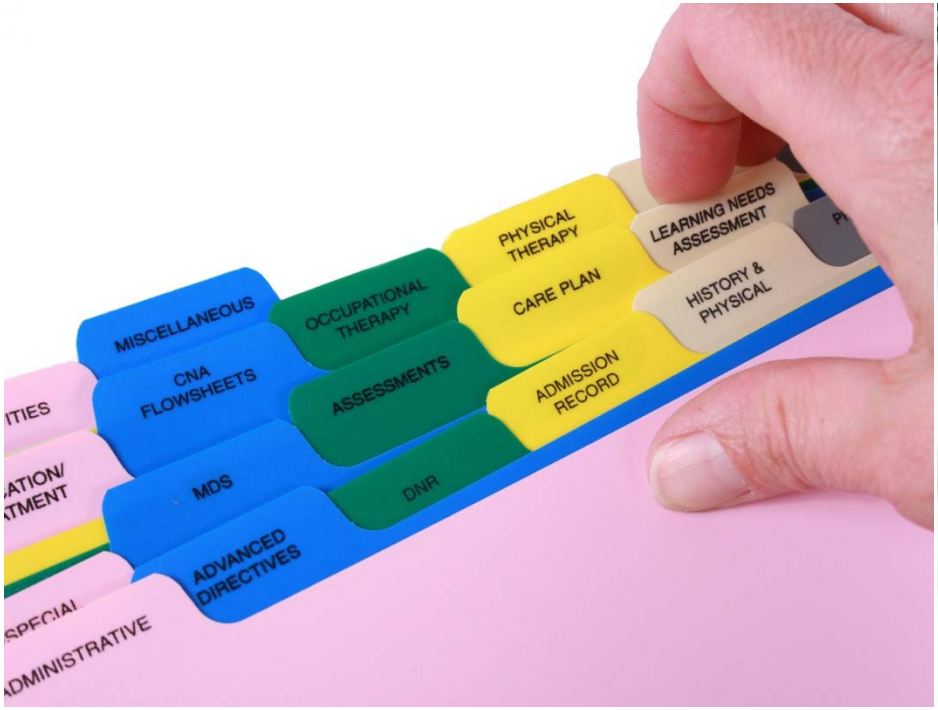
KCE REPORT 203S1

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

A NATIONAL GUIDELINE FOR THE TREATMENT OF PRESSURE ULCERS

APPENDIX VOLUME I



KCE REPORT 203S1
GOOD CLINICAL PRACTICE

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
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A NATIONAL GUIDELINE FOR THE TREATMENT OF PRESSURE ULCERS

APPENDIX VOLUME I (APPENDICES 1-2)

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

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COLOPHON

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Authors:	Dimitri Beeckman (UGent), Cathy Matheï (KULeuven), Aurélie Van Lancker (UGent), Geert Vanwalleghem (CNC vzw/ WCS/ AZ Delta), Sabine Van Houdt (KULeuven), Luc Gryson (CNC vzw), Hilde Heyman (WCS), Christian Thyse (AFISCeP.be), