setting: military tertiary-care academic medical centre.** **Length of study: follow-up period unclear** **Categorisation of PUs: NPUAP** **Assessment of PUs: skin assessed daily** **Multiple ulcers: N/A**	unclear Completed N: 87 Dropouts: unclear Group 2 Randomised N: unclear Completed N: 76 Dropouts: unclear Inclusion criteria: patients with moderate or high risk of pressure ulcer development (Braden score</= 14). Exclusion criteria: Patients with hip surgery; patients anticipated to be admitted for <72 hours; those with pre-existing heel pressure ulcers.				

Table 16 – TYMEC1997

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Tymec 1997 **Title: A comparison of two pressure-relieving devices on the prevention of heel pressure ulcers** **Journal: Advances in wound care, 1997, 10 (1), 39-44.** **Type of study: factorial design RCT** **Sequence generation: block randomisation list and the patient's position order was determined by a coin toss** **Allocation concealment: not reported (unclear)** **Blinding: not reported (unclear)** **Addressing incomplete outcome data: the number/group not reported. 8/52 developed grade 1 pressure ulcers and**	Patient group: patients from nursing units of hospital with a low Braden score (at risk) All patients Randomised N: 52 Completed N: 44 Dropouts: 8 developed grade 1 pressure ulcers and were removed from the study. f/m: 23/29 Age, mean (range): 66.6 s.d 16.5 years (27-90 years) Mean Braden score at admission: 11.8 Respiratory conditions: 21 Cancer: 6 Stroke: 5 Group 1 Randomised N: not reported Completed N: not reported	Group 1: Foot waffle (FDA approved, non-abrasive vinyl boot with built in foot cradle and inflated air chamber Group 2: Hospital pillow under both legs from below knee to the Achilles tendon. In this hospital the standard pillow is a 20-ounce (+/-2 ounces) polyfiber-filled pillow.	Outcome 1: number of heel pressure ulcers developed Outcome 2: time until pressure ulcer occurred (mean survival time)	Group 1: 0/26 Group 2: 1/26 Logistic regression pillow/foot waffle -1.48, s.e 0.44 , p=0.001, OR 4.38 Group 1: 10 days Group 2: 13 days Kaplan Meier – significant difference Log-rank tests p=0.036	Funding: not reported Limitations: unclear allocation concealment, blinding, reporting of incomplete outcome data. Additional outcomes: tissue interface pressures. Notes: number of other ulcers eg. Metatarsal, top of foot.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
were removed from the study, so it would appear that the 52 participants were followed-up. **Analysis: not reported** **Statistical analysis: logistic regression** **Baseline differences: no details given for characteristics of the groups** **Study power/sample size: power calculation for 80% power required 52 sample size.** **Setting: selected nursing units of a large hospital** **Length of study: 14 days** **Categorisation of PUs: AHCPR guideline pressure ulcer stages** **Assessment of PUs: skin inspection** **Multiple ulcers: N/A**	Dropouts: not reported Group 2 Randomised N: not reported Completed N: not reported Dropouts: not reported Inclusion criteria: Braden score of <<16 (risk); intact skin on heels. Exclusion criteria: not reported.				

Table 17 – DONNELLY2011

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Donnelly 2011 **Title: An RCT to determine the effect of a heel elevation device in pressure ulcer prevention post-hip fracture** **Journal: Journal of wound care, 20 (7), 309-318** **Type of study: RCT** **Sequence generation: computer-generated block randomisation schedule (permuted blocks of 20)** **Allocation concealment: randomisation schedule was held and managed by a senior research nurse manager not directly involved in the study.** **Blinding: authors state that it was not possible to blind either the patient or the investigator as the intervention was very**	Patient group: post-hip fracture patients. All patients Randomised N: 239 Completed N: 227 f/m: 184/55 age (mean, range): 81 years (65-100) Group 1 Randomised N: 120 Completed N: 111 Dropouts: 9 (deteriorating medical condition n=6, lost-to follow-up n=1, adverse event possibly linked to the intervention n=1, patient withdrew consent n=1). Group 2 Randomised N: 119 Completed N: 116 Dropouts: 3 (lost to follow up n=1,	Group 1: Heel elevation (Heelift Suspension Boot) plus pressure-redistributing support surface Group 2: standard care plus pressure-redistributing support surface alone). Mattress type determined by ward nurses according to perceived need. Their choice was recorded and analysed as a covariate.	Outcome 2: incidence of heel ulcers (all categories) Outcome 3: comfort (themed analysis)	Group 1: 0/120 Group 2: 17/119 Group 1: 32% of subjects felt the boots interfered with sleep and 41% felt that they adversely affected movement in bed, 59% rated them as comfortable overall. Poor concordance reasons were the weight and bulk of the boot (36%), heat (particularly at night) (31%) and discomfort (24%).	Funding: research supported by a Special Nursing Research Fellowship funded by the Research and Development Office for Health and Social Care in Northern Ireland. Limitations: No blinding of patient or investigator; underpowered. Additional outcomes: Notes: *

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
distinctive. Outcome assessor was blinded. **Addressing incomplete outcome data: yes, flow diagram given** **Analysis: ITT** **Statistical analysis: Chi-squared test for association for proportion of patients developing one or more PU. Kaplan-Meier for group survival. Cox Hazards Regressional Model to analyse the potential impact of covariates.** **Baseline differences: no statistically significant differences at baseline.** **Study power/sample size: powered for 240 patients per group to give 87.5% power, whereas had half this amount.** **Setting: fracture trauma unit of a major tertiary referral centre** **Length of study: 12 days**	deteriorating medical condition n=1, recruited incorrectly n=1) Inclusion criteria: aged 65 years or over on day of fracture; suffered a hip fracture, including any bony injury to the femoral head or femoral neck, in the previous 48 hours Exclusion criteria: did not give written, informed consent, or indicate willingness to participate through a process of inclusionary consent; existing heel pressure damage (NPUAP); and/or history of previous pressure ulceration; patients for whom the investigator or medical/nursing team considered unsuitable.				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Categorisation of PUs: NPUAP scale. **Assessment of PUs: skin risk assessment tool – modified Knoll risk assessment tool** **Multiple ulcers: N/A**					

Table 18 – TORRA2009

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Torra 2009 **Title: Preventing pressure ulcers on the heel: a Canadian cost study** **Journal: Dermatology Nursing 2009, 21 (5), 268-272.** **Type of study: multicentre RCT** **Sequence generation: no details of method** **Allocation concealment: no details**	Patient group: Nursing home patients and home care program patients from primary health care centres. All patients Randomised N: 130 Completed N: 111 Dropouts: 19 – 6 died, 8 left study (four because of setting change and the other four following clinical decision), 4 abandoned the study (died) Group 1	Group 1: special polyurethane foam hydrocellular dressing for the protection of the heel (Allevyn Heel) and normal measures of preventing pressure ulcers. Dressings were fixed with a socket or a net bandage. Group 2: protective bandage of the heel (Soffban and gauze bandage). The bandage covered all the ankle articulation. Normal measures for preventing pressure ulcers.	Outcome 1: incidence of pressure ulcers	Group 1: 3.3% Group 2: 44% RR: 13.42 (95% CI 3.31 to 54.3) P<0.001	Funding: not reported. Limitations: open study. Unclear how many in each group but relative risk reported. No details of allocation concealment and randomisation method. Unclear addressing of incomplete outcome data. Additional

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Blinding: open study **Addressing incomplete outcome data: no details by group.** **Analysis: no details** **Statistical analysis: no details** **Baseline differences: no statistically significant differences** **Study power/sample size: no a priori power calculation given but 130 entered study** **Setting: nursing homes and three home care programmes from primary care centres.** **Length of study: 8 weeks** **Categorisation of PUs: no details** **Assessment of PUs: no details** **Multiple ulcers: no details**	Randomised N: unclear Completed N: unclear Dropouts: unclear Group 2 Randomised N: unclear Completed N: unclear Dropouts: unclear Inclusion criteria: patients at risk of developing pressure ulcers according to Braden Scale; patients who could give consent to participate in the study Exclusion criteria: patients with existing pressure ulcers in heels; patients with diabetes; patients using special prevention surfaces; patients using devices for relieving local pressure at heels				outcomes: Notes: The Allevyn heel is said to be a dressing but looks to be also a device for the heel. Another study Torra I Bou et al (2002) was the original study but this was a foreign language paper.

9. NUTRITION AND HYDRATION

9.1. Review protocol

Table 1 – Review protocol

Protocol	Nutrition/hydration
Review question	What are the most clinically effective interventions with nutrition or hydration for the prevention of pressure ulcers for people with and without nutritional deficiency?
Population	• Individuals of all ages in all settings • *With and without nutritional deficiencies*
Intervention	• Nutritional interventions (supplementation or special diet) • Hydrational strategies • As preventive strategies
Comparison	• Usual diet (participant's usual diet or the standard hospital diet) • Other supplementation • Other special diet
Outcomes	**Critical outcomes for decision-making:** • Proportion of participants developing new pressure ulcers (dichotomous outcome) (describe different categories of ulcer) **Important outcomes:** • Patients acceptability of supplements – e.g. measured by compliance, tolerance, reports of unpalatability • Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital or NHS care (continuous data) • Side effects (nausea, vomiting, diarrhoea) (dichotomous data) • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised o Short-form health survey (SF36)

Protocol	Nutrition/hydration
	o Manchester Short Assessment of Quality of Life o EQ-5D o WHO-QOL BREF o Cardiff HRQoL tool o HUI o Pressure ulcer quality of life (Gorecki)
Study design	• High quality systematic reviews of RCTs and/or RCTs only • Cochrane reviews will be included if they match our inclusion criteria and have appropriate assumptions for missing data such as available case analysis or ITT (with the appropriate assumptions) • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies with outcomes that do not involve pressure ulcers • Abstracts unless no RCTs are found • Non-English language papers
Search strategy	**The databases to be searched are:** • Medline, Embase, Cinahl, the Cochrane Library. • All years. • Studies will be restricted to English language only
The review strategy	**How will individual PICO characteristics be combined in a meta-analysis?:** • Population – any population will be combined for meta-analysis except for different strata • Intervention – Different types of nutritional supplementation and hydration strategies and nutritional interventions will not be combined for meta-analysis • Outcomes – single side effects eg nausea will be meta-analysed separately from other side effects • Study design – randomised and quasi-randomised studies will be meta-analysed together. Blinded and unblinded studies will be meta-analysed together. Crossover trials will be meta-analysed together with parallel trials • Unit of analysis – patients, clusters (hospital wards), individual pressure ulcers – for those where patients are the unit of analysis and the patient has multiple ulcers it should be the first pressure ulcer occurring (describe different categories of ulcer)

Protocol	Nutrition/hydration
	• Minimum duration of treatment = no minimum, but would expect at least a fortnight before they show improvements. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use available case analysis for dealing with missing data if there is a 10% differential or higher between the groups or if the missing data is higher than the event rate, if cannot work out the available case analysis will take the author's data.. • MIDs: 0.75 to 1.25 for dichotomous variables and 0.5 x standard deviation for continuous variables.
Analysis	**Strata** – where included studies are split up at outset as separate reviews (dissimilar groups and we need to be confident that the intervention will work very differently in the two (or more) strata. The GDG will make separate recommendations on these. **The following groups will be considered separately as strata if data are present:** • Children (neonates, infants, children) and adults • With and without nutritional deficiency • Different nutritional supplements • Hydrational strategies and nutritional interventions **Subgroup analysis** – combining all the studies together initially and then looking at any inconsistency between studies on the basis of pre-defined subgroups. **The following groups will be considered separately as subgroups:** • different risk stratification
Other terms	
Notes	**Where have said 'describe' or 'descriptive' this will be noted in the summary table.**

9.2. search strategy

9.2.1. Search strategy

There were no limitations on sample size and only direct studies relating to pressure ulcers and nutrition or hydration were included. No indirect interventions, comparisons or outcomes were considered. Only randomised controlled trials were included. Abstracts were not included unless there were no randomised controlled trial full papers for the comparison. No studies were found for hydrational interventions to prevent the occurrence of pressure ulcers.

9.2.2. Search filters

Table 2 – Search filters in OVID Medline

Search strategy			Results
Date	27th Mar 2012		
Database	Medline-Ovid		
Search strategy (part I – nurition)	1	pressure ulcer/	9086
	2	decubit*.ti,ab.	3915
	3	(pressure adj (sore* or ulcer* or damage)).ti,ab.	6200
	4	(bedsore* or bed-sore*).ti,ab.	508
	5	or/1-4	13124
	6	limit 5 to english language	10393
	7	exp diet/	170157
	8	exp food/	944480
	9	exp nutritional support/	35531
	10	enteral nutrition/	14514
	11	exp parenteral nutrition/	20532
	12	malnutrition/	4931
	13	exp diet therapy/	37786
	14	dh.fs.	34571
	15	(nutri* or food* or diet*).ti,ab.	662638
	16	or/7-15	1465966
	17	6 and 16	753
	18	randomized controlled trial.pt.	322698
	19	controlled clinical trial.pt.	84030
	20	randomi#ed.ab.	284036

Search strategy			Results
	21	placebo.ab.	134576
	22	drug therapy.fs.	1518236
	23	randomly.ab.	174415
	24	trial.ab.	246780
	25	groups.ab.	1145216
	26	or/18-25	2903459
	27	Clinical Trials as topic.sh.	159472
	28	trial.ti.	102183
	29	or/18-21,23,27-28	789656
	30	letter/	750353
	31	editorial/	299086
	32	news/	142410
	33	exp historical article/	306887
	34	Anecdotes as Topic/	4116
	35	comment/	487891
	36	case report/	1571028
	37	(letter or comment*).ti.	82116
	38	or/30-37	3034289
	39	randomized controlled trial/ or random*.ti,ab.	672095
	40	38 not 39	3019416
	41	animals/ not humans/	3624822
	42	exp Animals, Laboratory/	675879
	43	exp Animal Experimentation/	5199
	44	exp Models, Animal/	371043
	45	exp Rodentia/	2493649
	46	(rat or rats or mouse or mice).ti.	1040004
	47	or/40-46	7176100
	48	Meta-Analysis/	31869
	49	Meta-Analysis as Topic/	12015
	50	(meta analy* or metanaly* or metaanaly*).ti,ab.	41158

Search strategy				Results
		51	((systematic* or evidence*) adj2 (review* or overview*)).ti,ab.	48805
		52	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.	19812
		53	(search strategy or search criteria or systematic search or study selection or data extraction).ab.	21689
		54	(search* adj4 literature).ab.	19180
		55	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.	60492
		56	cochrane.jw.	8210
		57	or/48-56	142473
		58	(29 or 57) not 47	780799
		59	17 and 58	106
		60	limit 59 to yr="2002 -Current"	59
Part (hydration)	**II**	1	pressure ulcer/	9086
		2	decubit*.ti,ab.	3915
		3	(pressure adj (sore* or ulcer* or damage)).ti,ab.	6200
		4	(bedsore* or bed-sore*).ti,ab.	508
		5	or/1-4	13124
		6	limit 5 to english language	10393
		7	fluid therapy/	12793
		8	dehydration/	9572
		9	drinking/	11760
		10	(hydrat* or rehydrat* or re-hydrat* or dehydrat* or de-hydrat*).ti,ab.	63383
		11	or/7-10	87489
		12	6 and 11	95
		13	letter/	750353
		14	editorial/	299086
		15	news/	142410
		16	exp historical article/	306887
		17	Anecdotes as Topic/	4116
		18	comment/	487891
		19	case report/	1571028

Search strategy			Results
	20	(letter or comment*).ti.	82116
	21	or/13-20	3034289
	22	randomized controlled trial/ or random*.ti,ab.	672095
	23	21 not 22	3019416
	24	animals/ not humans/	3624822
	25	exp Animals, Laboratory/	675879
	26	exp Animal Experimentation/	5199
	27	exp Models, Animal/	371043
	28	exp Rodentia/	2493649
	29	(rat or rats or mouse or mice).ti.	1040004
	30	or/23-29	7176100
	31	12 not 30	86

Table 3 – Search filters in Embase

Search strategy			Results
Date	27th Mar 2012		
Database	Embase-OVID		
Search strategy (part I – nutrition)	1	decubitus/	12024
	2	decubit*.ti,ab.	4568
	3	(pressure adj (sore* or ulcer* or damage)).ti,ab.	6772
	4	(bedsore* or bed-sore*).ti,ab.	630
	5	or/1-4	15589
	6	limit 5 to english language	11928
	7	exp diet/	153794
	8	exp food/	526257
	9	exp diet therapy/	186661
	10	exp nutritional support/	10892
	11	exp artificial feeding/	49886
	12	exp food intake/	168353

Search strategy			Results
	13	exp malnutrition/	90561
	14	(nutri* or food* or diet*).ti,ab.	734983
	15	or/7-14	1319130
	16	6 and 15	1068
	17	random*.ti,ab.	665174
	18	factorial*.ti,ab.	17410
	19	(crossover* or cross over*).ti,ab.	57063
	20	((doubl$ or singl$) adj blind$).ti,ab.	129012
	21	(assign* or allocat* or volunteer* or placebo*).ti,ab.	518363
	22	crossover procedure/	31195
	23	double blind procedure/	101701
	24	single blind procedure/	14442
	25	randomized controlled trial/	292701
	26	or/17-25	1106203
	27	letter.pt. or letter/	750039
	28	note.pt.	457705
	29	editorial.pt.	385981
	30	case report/ or case study/	1762297
	31	(letter or comment*).ti.	131461
	32	or/27-31	3234388
	33	randomized controlled trial/ or random*.ti,ab.	740298
	34	32 not 33	3210903
	35	animal/ not human/	1264585
	36	nonhuman/	3741600
	37	exp Animal Experiment/	1475898
	38	exp experimental animal/	361812
	39	animal model/	612474
	40	exp Rodent/	2401842
	41	(rat or rats or mouse or mice).ti.	1065594
	42	or/34-41	8534950

Search strategy				Results
		43	systematic review/	45174
		44	meta-analysis/	57412
		45	(meta analy* or metanaly* or metaanaly*).ti,ab.	49825
		46	((systematic or evidence) adj2 (review* or overview*)).ti,ab.	53088
		47	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.	22849
		48	(search strategy or search criteria or systematic search or study selection or data extraction).ab.	24490
		49	(search* adj4 literature).ab.	21961
		50	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.	68666 28922
		51	((pool* or combined) adj2 (data or trials or studies or results)).ab.	10982
		52	cochrane.jw.	205807
		53	or/43-52	1031869
		54	(26 or 53) not 42	151
		55	16 and 54	105
		56	limit 55 to yr="2002 -Current"	
Part II (hydration)		1	decubitus/	12024
		2	decubit*.ti,ab.	4568
		3	(pressure adj (sore* or ulcer* or damage)).ti,ab.	6772
		4	(bedsore* or bed-sore*).ti,ab.	630
		5	or/1-4	15589
		6	limit 5 to english language	11928
		7	rehydration/	3444
		8	fluid therapy/	12893
		9	drinking/	9832
		10	(hydrat* or rehydrat* or re-hydrat* or dehydrat* or de-hydrat*).ti,ab.	67509
		11	or/7-10	89258
		12	6 and 11	118
		13	letter.pt. or letter/	750039
		14	note.pt.	457705
		15	editorial.pt.	385981

Search strategy			Results
	16	case report/ or case study/	1762297
	17	(letter or comment*).ti.	131461
	18	or/13-17	3234388
	19	randomized controlled trial/ or random*.ti,ab.	740298
	20	18 not 19	3210903
	21	animal/ not human/	1264585
	22	nonhuman/	3741600
	23	exp Animal Experiment/	1475898
	24	exp experimental animal/	361812
	25	animal model/	612474
	26	exp Rodent/	2401842
	27	(rat or rats or mouse or mice).ti.	1065594
	28	or/20-27	8534950
	29	12 not 28	98

Table 4 – Search filters in CINAHL

Search strategy			Results
Date	27th Mar 2012		
Database	CINAHL		
Search strategy (part I – nutrition)	S10	s8 not s9	109
	S9	PT anecdote or PT audiovisual or PT bibliography or PT biography or PT book or PT book review or PT brief item or PT cartoon or PT commentary or PT computer program or PT editorial or PT games or PT glossary or PT historical material or PT interview or PT letter or PT listservs or PT masters thesis or PT obituary or PT pamphlet or PT pamphlet chapter or PT pictorial or PT poetry or PT proceedings or PT "questions and answers" or PT response or PT software or PT teaching materials or PT website	974559
	S8	S5 and S6 Limiters – Published Date from: 20020101-20111231; English Language; Exclude MEDLINE records	164
	S7	S5 and S6	786
	S6	nutri* or food* or diet*	138288
	S5	S1 or S2 or S3 or S4	8354
	S4	bedsore* OR bed-sore*	152

Search strategy			Results
	S3	pressure n1 sore* OR pressure n1 ulcer* OR pressure n1 damage*	8090
	S2	decubit*	466
	S1	(MH "Pressure Ulcer")	7352
Part II (hydration)	S11	S5 and S9 Limiters – English Language; Exclude MEDLINE records	29
	S10	S5 and S9	72
	S9	S6 or S7 or S8	5691
	S8	hydrat* or rehydrat* or re-hydrat* or dehydrat* or de-hydrat*	4196
	S7	(MH "Fluid Therapy")	2106
	S6	(MH "Dehydration")	1724
	S5	S1 or S2 or S3 or S4	8354
	S4	bedsore* OR bed-sore*	152
	S3	pressure n1 sore* OR pressure n1 ulcer* OR pressure n1 damage*	8090
	S2	decubit*	466
	S1	(MH "Pressure Ulcer")	7352

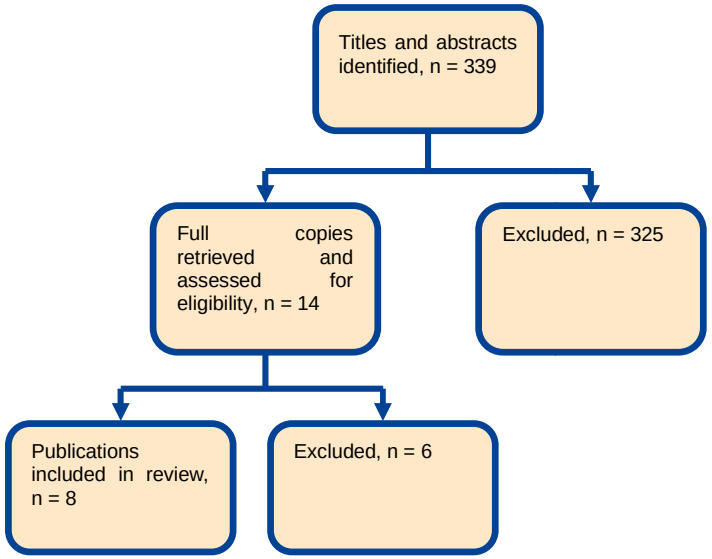
Table 5 – Search filters in Cochrane

Search strategy			Results
Date	27th Mar 2012		
Database	Cochrane (- CDSR [3/2012]; DARE; Central [3/2012]; NHS EED; HTA)		
Search strategy (part I – nutrition)	#1	MeSH descriptor Pressure Ulcer explode all trees	472
	#2	decubit*:ti,ab,kw	340
	#3	(pressure near/2 (sore* or ulcer* or damage)):ti,ab,kw	805
	#4	(bedsore* or bed-sore*):ti,ab,kw	31
	#5	(#1 OR #2 OR #3 OR #4)	1076
	#6	Any MeSH descriptor with qualifier: DH	4606
	#7	(nutri* or food* or diet*):kw,ti,ab	42630
	#8	(#6 OR #7)	42630
	#9	(#5 AND #8)	65
	#10	(#9), from 2002 to 2011	35

Part (hydration)	**II**	S5 and S9 Limiters – English Language; Exclude MEDLINE records	29
		S5 and S9	72
		S6 or S7 or S8	5691
		hydrat* or rehydrat* or re-hydrat* or dehydrat* or de-hydrat*	4196
		(MH "Fluid Therapy")	2106
		(MH "Dehydration")	1724
		S1 or S2 or S3 or S4	8354
		bedsore* OR bed-sore*	152
		pressure n1 sore* OR pressure n1 ulcer* OR pressure n1 damage*	8090
		decubit*	466
		(MH "Pressure Ulcer")	7352

9.2.3. Flow diagram for article selection

Figure 1 – Flow diagram for article selection



9.2.4. Excluded studies

Author/title REF ID	Reason for exclusion
Larsson 1990/ Effect of dietary supplement on nutritional status and clinical outcome in 501 Geriatric Patients – A Randomised Study	None of our outcomes except mortality
Ek 1987/ Prediction of pressure sore development	Only outcome given is incidence of pressure sores, but this is given as 9.9% in the experimental and 12% in the control group. There are no details of how many patients were in the experimental and control groups. Is linked to Larsson 1990 but it has a different number withdrawn so don't think figures can be used as the denominator for this outcome.
Neander 2004/A specific nutritional supplement reduces the incidence of pressure ulcers in elderly people	Abstract
Okuwa2009/ The prevalence and incidence of pressure ulcers in home care setting in Japan	Abstract
Gallart 2010/ Prevention of pressure sores in patients with poor perfusion tissue: a pilot study comparing oil vs milk hyperoxygenated fatty acids	Abstract
Sampson 2009/ Enteral tube feeding for older people with advanced dementia (Review)	Cochrane review but did not include RCTs.

9.3. Clinical evidence

No studies were found for hydrational interventions to prevent the occurrence of pressure ulcers. A Cochrane Review by Langer (2003)[136] including four RCTs about the effect of nutritional interventions to prevent pressure ulcers was found. We updated the Cochrane review with four other studies, Dennis et al. (2005)[137], Craig et al. (1998)[138], Theilla et al. (2007)[139] and Oloffson et al. (2007)[140]. Dennis et al. (2005)[137], Craig et al. (1998)[138] and Oloffson et al. (2007)[140] were not looking at pressure ulcers, but rather pressure ulcers were an event or complication that occurred during these trials.

The literature search and Cochrane reviewers identified five RCTs comparing participants who received nutritional supplementation in addition to their standard diet (which was the hospital standard diet) to those who received only the standard hospital diet.[137,141 , 142 , 143,144] These studies all included older people who were in hospital. Houwing et al. (2003)[143] and Hartgrink et al. (1998)[144] included patients with hip fracture, Delmi et al. (1990)[142] included patients with fractured neck of the femur, Bourdel-Marchasson et al. (2000)[141] included critically ill patients and Dennis et al. (2005)[137] included stroke patients. Hartgrink et al. (1998)[144] gave patients a supplement of energy and protein by nasogastric tube compared to the standard hospital diet. Studies follow-up period ranged from 2 weeks to 6 months. The supplements included various compositions of protein, carbohydrate, vitamins and minerals.

One study[138] included long-term patients with type 2 diabetes. Researchers gave the patients a disease-specific (reduced-carbohydrate and modified fat) formula compared to the standard high carbohydrate formula. Patients were followed up for 3 months.

Another study[139] gave patients suffering from lung injury a macronutrient diet plus lipids and vitamins compared to a macronutrient diet alone. These patients were followed up for 7 days.

One RCT[140] with femoral neck fracture patients who were given protein-enriched meals compared to normal postoperative care and followed them up for 4 months.

We have meta-analysed the results in contrast to the original Cochrane review[136] to lump the studies together aiming to gain a greater confidence in the evidence and then report on heterogeneity of studies if this exists.

We meta-analysed studies together that looked at nutritional supplements in addition to standard hospital diet (which mainly included energy and protein) versus the standard hospital diet.[137,141 , 142 , 143,144] We conducted another meta-analysis of these studies of nutritional supplements and also included a study (Oloffson et al., 2007)[140] with a protein diet compared to the standard hospital diet since all of the interventions had a high proportion of protein.

Some of the studies gave the results separately by grade of pressure ulcer that occurred as well as all grades of ulcers that occurred. We have split the results (see appendix 9) to show data for all pressure ulcers and for those with grade 2-4 ulcers (with details of the classification system of grading).

9.3.1. Summary table

Table 6 – RCTs and outcomes included in the review

Study	Study design	Population	Interventions/comparison	Outcomes	Follow-up period (weeks)
Houwing 2003[143]	RCT Double blind	Older people with hip fracture	Standard diet with additional oral supplementation (high protein enriched with arginine zinc and antioxidants) versus standard diet with a placebo.	Incidence of pressure ulcers; time to first day of pressure ulcer; mortality.	28 days
Bourdel-Marchasson 2000[141]	RCT Unblinded	Critically ill older people	Standard diet with additional oral supplementation (protein, fat, carbohydrate and minerals and vitamins) versus standard diet.	Incidence of pressure ulcers	15 days.
Hartgrink 1998[144]	RCT Unblinded	Older people with hip fracture	Standard diet with tube feeding (energy, protein, Nutricia) versus standard diet	Incidence of pressure ulcers	2 weeks
Delmi 1990[142]	RCT Unblinded	Older people with fractured neck of the femur	Standard diet with additional oral nutrition supplements (protein, carbohydrate, lipid, calcium, vitamin A, vitamin D, vitamins E, B1, B2, B6, B12,	Incidence of pressure ulcers	Assessed at 14, 21 and 28 days and followed up at 6 months

Study	Study design	Population	Interventions/comparison	Outcomes	Follow-up period (weeks)
			C, nicotinamide, folate, calcium pantothenate, biotin, and minerals) versus standard diet		
Craig 1998[138]	RCT double-blinded pilot study	LTC residents with type 2 diabetes	Disease-specific (reduced-carbohydrate, modified-fat) formula vs standard high-carbohydrate formula	Incidence of pressure ulcers	3 months
Theilla 2007[139]	RCT unblinded	Critically ill, mechanically ventilated patients suffering from acute lung injury	Macronutrient diet plus lipids (elcosapentanoic acid, gamma-linolenic acid, vitamins A, C and E) vs macronutrient diet read to feed (high fat, low carbohydrate, enteral formula)	Incidence of pressure ulcers	7 days
Olofsson 2007[140]	RCT	Femoral neck fracture patients	Protein-enriched meals vs normal postoperative care	Incidence of pressure ulcers; time in hospital	4 months follow-up
Dennis 2005[137]	Multicentre RCT	Elderly stroke patients in hospital	Normal hospital diet plus oral supplements vs normal hospital diet	Incidence of pressure ulcers; length of stay in hospital	6 months follow-up

9.3.2. Clinical evidence GRADE tables

Table 7 – Protein, fat, carbohydrate, minerals and vitamins supplement (twice daily 200kcal, protein 30%, fat 20%, carbohydrate 50%, zinc 1.8mg, vitamin C 15mg) and standard diet versus standard diet – patients not specified as malnourished but thought at higher risk as critically ill older population

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Nutritional supplement plus standard hospital diet	Standard hospital diet	Relative (95% CI)	Absolute		
Incidence of PU – critically ill older patients												
1Bourdel-Marchasson 2000	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious imprecision[b]	None[d]	118/295 (40%)	181/377 (48%)	RR 0.83 (0.7 to 0.99)	82 fewer per 1000 (from 5 fewer to 144 fewer)	⊕OOO VERY LOW	Critical
								48%		82 fewer per 1000 (from 5 fewer to 144 fewer)		
Acceptability of supplements – compliance – critically ill older patients												
1Bourdel-Marchasson 2000	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	N/A	None[d]	See footnote[c]	N/A	N/A	N/A	N/A	Critical

a Unclear details of sequence generation, no blinding and high levels of missing data in both groups. Difference at baseline for risk of pressure ulcers – the control group had a higher risk of pressure ulcers (Norton score and were more dependent (Kuntzmann score), however the level of serum albumin was lower in the nutritional intervention group which indicates a higher risk of pressure ulcers. The authors thought it was not easy to propose a placebo oral supplement with similar taste and consistency in a double-blind manner as this could have a deleterious effect on the energy intake in the control group because in elderly hospitalised patients, the volume rather than the energy content of food could limit voluntary energy intake. The study was randomised by hospital wards (19) which were stratified according to their specialty and recruitment for critically ill older patients. The nurses in the wards were trained by the research nurse and the dietician to monitor patients. Multivariate analyses took into account the intra-ward correlation.
b The confidence interval crossed one MID point.
c 60% in the supplement group were compliant at end of the 1st week and this was 99% at the end of the second week. 7% of the control group had the supplement during follow-up.
d The nutritional intervention group had energy intake of 1081 +/595 kcal and the standard hospital diet group had 957 +/- 530 kcal, p=0.006 and protein 45.9 +/-27.8grams and 38.3+/-23.8g respectively, p<0.001.

Table 8 – High protein enriched with arginine zinc and antioxidants supplement (energy 125kcal, protein 10g, l-arginine 1.5mg, zinc 5mg, vitamin c 125 mg, vitamin E 50mg x-TE, carotenoids 1g) and standard diet versus placebo and standard diet – patients not specified as malnourished but assumed as population had hip fracture

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Nutritional supplement plus standard diet	Placebo plus standard diet	Relative (95% CI)	Absolute		
Incidence of all pressure ulcers – older patients with hip fracture												
1Houwing 2003	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	27/51 (52.9%)	30/52 (57.7%)	RR 0.92 (0.65 to 1.3)	46 fewer per 1000 (from 202 fewer to 173 more)	⊕OOO VERY LOW	Critical
								57.7%		46 fewer per 1000 (from 202 fewer to 173 more)		
Incidence of stage II pressure ulcers – older patients with hip fracture												
1Houwing 2003	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	9/51 (17.6%)	14/52 (26.9%)	RR 0.66 (0.31 to 1.38)	92 fewer per 1000 (from 186 fewer to 102 more)	⊕OOO VERY LOW	Critical
								26.9%		-		
Acceptability of treatment – compliance – older patients with hip fracture												
1Houwing 2003	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	N/A	N/A	See footnote[c]	N/A	N/A	N/A	N/A	Critical

a No details of sequence generation or allocation concealment.
b Confidence interval crossed both MID points.
c Approximately 70% of patients consumed the supplement for a week or more. 75% of the patients consumed 75% or more of their daily dose.

Table 9 – Protein, carbohydrate, lipid, calcium, vitamin A, vitamin D, vitamins E, B1, B2, B6, B12, C, nicotinamide, folate, calcium p antothenate, biotin, and minerals supplement (250ml supplement energy 254kcal, protein 20.4g, carbohydrate 29.5g, lipid 5.8g, calcium 525m g, vitamin A 750 IU, vitamin Ds 25 IU) and standard hospital diet versus standard hospital diet – most patients nutritionally deficient

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Nutritional Supplement plus standard hospital diet	Standard hospital diet	Relative (95% CI)	Absolute		
Incidence of pressure ulcers (at 6 months) – older patients with fractured neck of the femur												
1 Delmi 1990	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none[f]	0/25[d] (0%)	2/27[d] (7.4%)	RR 0.22 (0.01 to 4.28)	58 fewer per 1000 (from 73 fewer to 243 more)	⊕OOO VERY LOW	Critical
Acceptability of treatment – compliance – older patients with fractured neck of the femur												
1 Delmi 1990	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	N/A	none[f]	See footnote[e]	N/A	N/A	N/A	N/A	Critical
Time in hospital – older patients with fractured neck of the femur												
1 Delmi 1990	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none[f]	Median 24 days (range 13-157) N=27	Median 40 days (range 10-259) N=32	P=0.09	-	⊕OOO VERY LOW	Important

a No details of sequence generation, allocation concealment or blinding. High drop-out. Baseline difference for plasmas level, which was lower in non-supplemented patients.
b Confidence interval crossed both MID points.
c No standard deviations given.
d This is the number at 6 months follow-up.
e The supplement was said to be well-tolerated and completely ingested and no side-effects were observed.
f A dietary survey of 50 daily measurements of foot intake showed energy intake was only 1100kcal (SD 300) per day – protein 34g (11) per day, calcium 400mg (250) per day. The supplement increased the intake of energy by 23%, protein 62%, calcium 130%. The supplements did not reduce the voluntary oral intake.

Table 10 – Nutritional supplement (360mL at 6.27kJmL and 62.5gL in protein) plus standard hospital diet versus standard hospital diet – majority were undernourished

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Nutritional supplement plus standard hospital diet	Standard hospital diet	Relative (95% CI)	Absolute		
Incidence of pressure ulcers – older stroke patients												
1Dennis 2005	randomised trials	Very Serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	15/2016 (0.7%)	26/2007 (1.3%) 1.3%	RR 0.57 (0.31 to 1.08)	6 fewer per 1000 (from 9 fewer to 1 more) 6 fewer per 1000 (from 9 fewer to 1 more)	⊕OOO VERY LOW	Critical
Acceptability of supplements – compliance – older stroke patients												
1Dennis 2005	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	N/A	N/A	See footnote[c]	N/A	N/A	N/A	N/A	Critical
Length of time in hospital – older stroke patients												
1Dennis 2005	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	34.0 (48.0) N=2016	32.0 (46.0) N=2007	-	MD 2.00 higher (0.91 lower to 4.91 higher)	⊕⊕OO LOW	Critical

a Aim not to look at pressure ulcers and there were no details of pressure ulcers at start of the trial. No blinding to treatment allocation. . Higher drop-out rate than the event rate. Trial was stopped before they reached their target as no funding was available to continue beyond 2004 and to ensure the trial was closed in an orderly manner.
b Confidence interval crossed one MID point
c Crude compliance rate of 79 (4%) did not receive any supplement. 48 of those who were supposed to only receive the normal diet had some supplements, crude compliance of 98%.

Table 11 – Tube fed energy, protein (1 litre Nutrion Steriflo Energy-plus – energy 1500kcal/l, protein 60 g/l) and standard diet versus standard diet – patients not specified as malnourished but assumed as older population with hip fracture

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Nutritional supplement plus standard hospital diet	Standard hospital diet	Relative (95% CI)	Absolute		
Incidence of grade 2-4 pressure ulcers **(Stage 0=normal skin, 1=persistent erythema of the skin, stage 2=blister formation, stage 3=superficial (sub)cutaneous necros is, stage 4=subcutaneous necrosis, according to the Dutch consensus meeting for the prevention of pressure sores)** – older patients with hip fracture												
1Hartgrink 1998	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	25/48 (52.1%)	30/53 (56.6%)	RR 0.92 (0.64 to 1.32)	45 fewer per 1000 (from 204 fewer to 181 more)	⊕OOO VERY LOW	Critical
								56.6%		45 fewer per 1000 (from 204 fewer to 181 more)		
Incidence of all pressure ulcers – older patients with hip fracture												
1Hartgrink 1998	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	serious[c]	none	30/48 (62.5%)	37/53 (69.8%)	RR 0.90 (0.68 to 1.19)	70 fewer per 1000 (from 223 fewer to 133 more)	⊕OOO VERY LOW	Critical
								0%		-		

a No details of sequence generation, allocation concealment and no blinding. High drop-out in both groups. Very few remained tube fed at 2 weeks (16/70). Blinding was not done as it was thought unethical to discomfort the control group with a nasogastric tube.
b The confidence interval crossed both MID points.
c The confidence interval crossed one MID point.

Table 12 – Disease-specific (reduced-carbohydrate, modified-fat) formula (1000kcal, 41.8g protein,93.7g carbohydrate, 55.7g fat) versus standard (high-carbohydrate) formula (1060kcal, 44.4g protein, 151.7g carbohydrate, 35.9g fat) – patients not specified as malnourished but older long-term care patients

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Disease-specific (reduced-carbohydrate, modified-fat) formula	Standard (high-carbohydrate) formula	Relative (95% CI)	Absolute		
Incidence of pressure ulcers – older long-term care patients with type 2 diabetes												
1Craig 1998	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	7/17 (41.2%)	8/15 (53.3%)	RR 0.77 (0.37 to 1.62)	123 fewer per 1000 (from 336 fewer to 331 more)	⊕OOO VERY LOW	Critical
								53.3%		123 fewer per 1000 (from 336 fewer to 330 more)		
Adverse events – older long-term care patients with type 2 diabetes												
1Craig 1998	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	N/A	N/A	See footnote[c]	N/A	N/A	N/A	N/A	Critical

a study aim was not to look at pressure ulcers, it was only an event experienced during the study. No details of sequence generation or allocation concealment.
b Confidence interval crossed both MID points.
c No statistically significant differences for number of adverse events reported.
d Disease-specific formula was 1000kca

Table 13 – Macronutrient diet plus lipids (elcosapentanoic acid, gamma-linolenic acid, vitamins A, C and E) vs macronutrient diet ready to feed (high fat, low carbohydrate, enteral) formulac – patients not specified as malnourished

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Macronutrient diet plus lipids, gamma-linolenic acid, vitamins A,C and E	Macronutrient diet ready to feed, high fat, low carbohydrate, enteral formula	Relative (95% CI)	Absolute		
Incidence of pressure ulcers – Critically ill, mechanically ventilated patients suffering from acute lung injury												
1Theilla 2007	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none[d]	8/46 (17.4%)	10/49 (20.4%)	RR 0.85 (0.37 to 1.97)	31 fewer per 1000 (from 129 fewer to 198 more)	⊕OOO VERY LOW	Critical
								20.4%		31 fewer per 1000 (from 129 fewer to 198 more)		
Incidence of grade 2-4 pressure ulcers – Critically ill, mechanically ventilated patients suffering from acute lung injury												
1Theilla 2007	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none[d]	4/49 (8.2%)	6/49 (12.2%)	RR 0.71 (0.21 to 2.36)	36 fewer per 1000 (from 97 fewer to 167 more)	⊕OOO VERY LOW	Critical
								12.2%				

a no details of sequence generation, allocation concealment. No blinding. BMI was higher in the intervention group at baseline.
b Confidence interval crossed both MID points.
c Formulas contained: EPA+GLA – 62.5g/L protein, 105.5g/L carbohydrate, 93.7g/L lipids, 317IU/L vitamin E, 844mg/L vitamin C , 5.0 B-carotene (mg/L), 316g/L Taurine, 181mg/L L-carnitine; the control group – 62.6g/L protein; 105.7g/L carbohydrate; 92.1g/L lipids, 85IU/L vitamin E, 317mg/L vitamin C, 160mg/L taurine, 160mg/L L -carnitine. The lipids in EPA+GLA had 31.8% canola oil, 25% MCT, 20% fish oil, 3.2% soy lecithin the control group had 55.8% canola oil, 20% MCT, 14% corn oil, 7% high oleic safflower oil and 3.2% soy lecithin.
d Nutritional intake at baseline for EPA+GLA was 1053+/-351kcal/day (49%)and 1624+/-512 (69%) at day 7; the nutritional intake at baseline for the control diet was 1055+/-378kcal/day (57%), and 1420+/-437kcal/day (71%) at 7 days.

Table 14 – Protein-enriched mealsd vs normal postoperative care – large proportion were malnourished

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Protein-enriched meals	Normal postoperative care	Relative (95% CI)	Absolute		
Incidence of pressure ulcers – Older femoral neck fracture patients												
1Oloffson 2007	randomised trials	Very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	7/83 (8.4%)	14/74 (18.9%)	RR 0.45 (0.19 to 1.04)	104 fewer per 1000 (from 153 fewer to 8 more)	⊕OOO VERY LOW	Critical
								18.9%		104 fewer per 1000 (from 153 fewer to 8 more)		
Time in hospital (Better indicated by lower values) – Older femoral neck fracture patients												
1Oloffson 2007	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	Serious imprecision[c]	none	27.4 (14.9) days N=83	39.8 (41.9) days N=74	-	MD 12.4 lower (22.47 to 2.33 lower)	⊕⊕OO LOW	Important

a Randomised to different wards. No blinding. Higher drop-out rate than the event rate.
b Confidence interval crossed one MID point.
c Limited number of events.
d The intervention group had a nutritional journal for the first four days established the patients' nutrition deficiencies. Protein-enriched meals were calculated at approximately 30 calories per kilo body weight to supply the extra energy requirement for the first four postoperative days or longer if required. At lunch an appetiser was served with the protein-enriched meals and a dessert at dinner. If the patients were malnourished on admission the nurses found out when or why they lost their appetite to see if the patients needed even more energy/caloiries. If had problems in these areas they consulted a dietitian. The patients in the intervention group also received two nutritional land protein drinks 2x200ml daily while hospitalised. Additional nutritional and protein drinks were served after every meal for patients who needed extra calories. The environment was also optimised to facilitate the intake of nutrition eg no unnecessary noise. The control group had conventional postoperative care routines.

Table 15 – Oral supplements plus standard hospital diet versus standard hospital diet – mixed population

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Nutritional supplement	Standard hospital diet	Relative (95% CI)	Absolute		
Incidence of pressure ulcers												
5 (Bourdel-Marchasson 2000; Delmi 1990; Dennis 2005; Hartgrink 1998; Houwing 2003)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	185/2435 (7.6%)	269/2516 (10.7%)	RR 0.82 (0.71 to 0.95)	19 fewer per 1000 (from 5 fewer to 31 fewer)	⊕OOO VERY LOW	Critical
								48%		86 fewer per 1000 (from 24 fewer to 139 fewer)		

a Unclear details of sequence generation and allocation concealment. Majority of studies had a lack of blinding. Some trials had high level of missing data in both groups.
b Confidence interval crossed one MID point.

The results were pooled for all studies that included an oral supplement compared to normal hospital diet, as the main constituents of the supplement were protein and energy.

Table 16 – Nutritional supplementation (supplements/diet containing protein and energy) plus standard hospital diet versus standard hospital diet – mixed population

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Nutritional supplements/diet	Standard hospital diet	Relative (95% CI)	Absolute		
Incidence of pressure ulcers												
6 (Bourdel-Marchasson 2000; Delmi 1990; Dennis 2005; Hartgrink 1998; Houwing 2003; Oloffson 2007)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	192/2518 (7.6%)	283/2590 (10.9%)	RR 0.8 (0.69 to 0.92)	22 fewer per 1000 (from 9 fewer to 34 fewer) 33.5% 67 fewer per 1000 (from 27 fewer to 104 fewer)	⊕OOO VERY LOW	Critical

a Unclear details of sequence generation and allocation concealment. Majority of studies had a lack of blinding. Some trials had high level of missing data in both groups.
b Confidence interval crossed one MID point.

The results were pooled for all studies that included nutritional supplementation compared to a normal hospital diet, as the main constituents of the supplement were protein and energy. This included a study of nutritional supplements which were given by tube feeding.

9.3.3. Appendix II: Forest plots

Figure 2 – Incidence of pressure ulcers – Bourdel MarchassonProtein, fat, carbohydrate, minerals and vitamins supplement and standard diet versus standard diet

Study or Subgroup	Supplement Events	Total	Standard hospital Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Bourdel-M 2000	118	295	181	377	100.0%	0.83 [0.70, 0.99]
Total (95% CI)		**295**		**377**	**100.0%**	**0.83 [0.70, 0.99]**
Total events	118		181			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.05 (P = 0.04)

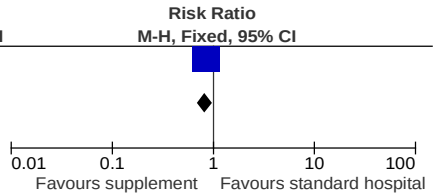


Figure 3 – Incidence of all pressure ulcers – Houwing High protein enriched with arginine zinc and antioxidants supplement and standard diet versus standard diet

Study or Subgroup	Supplement Events	Total	Standard hospital Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Houwing, 2003	27	51	30	52	100.0%	0.92 [0.65, 1.30]
Total (95% CI)		**51**		**52**	**100.0%**	**0.92 [0.65, 1.30]**
Total events	27		30			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.48 (P = 0.63)

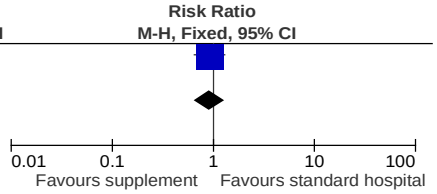


Figure 4 – Incidence of stage II pressure ulcers – HouwingHigh protein enriched with arginine zinc and antioxidants supplement and standard diet versus standard diet

Study or Subgroup	Supplement Events	Total	Standard hospital Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Houwing 2003	9	51	14	52	100.0%	0.66 [0.31, 1.38]
Total (95% CI)		**51**		**52**	**100.0%**	**0.66 [0.31, 1.38]**
Total events	9		14			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.11 (P = 0.27)

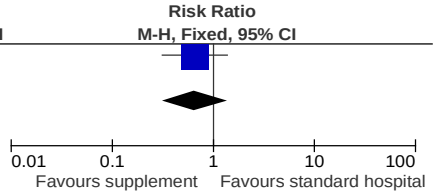


Figure 5 – Incidence of pressure ulcers – Delmi Protein, carbohydrate, lipid, calcium, vitamin A, vitamin D, vitamins E, B1, B2, B6, B12, C, nicotinamide, folate, calcium pantothenate, biotin, and minerals supplement and standard diet versus standard diet

	Supplement		Standard hospital diet			Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Delmi, 1990	0	25	2	27	100.0%	0.22 [0.01, 4.28]
Total (95% CI)		**25**		**27**	**100.0%**	**0.22 [0.01, 4.28]**
Total events	0		2			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.01 (P = 0.31)

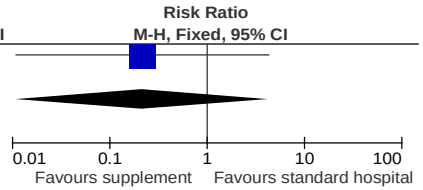


Figure 6 – Incidence of pressure ulcers – Dennis Standard hospital diet plus nutritional supplements (360mL at 6.27kJ/mL and 62.5g/L in protein) vs standard hospital diet

	Supplement		Normal hospital			Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Dennis, 2005	15	2016	26	2007	100.0%	0.57 [0.31, 1.08]
Total (95% CI)		**2016**		**2007**	**100.0%**	**0.57 [0.31, 1.08]**
Total events	15		26			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.72 (P = 0.09)

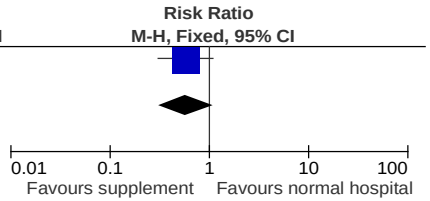


Figure 7 – Length of time in hospital – Dennis Standard hospital diet plus nutritional supplements (360mL at 6.27kJ/mL and 62.5g/L in protein) vs standard hospital diet

	Supplement			Normal hospital				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Dennis, 2005	34	48	2016	32	46	2007	100.0%	2.00 [-0.91, 4.91]
Total (95% CI)			**2016**			**2007**	**100.0%**	**2.00 [-0.91, 4.91]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.35 (P = 0.18)

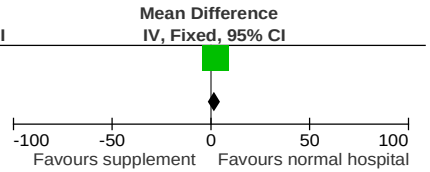


Figure 8 – Incidence of grade 2-4 pressure ulcers – Hartgrink Tube fed energy, protein versus standard diet

	Supplement		Standard hospital diet			Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Hartgrink, 1998	25	48	30	53	100.0%	0.92 [0.64, 1.32]
Total (95% CI)		**48**		**53**	**100.0%**	**0.92 [0.64, 1.32]**
Total events	25		30			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.45 (P = 0.65)

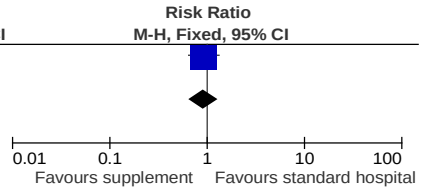


Figure 9 – Incidence of all pressure ulcers – Hartgrink Tube fed energy, protein versus standard diet

Study or Subgroup	Supplement Events	Total	Standard hospital diet Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Hartgrink, 1998	30	48	37	53	100.0%	0.90 [0.68, 1.19]
Total (95% CI)		**48**		**53**	**100.0%**	**0.90 [0.68, 1.19]**
Total events	30		37			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.77 (P = 0.44)

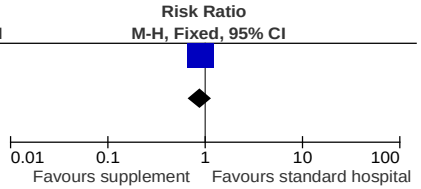


Figure 10 – Incidence of pressure ulcers – Craig Disease-specific (reduced-carbohydrate, modified-fat formula vs standard high-carbohydrate formula

Study or Subgroup	Disease-specific Events	Total	Standard Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Craig, 1998	7	17	8	15	100.0%	0.77 [0.37, 1.62]
Total (95% CI)		**17**		**15**	**100.0%**	**0.77 [0.37, 1.62]**
Total events	7		8			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.69 (P = 0.49)

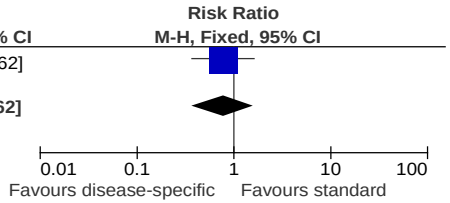


Figure 11 – Incidence of all pressure ulcers – Theilla Macronutrient diet plus lipids, gamma-linolenic acid, vitamins A,C and E vs macronutrient diet ready to feed, high fat, low carbohydrate, enteral formula

Study or Subgroup	Lipids and macronutrients Events	Total	Macronutrients Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Theilla, 2007	8	46	10	49	100.0%	0.85 [0.37, 1.97]
Total (95% CI)		**46**		**49**	**100.0%**	**0.85 [0.37, 1.97]**
Total events	8		10			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.37 (P = 0.71)

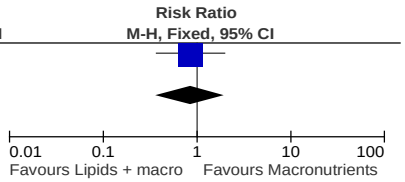


Figure 12 – Incidence of grade 2-4 pressure ulcers – Theilla Macronutrient diet plus lipids, gamma-linolenic acid, vitamins A,C and E vs macronutrient diet ready to feed, high fat, low carbohydrate, enteral formula

Study or Subgroup	Lipids and macronutrients Events	Total	Macronutrients Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Theilla, 2007	4	46	6	49	100.0%	0.71 [0.21, 2.36]
Total (95% CI)		**46**		**49**	**100.0%**	**0.71 [0.21, 2.36]**
Total events	4		6			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.56 (P = 0.58)

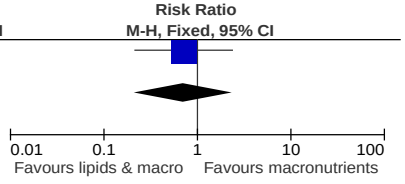


Figure 13 – Incidence of pressure ulcers – Oloffson 2007 Protein-enriched meals vs normal postoperative care

Study or Subgroup	Protein-enriched meals Events	Total	Normal postoperative care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Oloffson, 2007	7	83	14	74	100.0%	0.45 [0.19, 1.04]
Total (95% CI)		**83**		**74**	**100.0%**	**0.45 [0.19, 1.04]**
Total events	7		14			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.86 (P = 0.06)

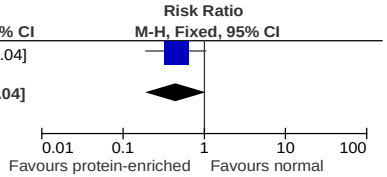


Figure 14 – Time in hospital – Oloffson Protein-enriched meals vs normal postoperative care

Study or Subgroup	Protein-enriched meals Mean	SD	Total	Normal postoperative care Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Oloffson, 2007	27.4	14.9	83	39.8	41.9	74	100.0%	-12.40 [-22.47, -2.33]
Total (95% CI)			**83**			**74**	**100.0%**	**-12.40 [-22.47, -2.33]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.41 (P = 0.02)

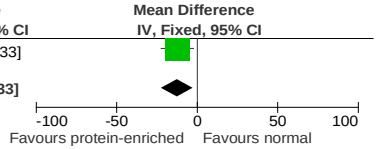


Figure 15 – Incidence of pressure ulcers – Bourdel-Marchasson, Delmi, Dennis, Hartgrink, Houwing Standard hospital diet plus nutritional supplement vs standard hospital diet

Study or Subgroup	Oral supplement Events	Total	Standard hospital Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Bourdel-M 2000	118	295	181	377	64.7%	0.83 [0.70, 0.99]
Delmi, 1990	0	25	2	27	1.0%	0.22 [0.01, 4.28]
Dennis, 2005	15	2016	26	2007	10.6%	0.57 [0.31, 1.08]
Hartgrink, 1998	25	48	30	53	11.6%	0.92 [0.64, 1.32]
Houwing, 2003	27	51	30	52	12.1%	0.92 [0.65, 1.30]
Total (95% CI)		**2435**		**2516**	**100.0%**	**0.82 [0.71, 0.95]**
Total events	185		269			

Heterogeneity: Chi² = 2.81, df = 4 (P = 0.59); I² = 0%
Test for overall effect: Z = 2.73 (P = 0.006)

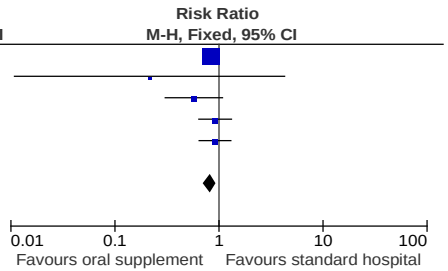


Figure 16 – Incidence of pressure ulcers – Bourdel-Marchasson, Delmi, Dennis, Hartgrink, Houwing, Oloffson Standard hospital diet plus nutritional supplement vs standard hospital diet

9.3.4. Evidence tables

Table 17 – LANGER2003

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Quality assessment	Comments
Author and year: **Langer 2003** Title: **Nutritional interventions for preventing and treating pressure ulcers (Review)** Journal: **Cochrane Database of Systematic Reviews 2003, Issue 4.**	**N of studies:** 4 **Inclusion criteria:** **Population:** People of any age and sex with or without existing pressure ulcers, in any care setting, irrespective of primary diagnosis. A pressure ulcer was defined as an area of localised damage to the skin and underlying tissue caused by pressure, shear, friction and/or a	Clearly described nutritional supplementation (enteral or parenteral nutrition) or special diet. Comparisons between supplementary nutrition plus standard diet versus standard diet alone and between different types of supplementary nutrition (e.g. enteral vs. parenteral) were eligible.	Primary outcome: Incidence of pressure ulcers	Does the review address an appropriate question relevant to the guideline review question? yes Does the review collect the type of studies you consider relevant to the guideline review question? yes Was the literature search sufficiently rigorous to identify all relevant studies? yes Was study quality assessed reported? Yes but the study quality was in a narrative and no traffic lights or tables of quality were reported.	**Quality grade:** very low risk of bias

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Quality assessment	Comments
	combination of these for the purpose of this review. **Studies:** Randomised controlled trials (RCTs) of parallel or crossover design evaluating the effect of enteral and/or parenteral nutrition on the prevention and treatment of pressure ulcers by measuring the incidence of new ulcers, ulcer healing rates or changes in pressure ulcer severity. Controlled clinical trials (CCT) were only considered eligible for inclusion in the absence of RCTs. **Exclusion criteria:** see above for inclusion criteria			Was an adequate description of the methodology used and included, and the methods used are appropriate to the question? yes	

Table 18 – CRAIG1998

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Craig 1998**[138] Title: **Use of a reduced-carbohydrate, modified-fat enteral formula for improving metabolic control and clinical outcomes in long-term care residents with type 2 diabetes: results of a pilot trial** Journal: **Nutrition, 1998, 14 (6), 529-534.** Study type: **RCT double-blinded pilot trial** Sequence generation: **says randomised but no details of sequence generation** Allocation concealment: **no details of allocation concealment**. Blinding: **double-blinded but no details of who was blinded.** Addressing incomplete outcome data: **adequate** Type of analysis: **Available Case Analysis** Statistical analysis:	**Patient group:** LTC residents with type 2 diabetes **All patients randomised N=** 34 **Completed:** 27 **Drop-outs:** 7 **Group 1:** **Randomised N:** 18 **Completed:** 16 at 4 weeks, 14 at 12 weeks **Dropouts:** 3 died **Age mean (sd):** 82 (3), range 52-94 years **Males:** not reported **Group 2:** **Randomised N:** 16 **Completed:**14 at 4 weeks and 13 at 12 weeks **Dropouts:** 2 died, 1 removed due to uncontrolled blood glucose levels.	**Group 1**: disease-specific (reduced-carbohydrate, modified-fat) formula (Energy 1000 kcal, 41.8 g protein, 16.7% kcal – source sodium and calcium caseinates, 93.7g carbohydrate, 33.3% kcal – source maltodextrin, soy polysaccharide; fructose; fat 55.7 g, 50%kcal – source high-oleic safflower oil, soy oil). **Group 2:** standard high-carbohydrate formula (Energy 1060kcal, 44.4g protein, 16.7% kcal – source sodium and calcium caseinates; carbohydrate 151.7g (includes soy fiber that provides 39 kcal and 14g of total dietary fiber per L) carbohydrate, 53.3% kcal – source maltodextrin, soy polysaccharide; fat 35.9g, 30.0% kcal – source high-oleic safflower oil, canola oil, MCT oil.	**Outcome 1: Incidence of PU:**	**Group 1:** 7/17 (41.2%) **Group 2:** 8/15 (53.3%) **Relative risk:** 0.77 **95% CI:** 0.37 to 1.62	**Funding: supported by Ross Products Division, Ohio** **Limitations:** study aim was not to look at pressure ulcers, it was only an event experienced during the study. No details of sequence generation or allocation concealment. Small sample size. **Additional outcomes:**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
ANOVA for continuous data; secondary outcomes Pearson chi-square test, Cochran-Mantel-Haenszel mean rank scores statistic for treatment group differences. Baseline differences: **no significant differences.** Study power/sample size: **no power calculation very small sample size** Setting: **2 long-term care facilities in USA.** Length of study: **3 months** Categorisation of Pus: **not reported** Assessment of PUs: **clinical outcomes collected daily but no details of how.** Multiple ulcers: **not reported**	**Age mean (sd):** 80 (2), range 52-100. **Males:** not reported **Inclusion criteria:** at least 50 years of age; history of type 2 diabetes mellitus or had documented hyperglycemia as evidenced by either a plasma glucose random measurement of >200mg/dL or a fasting plasma glucose >140mg/dL on tow occasions; required total enteral nutrition support by tube; were able to tolerate a volume of formula that maintained body weight; informed consent provided. **Exclusion criteria:** see above.				

Table 19 – THEILLA2007

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Theilla 2007 Title: **A diet enriched in eicosapentanoic acid, gamma-linolenic acid and antioxidants in the prevention of new pressure ulcer formation in critically ill patients with acute lung injury: a randomised, prospective, controlled study** Journal: **Clinical Nutrition, 26, 752-757.** Study type: **RCT** Sequence generation: **no details** Allocation concealment: **no details** Blinding: **Not blinded.** Addressing incomplete outcome data: **no further drop-outs except those who were excluded as did not meet inclusion**	**Patient group:** critically ill, mechanically ventilated patients suffering from acute lung injury (secondary outcome from a larger study on acute lung injury) **All patients** **Randomised N=100** **Completed N: 95** **Drop-outs:** 5 excluded due to diarrhoea or food intolerance (gastric residue larger than 250mL. **Group 1** **Randomised N:** **Completed N: 46** **Dropouts:** **Age (mean +/-SD): 57.0 (18.7)** **Gender (Male): 29 (63.0)** **Diagnostic category for ICU admission:** **Medical: 28 (60.9%)**	Group 1: same macronutrient diet as control group plus a lipids (elcosapentanoic acid (EPPA), gamma-linolenic acid (GLA)), vitamins A,C and E Group 2: macronutrient diet: ready to feed, high fat, low carbohydrate, enteral formula.	**Outcome 1: incidence of all pressure ulcers** **Outcome 2: incidence of grade 2-4 pressure ulcers**	**Group 1:**8/46 (17.4%) **Group 2:** 10/49 (20.4%) **Relative risk:** 0.85 **95% CI:** 0.37 to 1.97 **Group 1:** 4/49 (8.2%) **Group 2:** 6/49 (12.2%) **Relative risk:** 0.71 **95% CI:** 0.21 to 2.36	**Funding:** no details of funding **Limitations:** no details of sequence generation, allocation concealment. No blinding. BMI was higher in the intervention group at baseline. **Additional outcomes:** pressure ulcers at day 7 (all ulcers including those at start of study)

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
criteria as had diarrhoea or food intolerance Analysis: **not reported** Statistical analysis: **ANOVA with repeated measure for difference between dependent variables. Chi-square test for associations between no-dependent variables** Baseline differences: **BMI was significantly higher in the study group** Study power/sample size: **no a priori sample size calculation given and small sample size.** Setting: **ICU, Israel.** Study length: **7 days** Categorisation of PUs: **NPUAP** Assessment of PUs: **NPUAP grading, assessed daily by researchers.**	**Surgical: 18 (39.1%)** **Trauma: 0** **No. with pressure ulcers: 7/46** **Grade 1: n=5** **Grade 2: n=1** **Grade 3: n=1** **BMI (SD): 28.9 (6.2)kg/m2** **Group 2** **Randomised N:** **ITT N:49** **Dropouts:** **Age (mean+/-SD):62.3 (17.2)** **Gender (Male): 28 (57.1%)** **Diagnostic category for ICU admission**: **Medical: 34 (69.4%)** **Surgical: 15 (30.6%)** **Trauma: 0** **No. with pressure ulcers: 14/49 (p=NS)** **Grade 1: n=6** **Grade 2: n=7** **Grade 3: n=1**				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	BMI (SD): 26.5 (5.4)kg/m2, p=0.05 **Inclusion criteria:** patients with acute lung injury defined by a PaO2/FIO2 ratio below 250. **Exclusion criteria:** patients with head trauma, cerebral bleeding, coagulation disorders, receiving steroids in a dose >0.25mg/kg/day methylprednisolone or non-steroidal anti-inflammatory agents, patients less than 18 years and pregnant patients. If diarrhoea occurred more than three times.				

Table 20 – OLOFSSON2007

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Olofsson 2007** Title: **Malnutrition in hip fracture patients: an intervention study** Journal: **Journal of Clinical Nursing, 16(11), 2027-2038.** Sequence generation: **randomised to postoperative care in a geriatric ward with a special intervention programme or to conventional care in the orthopaedic department** Allocation concealment: **sealed, opaque envelopes stratified according to operation method. Nurse on duty at the orthopaedic dept, not involved in the study, opened the envelope.** Blinding: **the staff on the intervention ward was aware of the nature of the study, and the staff working on the control ward was informed that**	**Patient group:** femoral neck fracture patients **All patients** **Randomised N:** 199 **Completed N:** 157 **Drop-outs:** 42 **Group 1** **Randomised N:** 102 **Completed N:** 83 **Dropouts:** 19 (18.6%) Six patients died during hospitalisation and five patients had missing MNA[(a)] (91 were assessed at 4 months), 3 patients died after discharge, one patient declined to continue and four patients had missing MNA[(a)]. **Group 2** **Randomised N:** 97	**Group 1:** protein enriched meals (calculated at approximately 30 calories per kilo body weight) served during the first four postoperative days and longer if necessary. At lunch an appetizer was always served with the protein-enriched meals and a dessert at dinner. When the registered nurses suspected malnourishment on admission they found out when or why they had lost their appetite to discover whether the patients needed even more energy/calories. If there were problems in these areas, a dietician was consulted. They also received two nutritional and protein drinks (2x200ml) daily during whole hospitalisation period. Additional nutritional and protein drinks were served after every meal for patients who needed extra calories. If patients could not sleep or were anxious at night an extra meal was offered	**Outcome 1:** incidence of pressure ulcers **Outcome 2:** time in hospital	**Group 1:** 7/83 **Group 2:** 14/74 P=0.054 Those who did develop pressure ulcers were almost exclusively suffering from severe malnutrition. **Group 1:** 27.4 (14.9) **Group 2:** 39.8 (41.9) P=0.019	**Funding:** grants from the Borgerskapet in Umea Research Foundation, the Dementia Fund, the Vardal Foundation, the Joint Committee of the Northern Health Region of Sweden, the JC Kempe Memorial Foundation, the Foundation of the Medical Faculty, University of Umea, the County Councils of Vasterbotten and the Swedish Research Council grant. **Limitations:** randomised to different wards. No blinding. Small study no power calculation. **Additional**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
a new care programme was being implemented and that it was being evaluated in the geriatric intervention ward. Addressing incomplete outcome data: **explains what happened to all missing data.** **Statistical analysis: Student's t-test was used to analyse differences in MNA[(a)] scores on admission and at the four-month follow-up between groups.** Analysis: **Available Case Analysis** Statistical analysis: **Student's t-test to analyse differences in MNA[(a)] scores** Baseline differences: **there was a significantly higher score for the intervention group for heart failure at baseline. There were four patients missing data in the control group and**	**Completed N:** 74 **Dropouts:** 23 (23%) Seven patients died during hospitalisation, 8 patients had missing MNA[(a)] (82 were assessed at 4 months). Six patients died after discharge, 1 patient moved to another city and one patient had missing MNA[(a)]. **Inclusion criteria:** femoral neck fracture, aged 70 years or older, admitted consecutively to the orthopaedic dept of one hospital, from May 2000 to December 2002. **Exclusion criteria:** severe rheumatoid arthritis, severed hip osteoarthritis, severe renal failure, metastatic fracture and patients who were bedridden before their injury.	during the night shift. The environment around the meal was adjusted to facilitate good nutrition, by making the meal times nice and comfortable with no unnecessary noise, bustle or stress. Any aspect that might improve the patients' nutrition was considered eg they could choose their own food or ask what they wanted to eat. All physical problems that led to patients eating less were dealt with eg constipation, pain or bad oral hygiene. **Group 2:** postoperative care in the orthopaedic department in accordance with conventional postoperative care routines (described in table). Staffing ratio 1.01 nurses or aids per bed. Patients who needed a longer rehabilitation period were transferred to a general geriatric rehab ward but not to the ward where the intervention programme had been implemented (n=30). Staffing ratio was 1.07 nurses or aids per bed.			**outcomes:** compliance – the nutritional and protein drinks were served during the whole hospitalisation period in the intervention group but we do not know exactly how much were consumed. Should be noted when interpreting the results. Complications during hospitalisation were given in relation to the MNA[(a)] scores at baseline in each group (delirium, nutrition difficulties, constipation, pressure ulcers, urinary tract infection. Study was part of a multifactorial

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
one in the intervention group at this time. Study power/sample size: **small, no power calculation.** Setting: **orthopaedic department, Umea University Hospital Sweden.** Length of study: **four month follow-up** Categorisation of PUs: **not reported** Assessment of PUs: **not specifically mentioned as not main aim of study.** Other assessments: **the mini mental state examination, organic brain syndrome scale and the geriatric depression scale were used. The MNA[(a)] was used to assess the patients' nutritional status.** Multiple ulcers: **not reported.**		All patients: received same preoperative treatment in the orthopaedic department and had same mean waiting for surgery (25.1 hours in the control group and 24.6 hours in the intervention group, p=0.852).			multidisciplinary intervention study.

MNA – mini nutritional assessment scale

Table 21 – DENNIS2005

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Dennis 2005** Title: **Routine oral nutritional supplementation for stroke patients in hospital (FOOD): a multicentre randomised controlled trial** **Journal: Lancet, 2005, 365, 755-763.** study type: **Multicentre RCT** Sequence generation: **computer-generated** Allocation concealment: **international co-ordinating centre and computer-generated minimisation algorithm balanced treatment within each country** Blinding: **no blinding of assessment and treatment allocation.** Addressing incomplete outcome data:	**Patient group:** elderly stroke patients in hospital **All patients randomised N=** 4023 **Completed:** **Drop-outs:** **Group 1:** **Randomised N:** 2016 **Completed:** 1767 **Dropouts:** 4 lost to follow-up, 3 vital status only, 241 died **Age mean (sd):** 71 (12) **Males: 1071 (53%)** **Nutritional status:** **Undernourished:** 156 (8%) **Normal:** 1550 (77%) **Overweight:** 310 (15%) **Glasgow coma scale verbal normal:** 1644 (82%) **Group 2:** **Randomised N:** 2007	**Group 1**: normal hospital diet plus oral supplements (360mL at 6.27 kJ/mL and 62.5g/L in protein every day) Most centres used commercially available supplements of suitable consistency for patients with mild swallowing impairments eg liquid, yoghurt, pudding. The supplements were prescribed on drug-administration charts to increase compliance and to allow monitoring of compliance by the hospital coordinator so that there was an increase in the total protein and energy intake of elderly patients in hospital. **Group 2:** normal hospital diet	**Outcome 1: Incidence of PU:** **Outcome 2: length of stay in hospital – mean days (s.d)**	**Group 1: 15/2016 (0.7%)** **Group 2: 26/2007 (1.3%)** **Relative risk: 0.57** **95% CI: 0.31 to 1.08** **Group 1:** 34.0 (48.00) **Group 2:** 32.00 (46.00)	**Funding:** grants from the HTA board of NHS research and development in the UK, the Stroke Association, the Chief Scientist Office of the Scottish Executive, and Chest, Heart and Stroke Scotland. The Royal Australasian College of Physicians supported the trial in Hawkes Bay, New Zealand. **Limitations:** aim not to look at pressure ulcers and there were no details of pressure ulcers at start of the trial. Pressure ulcers were classified as a complication.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
adequate Analysis: **primary analyses ITT** Statistical analysis: **Log-rank test** Baseline differences: **no differences** Study power/sample size: **yes based on dichotomous outcome – dead or poor outcome (MRS[(a)] 3-5) at follow-up. 87% power 6000 participants.** Setting: **multicentre, UK** Length of study: **6-months follow-up** Categorisation of PUs: **not reported** Assessment of PUs: **not reported** How outcomes recorded: **postal questionnaire or structured telephone interview from patient, carer or proxy.** Multiple ulcers: **not**	**Completed:** 1740 **Dropouts:** 7 lost to follow-up, 5 vital status only, 253 died **Age mean (sd):** 71 (13) **Males:** 1078 (54%) **Nutritional status:** **Undernourished:** 158 (8%) **Normal:** 1542 (77%) **Overweight:** 307 (15%) **Glasgow coma scale verbal normal:** 1606 (80%) **Inclusion criteria:** patients admitted with a recent stroke (first or recurrent stroke no more than 7 days before admission) could be enrolled if they passed their swallow screen, the responsible clinician was uncertain whether to use oral nutritional supplements and the patient (or a relative) consented to enrolment. Enrolled within 30 days of admission, or within 30				The authors state that the data needs to be interpreted with caution because they could not mask the assessment to treatment allocation and it was not feasible for local source data to be verified for the occurrence of these. Trial was stopped before they reached their target as no funding was available to continue beyond 2004 and to ensure the trial was closed in an orderly manner. **Additional outcomes:** primary outcomes were death or poor outcome and overall survival.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
reported.	days of a stroke occurring in hospital. **Exclusion criteria:** subarachnoid haemorrhage				Aim of study was not to look at pressure ulcers.

MRS is the modified Rankin scale which is a scale for measuring the degree of disability or dependence in the daily activities of people who have suffered a stroke or other causes of neurological disability. Scoring: 0 No symptoms at all; 1 No significant disability despite symptoms; able to carry out all usual duties and activities; 2 Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance; 3 Moderate disability; requiring some help, but able to walk without assistance; 4 Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance; 5 Severe disability; bedridden, incontinent and requiring constant nursing care and attention; 6 Dead.

Table 22 – HOUWING2003

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Houwing et al 2003** Title: **A randomised, double-blind assessment of the effect of nutritional supplementation on the prevention of pressure ulcers in hip-fracture patients, Clinical Nutrition, 22(4),401-405** Study type: **Multicentre RCT**	**Patient group:** hip fracture patients **All patients randomised N=**103 **Drop-outs: 0** **Group 1:** **Randomised N:** 51 **Dropouts:** 0 **Age (mean):**81.5+/-0.9 **Sex (female):** 40/51 **Risk score CBO:**	**Group 1**: Standard diet with additional supplement. Supplement was a high-protein nutritional supplement enriched with arginine, zinc and antioxidants (400ml). Given immediately postoperatively for 4 weeks or until discharge **Group 2:** Standard diet with placebo: a non-caloric, water-based drink containing only sweeteners, colorants	**Outcome 1: incidence of all pressure ulcers**	**Group 1:**27/51 (55.1%) **Group 2:**30/52 (58.8%) **Relative risk:**0.037 **95% CI:**-0.16 to 0.23 **P value:** 0.420	**Funding:**Numico Research BV, Wageningen, the Netherlands **Limitations:** Unclear selection bias – no details of sequence generation or allocation concealment. **Additional outcomes:** total
			Outcome 2: Incidence of grade 2 pressure ulcers	**Group 1:** 9/51 (17.6%) **Group 2:** 14/52 (26.9%) **Relative risk:** 0.66 **95% CI:** 0.31 to 1.38	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Sequence generation: **no details** Allocation concealment: **no details** Blinding: **double-blinded. Look and taste of both supplements were not identical but supplements were given in similar, blinded packages to mask the differences.** Addressing incomplete outcome data: **no dropouts** Analysis: **ITT** Statistical analysis: **Distribution of variables evaluated visually by Kolmogorov-Smirnov test. Differences in continuous variables determined by Student's t-test or Mann-Whitney U-test. Difference in incidence rates by Fisher's exact test. Results adjusted for age or length of**	11.1+/-0.3 **Group 2:** **Randomised N:** 52 **Dropouts:** 0 **Age (mean):** 80.5+/-1.3 **Sex (female):** 44/52 **Risk score CBO:** 11.2+/-0.2 **Inclusion criteria:** hip fracture, patient with a pressure risk score over 8 according to the CBO-risk assessment tool (four-point scoring tool including: mental status, neurology, mobility, nutritional status, nutritional intake, incontinence, age, temperature, medication and diabetes). **Exclusion criteria:** terminal care, metastatic hip fracture, insulin-dependent diabetes, renal disease (creatinine >176mmol/l, hepatic disease, morbid obesity	and flavourings (400ml)			max wound size (cm^3), first day pressure ulcer, number of days with pressure ulcer. Notes: 57% developed PU within first 2 days of the study and 76% by the fourth day

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
surgery by ANOVA. Baseline differences: **no significant difference in baseline values.** Study power/sample size: **underpowered** Setting: **three centres in the Netherlands** Length of study: **28 days or until discharge** Categorisation of PUs: **EPUAP classification system** Assessment of PUs: **PU assessed daily by nursing staff** Multiple ulcers: **not reported**	(BMI>40), need for therapeutic diet incompatible with supplementation and pregnancy or lactation.				

Table 23 – BOURDEL-MARCHASSON2000

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Bourdel-Marchasson (2000)** Title: **A multi-centre trial of the effects of oral nutritional supplementation in critically ill older inpatients** Study type: **multi-centre cluster-randomised RCT** Sequence generation: **19 wards stratified by specialty and the wards randomised into 2 groups. No details on seq. gen.** Allocation concealment: **no details but multicentre stratified** Blinding: **not blinded (authors state it is not easy to propose placebo oral supplements with similar taste and consistency in a double-blind manner. Also it could have a deleterious effect on**	**Patient group:** Critically ill older patients. **All patients** **Randomised N= 672** **Drop-outs: 173** **Group 1** **Randomised N: 295** **Completed N: 107** **Dropouts: 188** **Age mean (s.d): 83.6 (7.3)** **Male (%): 96 (32.5)** **Other baseline data:** **Stroke: 23.6%** **Falls and gait disturbance: 13.7%** **Heart failure and dyspnea: 13.1%** **Infectious diseases: 13.7%** **Digestive diseases: 3.2%** **Delirium: 5.6%** **Dehydration: 2.9%** **Lower limb fractures:**	Group 1: standard diet of 1800kcal/day plus 2 oral supplements of 200kcal each (30% protein, 20% fat, 50% carbohydrate in addition to minerals and vitamins such as zinc 1.8mg and vitamin C (15mg) Group 2: standard diet of 1800kcal/day	**Outcome 1: pressure ulcer (cumulative) incidence at end of follow-up**	**Group 1:** 118/295 (40%) **Group 2:** 181/377 (48%) **Relative risk:** 0.83 **95% CI:** 0.70 to 0.99	**Funding:** Projet Hospitalier de Recherche Clinique, Ministère de la Santé et de l'Action Humanitaire, Direction Générale de la Santé et la Direction des Hôpitaux. **Limitations:** 25 died in Intervention and 22 in control group. No details of sequence generation for cluster randomisation. No blinding. There were baseline differences but author did multivariate analysis to account for these differences.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
the energy intake in the control group because in elderly hospitalised patients the volume rather than the energy content of food could limit voluntary energy intake). Addressing incomplete outcome data: **for subjects who died or were discharged without pressure ulcers before the day 15, the date of death or discharge were considered as censoring the data.** Analysis: **ITT** Statistical analysis: **Chi-square test for categorical variables and Student's t test for numerical variables after applying the Fisher test. Multiple hazard regression Cox model to adjust analysis. Homogeneity test used and a**	**0.3%** **Cancer: 1.1%** **Neurologic diseases: 2.4%** **Painful arthritis: 2.1%** **Deep Vein Thrombosis: 2.9%** **Miscellaneous medical diseases: 15.3%** **Group 2** **Randomised N: 377** **Completed N: 244** **Dropouts: 133** **Age mean (s.d):83.0 (7.1)** **Male (%): 139 (36.9)** **Other baseline data:** **Stroke: 6.8% (P<0.001)** **Falls and gait disturbance: 20.2% (p=0.02)** **Heart failure and dyspnea: 7.2% (p=0.009)** **Infectious diseases: 11% (N.S)** **Digestive disease: 14.4% (p<0.001)**				There was a very high drop-out 63% in intervention group and 35% in control group. **Additional outcomes:**

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
multivariate Cox proportional hazard model. Baseline differences: **the nutritional group included more patients with stroke, heart failure, and dyspnea and fewer with antecedent falls, delirium, lower limb fractures and digestive disease. The nutritional group had a lower risk of pressure ulcers, were less dependent (Kuntzman score) and a lower serum albumin level (indicates a higher risk for pressure ulcers)** Study power/sample size: **a priori power calculation not reported but large sample size.** Setting: **inpatients of hospital wards in Bordeaux or inpatients at geriatric units in Southwest**	**Delirium: 9.9% (p=0.001)** **Dehydration: 2.7% (N.S)** **Lower limb fractures: 4.1% (p=0.004)** **Cancer: 4.8% (N.S)** **Neurologic diseases: 2.4% (N.S)** **Painful arthritis: 2.1% (N.S)** **DVT: 0 (N.S)** **Miscellaneous medical diseases: 14.4% (N.S)** **Inclusion criteria:** older than 65 years, in the acute phase of a critical illness, unable to move by themselves, and unable to eat independently at admission. **Exclusion criteria:** pressure ulcers at admission.				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
France belonging to GAGE, a group for the evaluation and improvement of health care for the elderly. Length of study: **15 days follow-up** Categorisation of PUs: Assessment of PUs: Assessment: **Norton scale to assess risk of developing pressure ulcers; Kuntzman scale assessed the activities of daily living. Ulcers graded by four grades defined by the Agency for Health Care Policy and Research.** Multiple ulcers: **not reported**					

Table 24 – HARTGRINK1998

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Hartgrink 1998** Title: **Pressure sores and tube feeding in patients with a fracture of the hip: a randomised clinical trial** Journal: **Clinical Nutrition 1998, 17 (6), 287-292.** Study type: **single centre parallel RCT** Sequence generation: **no details.** Allocation concealment: **no details.** Blinding: **no blinding** Addressing incomplete outcome data: **adequate** Analysis: **per protocol** Statistical analysis: Baseline differences: **no differences** Study power/sample size: **no power calculation given.** Length of study: **2**	**Patient group: hip fracture patients** **All patients** **Randomised N=140** **Evaluable at admission: 129 (11 did not fulfil entry criteria)** **Drop-outs: 11 excluded at admission (randomisation not correctly performed).** **Evaluable at 1 week: 116** **Evaluable at 2 weeks: 101** **Group 1** **Randomised N: 70** **Evaluable at admission: 62** **Evaluable at 1 week: 54** **Evaluable at 2 weeks: 48** **Dropouts:** **Age (mean): 84.0 (7.1)** **Sex M/F: 10/52** **Time from entry to operation (min) mean (SD): 20.0 (16.3)** **Operation time (min): 58.2 (22.4)** **Pressure-sore risk score (mean, SD): 9.0 (1.3)**	All patients received standard hospital diet. In case they were randomised to tube feeding, a nasogastric tube was given during surgery or within 12 hours afterwards. Actual feeding started within 24 hours. Group 1: Standard hospital diet plus tube feeding (1 litre Nutrison Steriflo Engergy-plus (1500kcal/l energy, 60 gram/l protein, Nutricia, Netherlands)). Administered with a feeding pump through a polyurethane nasogastric feeding tube. Tube feeding was to be given for 2 weeks and administered between 21:00 and 05:00 to minimise interference with the normal hospital diet. Nurses kept record of food offered and food left over. Calculation of energy and protein intake	**Outcome 1: pressure sore incidence (grade 2 or more) [no. evaluable at 2 weeks]** **Outcome 3: Pressure sore incidence (all grades) [no. available at 2 weeks]** **Outcome 2: pressure sore incidence (grade 2 or more) [no. available at 1 week]** **Outcome 4: pressure sore incidence (all grades) [no. available at 1 weeks]**	**Group 1: 25/48 (44%)** **Group 2: 30/53 (57%)** **Relative risk: 0.92** **95% CI: 0.64 to 1.32** **Group 1: 30/48 (62.5%)** **Group 2: 37/53 (69.8%)** **Relative risk: 0.90** **95% CI: 0.68 to 1.19** **Group 1:20/54 (28%)** **Group 2: 30/62 (48%)** **Relative risk: 0.77** **95% CI: 0.50 to 1.18** **Group 1: 35/54 (64.8%)** **Group 2: 41/62 (66%)** **Relative risk: 0.98** **95% CI: 0.75 to 1.28**	**Funding: not stated.** **Limitations:** no details of sequence generation, allocation concealment and no blinding. High drop-out in both groups. Those who were still tube fed at 1 and 2 weeks were 25 and 16 patients respectively. Additional mortality: evaluable at week 1 and week 2.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
weeks treatment. Categorisation of PUs: **(Stage 0=normal skin, 1=persistent erythema of the skin, stage 2=blister formation, stage 3=superficial (sub)cutaneous necrosis, stage 4=subcutaneous necrosis, according to the Dutch consensus meeting for the prevention of pressure sores)** Assessment of PUs: **not reported** Multiple ulcers: **not reported**	**Group 2** **Randomised N: 70** **Evaluable at admission: 67** **Evaluable at 1 week: 62** **Evaluable at 2 weeks: 53** **Dropouts:** **Age (mean): 83.3 (8.1)** **Sex M/F: 6/6** **Time from entry to operation (min) mean (SD):21.1 (12.3)** **Operation time (min):** **63.1 (23.4)** **Pressure-sore risk score (mean, SD):9.2 (1.3)** **Inclusion criteria:** fractured hip; pressure-sore risk score of 8 points or more (calculated as sum of points scored on 10 risk indices – mental status, neurology, mobility, nutritional status, incontinence, age, temperature, medication and diabetes). **Exclusion criteria:** Patients with pressure sores of grade 2 or more at admission (Dutch consensus).	by diet and tube feeding done daily by dietician. Group 2: standard hospital diet.			

Table 25 – DELMI1990

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Delmi 1990** Title: **dietary supplementation in elderly patients with fractured neck of the femur** Journal: **Lancet 1990, 28, 335 (8696); 1013-1016.** Study type: **RCT** Sequence generation: **no details** Allocation concealment: **no details** Blinding: **no details** Addressing incomplete outcome data: **adequate** Analysis: **not reported** Statistical analysis: **unpaired t tests or U tests, and X2 and Fisher's exact tests for analysis of clinical course.** Baseline differences: **the 250HD plasma level was lower in**	**Patient group:** elderly patients with fractures of the proximal femur. **All patients** **Randomised N=59** **Completed N: 49** **Drop-outs: 10 died (not included in analysis)** **Group 1** **Randomised N: 27** **Completed N: 21** **Dropouts: 6 died (not included in analysis)** **Age (mean SD and range): 80.4 (8.5,61-93)** **Female/Male: 24/3** **Triceps skinfold (mm): Women 12.1 (4.6)** **Men 5,7,10** **Upper arm circumference (mm):** **Women 251 (30)** **Men* 255, 260, 260**	**Group 1:** Daily oral nutrition supplements, for mean 28 days in addition to standard hospital diet. **Group 2:** control group 250ml oral nutritional supplement provided 254kcal, 20.4g protein, 29.5g carbohydrate, 5.8g lipid, 525mg calcium, 750 IU vitamin A, 25 IU vitamin D3, vitamins E, B1, B2, B6, B12, C, nicotinamide, folate, calcium pantothenate, biotin, and minerals.	**Outcome 1: pressure ulcers at first hospital (orthopaedic)**	**Group 1**:2/27 (7.4%) **Group 2**:3/32 (9.38%) **Relative risk:** **95% CI:**	**Funding:** not reported. **Limitations:** small sample. No details of sequence generation, allocation concealment or blinding. Difference at baseline for plasma level. **Notes:** most patients had nutritional deficiencies. The authors state that elderly are often malnourished and patients with fractured proximal femur seem especially under-nourished. Supplement was well tolerated and completely ingested so no
			Outcome 2: pressure ulcers at 2nd hospital (recovery)	**Group 1:**0/9 (0%) **Group 2:**3/15 (20%) **Relative risk:** **95% CI:**	
			Outcome 3: pressure ulcers at 6 months [figures used in CR]	**Group 1: 0/25 (0%)** **Group 2: 2/27 (7.4%)** **Relative risk:** **95% CI:**	
			Outcome 4: total length of stay in orthopaedic ward and recovery hospital	**Group 1: median 24 days (range 13-157)** **Group 2: 40 (10-259)** **Relative risk:** **P=0.09**	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
non-supplemented patients (median 9.0nmol/l, range 2.3-61.5 vs 14.9, 4.2-87, p<0.05). Study power/sample size: **no power calculation.** Setting: **orthopaedic unit of University hospital of Geneva** Length of study: **assessments made on days 14, 21 and 28 and at 6 months.** Categorisation of PUs: **not reported** Assessment of PUs: **not reported** Multiple ulcers: **not reported**	**Group 2** **Randomised N: 32** **Completed N: 28** **Dropouts: 4 died (not included in analysis)** **Age (mean SD and range): 82.9 (1.9, 66-96)** **Female/Male: 29/3** **Triceps skinfold (mm): Women 11.4 (5.7)** **Men* 4,7, 13** **Upper arm circumference (mm):** **Women 261 (41)** **Men* 230, 270, 290** ***Data for 3 men in each group** **Inclusion criteria:** patients over 60 years old admitted between March 1st and May 15th 1985 with a femoral neck fracture after an accidental fall. All patients were well-oriented, able to understand the aim of the study, and willing to				side-effects observed. **Outcomes also reported but not specified here:** severe anaemia, cardiac failure, infection and GI ulcer. These were given for first hospital (orthopaedic), 2nd hospital (recovery) and at 6 months.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	cooperate. **Exclusion criteria:** Fractures from violent external trauma and pathological fractures due to tumours or non-osteoporotic osteopathies; dementia; renal, hepatic or endocrine disease, gastrectomy or malabsorption, or treatment with phenytoin, steroids, barbiturates, fluoride, or calcitonin.				

10. GRADE SYSTEM

10.1. Down- or upgrading the evidence

Study design	Initial level of evidence		Lower if	Higher if
Randomised trials	**High**	⇨	**Risk of Bias**	**Large effect**
			-1 Serious	+1 Large
			-2 Very serious	+2 Very large
			Inconsistency	**Dose response**
			-1 Serious	+1 Evidence of a gradient
Observational studies	**Low**	⇨	-2 Very serious	**All plausible residual confounding**
			Indirectness	+1 Would reduce a demonstrated effect
			-1 Serious	+1 Would suggest a spurious effect if no effect was observed
			-2 Very serious	
			Imprecision	
			-1 Serious	
			-2 Very serious	
			Publication bias	
			-1 Serious	
			-2 Very serious	

The quality evidence is downgraded based on the following elements: risk of bias, inconsistency, indirectness, imprecision, publication bias. The specific conventions agreed within the GDG and with our international partner for this study in case of inconsistency and imprecision are explained below.

10.1.1. Risk of bias

Limitations in the study design and implementation may bias the estimates of the treatment effect. Major limitations in studies decrease the confidence in the estimate of the effect.

10.1.2. Inconsistency

Results were considered to be heterogeneous in case the point estimates vary widely across studies or the confidence intervals show minimal or no overlap or a Chi square p<0.1 or I- squared inconsistency statistic of >50%. When no plausible explanation can be found for this heterogeneity, the quality of evidence was downgraded by one or two levels, depending on the extent of uncertainty to the results contributed by the inconsistency in the results. In addition to the I- square and Chi square values, the decision for downgrading was also dependent on factors such as whether the intervention is associated with benefit in all other outcomes or whether the uncertainty about the magnitude of benefit (or harm) of the outcome showing heterogeneity would influence the overall judgment about net benefit or harm (across all outcomes).[145]

10.1.3. Indirectness

Indirectness refers to differences in study population, intervention, comparator and outcomes between the available evidence and the protocol.

10.1.4. Imprecision

Results are often imprecise when studies include relatively few patients and few events and thus have wide confidence intervals around the estimate of effect. This, in turn, may mean that we are uncertain if there is an important difference between interventions or not. If this is the case, the evidence may be considered to be of lower quality of the evidence lower than it otherwise would be because of resulting uncertainty in the results.

The thresholds of important benefits or harms, or the minimal important difference (MID) for an outcome are important considerations for determining whether there is a “clinically important” difference between interventions and in assessing imprecision. For continuous outcomes, the MID is defined as “the smallest difference in score in the outcome of interest that informed patients or informed proxies perceive as important, either beneficial or harmful, and that would lead the patient or clinician to consider a change in the management”.[145] An effect estimate larger than the MID is considered to be “clinically important”. For dichotomous outcomes, the MID is considered in terms of changes in both absolute and relative risks.

The difference between two interventions, as observed in the studies, was compared against the MID when considering whether the findings were of “clinical importance”; this is useful to guide decisions. For example, if the effect size was small (less than the MID), this finding suggests that there may not be enough difference to strongly recommend one intervention over the other based on that outcome.

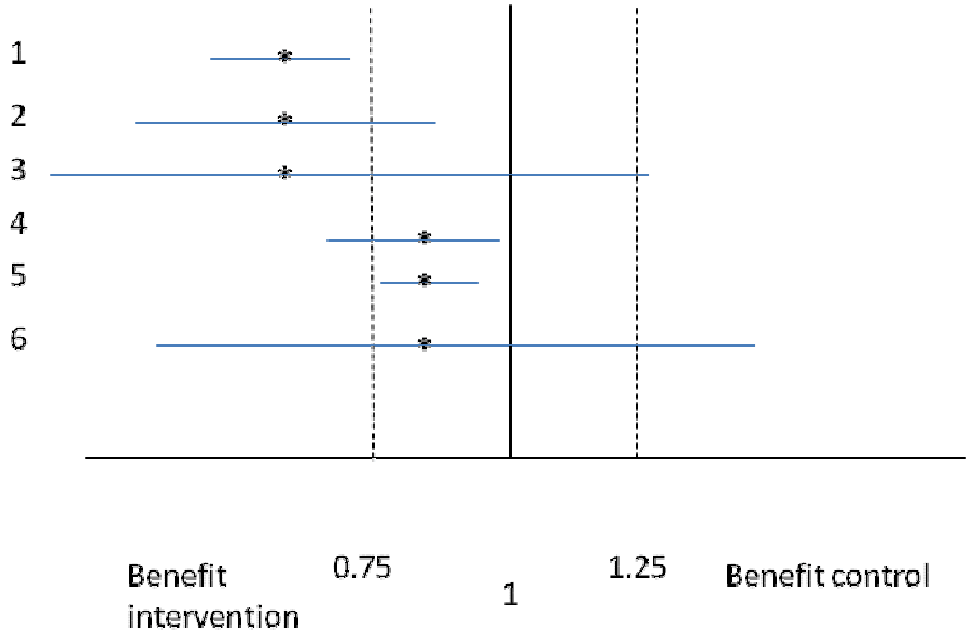
The default thresholds suggested by GRADE were a relative risk reduction of 25% (relative risk of 0.75 for negative outcomes) or a relative risk increase of 25% (risk ratio 1.25 for positive outcomes) for binary outcomes. For this guideline, default threshold suggested by GRADE was adopted. For continuous outcomes, a standardised mean difference (SMD) of 0.5 was considered the MID for most outcomes.

The CI for the pooled or best estimate of effect was considered in relation to the MID, as illustrated in Figure 1. Essentially, if the CI crossed the MID threshold, there was uncertainty in the effect estimate in supporting our recommendations (because the CI was consistent with two decisions) and the effect estimate was rated as imprecise.

Relation with Evidence statements used in this report

Figure 1 illustrates how the clinical importance of effect estimates and imprecision were considered in the evidence statements throughout this guideline.

Figure 1 – Six examples of point estimates and confidence intervals for relative risks



The evidence statements are linked with the GRADE-tables and Forest plots included in the evidence plots. The **Point estimates** are used to determine if a result is clinical important. In figure 1 we show 6 examples (more scenario's are possible) of relative risks. The dotted line indicates from which moment a result can be considered as 'clinical important' (i.e. a relative risk <0.75 or a relative risk >1.25). In the figure below this is the case in examples 1,2 and 3. This is of course only a 'rule of thumb' that was discussed with the clinical experts of the GDG and the external expert panel on a case-by-case basis.

The '**Confidence Intervals'** are used to specify the level of **precision or imprecision** of the point estimates. When point estimates are based on small studies, for instance, confidence intervals are wide, indicating a high level of imprecision.

In case of a **high level of precision** the evidence statements are formulated as follows: 'x studies showed intervention is more clinical effective than control' (**situation 1**) or 'x studies showed there is **no** clinical difference in effect between intervention and control" (**situation 5**)

In case of '**serious imprecision**, 'potentially' is used as terminology: X studies showed intervention **is potentially** more clinically effective at preventing pressure ulcers compared to control (**situation 2**); X studies showed there is **potentially no** clinical difference in effect between intervention and control (**situation 4**)

In case of '**very serious imprecision**' the wording '**May be'** is used (**situations 3 and 6**)

The above examples are not set in stone. The formulation of evidence statements could be altered after discussions within the GDG or with the external experts.

Evidence statements will be used as input together with other considerations (e.g. costs; user-friendliness of an intervention,…) to formulate recommendations.

10.1.5. Publication Bias

Publication bias is a systematic underestimate or an overestimate of the underlying beneficial or harmful effect due to the selective publication of studies.

11. ASSESSMENT OF EXISTING GUIDELINES

A scoping review was carried out to prepare the development of the guidelines for the prevention and treatment of pressure ulcers. A three styp search strategy was performed to identify clinical practice guidelines on the presvention and/or treatment of pressure ulcers. The first step involved a search of electronic databases were search using index-terms and free-text words. Following databases were included for this search: Medline (OVID), CINAHL (EBSCO-interface), Embase, and the Library of the Cochrane Collaboration. Secondly, websites of guideline developers and wound care organisations were searched using free-text words: American Medical Directors Association (AMDA), Australian Wound Management Association, Canadian Medical Association (CMA), Deutsches Netzwerk für Qualitätsentwicklung in der Pflege (DNQP), European Wound Management Association, Guidelines International Network (GIN), Haute Autorité de Santé (HAS), Institute for Clinical Systems Improvement (ICSI), Joanna Briggs Institute (JBI), Kwaliteitsinstituut voor de Gezondheidszorg (CBO), Landelijke Eerstelijns Samenwerkings Afspraken (LEVA'S), National Institute of Health and Clinical Excellence (NICE), National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel (NPUAP and EPUAP), Registered Nurses' Association of Ontario (RNAO), Scottish Intercollegiate Guidelines Network (SIGN), US National Guideline Clearinghouse, Verpleegkundigen & Verzorgenden Nederland, Wound, Ostomy, and Continence Nurses Society (WOCNS), Wounds international, Wounds UK, and 1ste lijn Amsterdam. Thirdly, the reference lists of all retrieved guidelines were searched to identify additional guidelines.

Eighteen clinical practice guidelines were identified trough the search of electronic databases and websites of guidelines developers and national/international wound care organizations.[146, 147 , 148 , 149-161]

The retrieved guidelines were evaluated by three independent reviewers using the Appraisal of Guidelines Research & Evaluation II (AGREE II). The AGREE II scores, particularly the scores of the domain 'Rigour of development', was used to guide the research team in the decision-making process whether to (1) include, (2) exclude or (3) adapt a guideline. None of the retrieved guidelines were considered to be suitable to be used in an ADAPTE-process. The most common reason for exclusion was the absence of a systematic search for evidence and a lack of quality appraisal of included studies.

It was decided to develop the guidelines de novo. However, the guidelines of NPUAP/EPUAP[161] and NICE[147, 148, 149] were considered as useful to support the formulation of best-practices for our purposes as they both made use of a systematic and extensive consultation process to gather expert opinion.

12. RECOMMENDATIONS: COMMENTS EXPERT PANEL

Item	Recommendation(s)	GOR	LoE	Comments	Min	Max	Mean	Median	% 4 or 5	Decision
Prevention Pressure Ulcers										
Pressure ulcer prevention should be tailored to individual needs and situations and should be based on the principles of shared decision making – Best Practice	**Prevention should take into account several factors such as the patients' medical condition, the overall plan of care and the patients' preferences. The circumstances and needs of the individual should be re-assessed regularly**	Best practice		R10: can we be more precise about "regularly"? R9: I suppose that 'principles of shared decision making' will be explained in text? I find the second sentence rather vague. What is meant by cirucumstances and needs? Is this risk assessment?	4	5	5	5	100%	
	When a patient is assessed to be at risk of pressure ulcer development: **o the aims of the preventive actions to be taken should be explained fully and unambiguously;** **o the possible risks and benefits related with the preventive actions to be taken should be discussed openly;** **o it should be confirmed that the patient was able to fully understand the information being provided;** **o the patient should be encouraged to clarify what he/she feels to be important, and the healthcare provider should evaluate whether this is consistent with the aims of the preventive actions to be taken;** **o Register the planned and agreed/refused actions.**	Best practice		R9: concerning the first bullet: to the patient? Second bullet: discussed with the caregivers? Third bullet: this will often not be possible. R3: Oui pour la prise de décision partagée mais le soignant doit être capable d'argumenter et de convaincre le patient à accepter une prévention adaptée à ses besoins,	3	5	5	5	91%	We propose a "softer" formulation: an individual plan of care is adopted based on assessment data, identified risk factors and patient goals and preferences. The plan is developed in interaction with the patient, significant others and the healthcare professional. The planned and agreed/refused actions are documented.
Training and education of professional caregivers should be an integral part of any pressure	**Training and education should be tailored both to the needs of individual caregiver and to the responsibilities of the group of professionals.**	Best practice		R10: we should take care that all responsibilities are met within the group. It is not necessary that each individual knows everything, but the sum of the knowledge of the persons in the group should be sufficient	4	5	5	5	100%	

Item	Recommendation(s)	GOR	LoE	Comments	Min	Max	Mean	Median	% 4 or 5	Decision
ulcer prevention policy in all healthcare settings – Best Practice	**Following components should be considered as part of each educational/training programme: o Risk assessment; o Skin assessment; o Selection and use of pressure redistributing devices; o Patient repositioning; o Methods of documenting risk assessments and preventive activities; o The importance of an interdisciplinary approach; o The education of patient and their informal caregivers.**	Best practice		R10: I suppose that nothing is told about the treatment, because this will be in another document? R8: Je propose d'ajouter l'évaluation nutritionnelle du patient – identification des risques liés à la mal nutrition	4	5	5	5	100%	We propose to add: etiology and risk factors predisposing to pressure ulcer; Classification pressure ulcers; Differntial diagnosis with other type of skin lesions; nutritional
Risk assessment – Recommendation	**Use a structured approach to risk assessment to identify individuals at risk of developing pressure ulcers. This structured approach should include all of following components: o Clinical judgement informed by knowledge of key risk factors; o The use of a risk assessment tool. As clinical studies do not demonstrate the superiority of one risk assessment tool over another, decisions about which risk assessment tool (Braden, Norton, Waterlow…) to be used should be based on the intended patient population (adults, children, elderly,…) and the intended care setting (ICU, general wards, paediatrics, home care…) and the experience and expertise of the healthcare staff; o A comprehensive skin assessment to evaluate any alterations to intact skin.**	Strong	Very Low	R9: First bullet: Can 'key risk factors' be explained? R8: Il serait utile de faire la différence entre plaie d'escarre et plaie de macération. En l'absence de preuves sur l'utilisation d'une échelle d'évaluation et en soulignant l'intérêt du jugement clinique des soignants, il serait utile de souligner l'intérêt du développement du jugement clinique dans la formation des soignants. R3: et une anamnèse complète du patient	4	5	5	5	100%	Risk factors (see below: this will be added)
Risk assessment – Best practice	**Pressure ulcer risk assessment should be performed at each first patient contact. Reassessment should be undertaken at regular time intervals and if there is any change in the individual's medical condition. The decision on time intervals should be based on an individual basis.**	Best practice		R10: is it feasible to give the maximal time interval that can be allowed?R1: risico evaluatie moet gebeuren op vastgestelde tijdstippen en niet op individuele basis. Groot risico dat het over het hoofd wordt gezien of niet wordt gedaan!	2	5	4	5	82%	

Item	Recommendation(s)	GOR	LoE	Comments	Min	Max	Mean	Median	% 4 or 5	Decision
	Clinical judgement should take into account several key risk factors such as reduced mobility, immobility, pressure, shear, sensory impairment, acute deterioration of general health status, incontinence, reduced level of consciousness, advanced age, previous history of pressure damage, vascular disaese, undernutrition, poor hydration status (Non-limitative list).	Best practice			5	5	5	5	100%	
	Risk assessment should be documented and made accessible to all members of the multidisciplinary team	Best practice			5	5	5	5	100%	
Skin assessment – recommendation	**A comprehensive skin assessment should be part of a structured risk assessment approach.**	Strong	Low	R8: OK mais la recommandation devrait être plus explicite sur ce qu'est une évaluation complète de la peau	4	5	5	5	100%	We suggest to add: "a head-to-toe skin assessment with special attention to vulnerable areas, especially bony prominences"
Skin assessment – best practice	**Skin assessment should be an integral part of daily routine care and the frequency of inspection may need to be increased in response to the evolution of the individual's condition (improvement or deterioration).**	Best practice		R9: Increase only in case of deterioration, I suppose, R8: et de l'évaluation du niveau de risque	4	5	5	5	100%	we will change "increased" into adapted and add "and level of risk" We will remove daily
	Inspect the skin regularly for signs of redness. A patient is considered at risk when non-blanchable erythema is observed.	Best practice			5	5	5	5	100%	delete "a patient considered at risk …
	Skin assessment should also include assessment for localized heat, edema, or induration (hardness).	Best practice		R10: in the case these parameters are observed: also important to document changes (increased heat eg is more important) and important to think about other possible diagnoses (infection, eczema, other skin diseases)	2	5	5	5	90%	We will add frail skin, NBE and combine it with the previous best-practice
	Observe the skin for pressure damage caused by medical devices.	Best practice			5	5	5	5	100%	

Item	Recommendation(s)	GOR	LoE	Comments	Min	Max	Mean	Median	% 4 or 5	Decision
	In patients with darkly pigmented skin, consider a patient at risk when there are: o purplish/bluish localised areas of skin; o localised heat which, if tissue becomes damaged, is replaced by coolness; o localised oedema; o localised induration.	Best practice		R10: analogous remarks as above	3	5	5	5	90%	
	Any skin changes should be documented and made accessible to all members of the multidisciplinary team.	Best practice		R10: also need for a system to "alert" the other teammembers when a certain skin change is observed	4	5	5	5	100%	We will change this in: Any skin changes should be documented, made accessible and communicated to the multidisciplinary team.
Skin massage – recommendation	**Skin massage and rubbing, particularly over bony prominences, should be avoided to prevent pressure ulcers**	Strong	Very Low		4	5	5	5	100%	
Skin massage – best practice	**The clinical effectiveness of various types of skin products (e.g. creams, ointments) being intended for other purposes (such as skin hydration, skin protection) was not studied for this guideline. However, applying such products requires a gentle massage technique; rubbing of the skin should be avoided.**	Best practice		R9: As this was not studied for this guideline, I would omit it form the recommendations. In my opinion you cannot include something that was not subject of the guideline. R3: Ok pour doit être évité et non devrait être évité	2	5	4	5	91%	The clinical effectiveness of various types of skin products (e.g. creams, ointments) being intended for other purposes (such as skin hydration, skin protection) was not studied for this guideline. Applying such products requires a gentle application technique; rubbing of the skin should be avoided.

Item	Recommendation(s)	GOR	LoE	Comments	Min	Max	Mean	Median	% 4 or 5	Decision
Repositioning – recommendation	**A repositioning protocol (including specifications about posture and frequency) should be established and documented for each person at risk for pressure ulcer development**	Strong	Very Low		5	5	5	5	100%	
	Individuals being at risk for pressure ulcer development should be repositioned. The frequency and method for repositioning and the posture should be determined and adapted based on an individual assessment and should take into account: o the patient's medical condition; o the patient's skin condition; o the patient's level of activity and mobility; o the patient's comfort; o the patient's overall plan of care; o the characteristics of the support surface.	Strong	Very Low	R9: Is the 'overall plan of care' an addition to the other mentioned points? I find it rather vague. R8: L'évaluation du risque doit aussi être un élément à prendre en compte	3	5	5	5	91%	We will add 'level of risk'
	Repositioning – lying position o Repositioning using the 30° tilted side-lying position is recommended if the individual can tolerate it and her/his medical condition allows (back supported and sacrum free).	Strong	Very Low	R10: shouldn't there be an "it" after allows?	5	5	5	5	100%	
Repositioning technique – best practices	**Repositioning should be undertaken (alternately, right side, back, left side) or the prone position if the individual can tolerate this and her/his medical condition allows. Avoid postures that increase pressure, such as the 90-degree side-lying position, or the semi- recumbent position.**	Best practice		R10: idem	5	5	5	5	100%	
	Increase the contact surface between the patient and the support surface to redistribute and reduce the pressure maximally on the patient's skin and underlying tissue.	Best practice			5	5	5	5	100%	
	Avoid the skin being exposed to pressure or shearing forces	Best practice		R9: This recommendation is somewhat superfluous in my opinion.	3	5	5	5	91%	
	Avoid positioning the individual on a bony prominence, especially if non -blanchable erythema is present	Best practice			4	5	5	5	100%	

Item	Recommendation(s)	GOR	LoE	Comments	Min	Max	Mean	Median	% 4 or 5	Decision
	Manual handling devices should be used correctly (Lift – don't drag – the individual) in order to minimise shear and friction damage. After patient manipulation, any slings, hoists, sleeves or other parts of the handling equipment being used should be removed immediately if they can damage the skin (a slide sheet can be tolerated and helps to prevent shear forces in combination with a good posture).	Best practice			3	5	5	5	82%	
	If sitting upright in bed is needed, a head-of-bed elevation and slouched position (increasing pressure and shear on the sacrum and coccyx.) should be avoided.	Best practice		R9: I don't understand why a head of bed elevation should be avoided if sitting upright in bed is needed.	4	5	5	5	100%	We suggest to change this as follows "more than 30° head-of bed elevation should be avoided"
	Avoid pressure of medical devices or other materials directly on the skin and underlying tissue (e.g. tubes, drainage systems, syringes, caps….).	Best practice		R10: if the device or material is thick enough, there could also be some problems if there is not a direct pressure (eg with clothes or bed linen in between.	4	5	5	5	100%	
Repositioning schedule – best practices	**Assess the individual's skin condition and general comfort on a regular basis. If the individual is not responding to the repositioning regimen as being expected(e.g. if Category I pressure ulcer occurs), the frequency, method, and applied postures for repositioning should be reconsidered, documented and made accessible to all members of the multidisciplinary team.**	Best practice		R9: e.g. If Cat I PU occurs,,, is in fact not a good example as sometimes patiënts are only considered at risk if they have Cat I PU)	4	5	5	5	100%	if a not pre-existing Category I pressure ulcer occurs
Repositioning seating – best practices	**Position the individual so as to maintain his/her full range of normal activities. Make sure that everything he/she needs is in reach;**	Best practice			4	5	5	5	100%	

Item	Recommendation(s)	GOR	LoE	Comments	Min	Max	Mean	Median	% 4 or 5	Decision
	The time that individuals at risk for pressure ulcer development are seated in a chair should be limited. The time a patient is seated in a chair should be determined and continuously adapted based on an individual assessment and should take into account comfort/dignity, the overall plan of care, the medical condition, and the characteristics of the pressure relieving devices used;	Best practice			3	5	5	5	91%	
	The posture of individuals who spend substantial periods of time in a chair or wheelchair should take into account: distribution of weight of the support surface (cushion); postural alignment; pressure points and support of feet.	Best practice		R9: Support of feet is in upright sitting position? Mention here also the principle of floating heels when sitting backwards? Can't be mentioned that sitting upright results in higher pressure than sitting in backwards position? R8: Des propositions de repositionnement du patient devraient être ajoutées	4	5	5	5	100%	We will take NPUAP formulation for 4.2 (p35) postural alignment (by the use of positioning devices)
Repositioning patient eucation – best practices	**Individuals (or informal carers assisting the individual) who are willing and able should be taught the principles of weight distribution and how to achieve this.**	Best practice			3	5	5	5	82%	
Redistributing devices – recommendation	**The use of pressure redistributing devices (low-tech constant low pressure surfaces or high-tech support surfaces) is recommended for individuals at risk of pressure ulcers development.**	Strong	Very Low		5	5	5	5	100%	
	Mattresses without pressure redistributing or relieving characteristics should be avoided to prevent ulcers development in at risk individuals.	Strong	Very Low	R10: "ulcer development" in stead of ulcers R8: Chez les patients à risques	2	5	5	5	90%	

Item	Recommendation(s)	GOR	LoE	Comments	Min	Max	Mean	Median	% 4 or 5	Decision
	Pressure redistributing overlays are recommended on the operating table. Consider the use of a visco elastic polymer support surface on the operating table.	Strong	Low		4	5	5	5	100%	
Redistributing devices – best practices	**The Choice of pressure-relieving devices: o As clinical studies do not demonstrate the superiority of one pressure redistributing device over another, decisions about which pressure redistributing device to use should be based on an overall assessment of the individual including level of risk, comfort and general health state. Appropriateness of each device in different care settings, and other considerations (e.g. cleaning, type of mattress cover, Cardiopulmonary resuscitation -function, disinfection and cost) can contribute to guide the choice.**	Best practice		R10: cardiopulmonary (minor case) R9: Is a very vague recommendation… R8: Ok mais pour tout patient à risque un matelas réducteur de pression doit être recommandé	4	5	5	5	100%	We will remove this part to the recommendation: As clinical studies do not demonstrate the superiority of one pressure redistributing device over another, decisions about which pressure redistributing device to use should be based on an overall assessment of the individual including level of risk, comfort and general health state. (line 35)
	Verify the functionality of the pressure redistributing device on a regular basis.	Best practice		R8: Sur base de quels critères ?; DD: I would complete this by "Ensure optimal use of the device" (by checking the manual)". In daily practice this seems to be often a bottleneck R3: Préciser davantage : à chaque prise de service, pause horaire..	4	5	5	5	100%	
	Use a pressure redistributing seat cushion for an individual at risk of pressure ulcer development when in a seated position: o No seat cushion showed to out-perform another, therefore no recommendation can be made about which type of cushion to use for pressure redistribution purposes.	Best practice		R9: Also very vague. ° No "pressure redistributing" seat cushion,,,	3	5	5	5	82%	ok

Item	Recommendation(s)	GOR	LoE	Comments	Min	Max	Mean	Median	% 4 or 5	Decision
	In addition to the use of overlays on the operating table, other general preventive measures should be undertaken during surgery: o Position the patient in such a way as to reduce the risk of pressure ulcer development, especially by avoiding shear forces. o Elevate the heels completely (offload them) in such a way to redistribute the weight of the leg along the calf without putting all the pressure on the Achilles tendon. The knee should be in flexion and supported. o Several devices to redistribute pressure (e.g. face pillows for patients in a prone position on the operating table) are available but no devices have shown to out-perform another, therefore no recommendation can be made about which type to use for pressure redistribution purposes.	Best practice		R9: First and second bullet: add 'if possible' R8: Ok mais cette bonne pratique devrait se retrouver plus haut (sous la recommandation relative à la table d'opération). Néanmoins, la mise en décharge de l'appui des talons ne doit pas être recommandée uniquement pour la salle d'op mais chez tous les patients à risque.	4	5	5	5	100%	
Heel ulcer prevention – recommendation	**The use of devices that ensure that heels are free of the surface of the bed in combination with a mattress with pressure-relieving characteristics is recommended for individuals at risk for pressure ulcers development. No device has been shown to out-perform another, therefore no recommendation can be made about which type to use for pressure redistribution purposes.**	Strong	Very Low	R8: OK voir ci-dessus R1: hielen moeten verplicht in zweefstand geplaatst worden bij risico	4	5	5	5	100%	

Item	Recommendation(s)	GOR	LoE	Comments	Min	Max	Mean	Median	% 4 or 5	Decision
Heel ulcer prevention – best practices	**Heel-protection devices should elevate the heel completely (offload them) in such a way as to distribute the weight of the leg along the calf without putting pressure on the Achilles tendon. The knee should be in slight flexion and supported.**	Best practice		R9: Pay also attention at heel PU prevention while sitting! R8: Un schéma devrait permettre de mieux comprendre la position proposée (idem pour les différentes positions du patient couché et assis)	4	5	5	5	100%	We will start the phrase with "for bedridden individuals or individuals restricted to a chair in " ma's decubitus.be integreren change putting pressure in applying pressure voorste Geert + schem's decubitus.be
	Inspect the skin of the heels regularly.	Best practice		R10: can we be more precise about "regularly"? Minimum frequency?	4	5	5	5	100%	
Nutrition – recommendation	**As clinical studies do not demonstrate the superiority of one nutritional intervention on another, a specific diet cannot be recommended to prevent the development of pressure ulcers.**	Strong	Very low	R3: préciser davantage	3	5	5	5	90%	
Nutrition best-practices	**Best practice includes monitoring the nutritional status of individuals as part of a general assessment procedure and as an ongoing process throughout an individual's episode of care. Initially, this assessment should include documentation and monitoring of the following factors: o current weight and height; o recent weight loss; o usual eating habits; o recent changes in eating habits and intake.**	Best practice		R9: I wonder if it needed to describe the elements of the nutritional assessment? R8: Il est important de noter que ces éléments doivent être suivis en pluridisciplinarité	4	5	5	5	100%	

Item	Recommendation(s)	GOR	LoE	Comments	Min	Max	Mean	Median	% 4 or 5	Decision
	If nutritional risk is suspected, practitioners should undertake more detailed screening. A formal nutritional risk assessment scale may be preferred to help with this and nutritionally compromised individuals should be referred to a dietician.	Best practice		R10: does this include blood levels of oligo-elements? Suggestion to foresee a multidiscplinary approach for the nutritionally compromised individuals (including a dietician, medical doctor) R9: This recommendation implies that a nutritional ris assessment scale is only used in suspected risk patients. However, a general assessment can also be done with a risk assessment scale… R3: biologie: préalbumine, protéine, CRP	3	5	5	5	90%	should referred to a dietician => should be discussed multidisciplinary

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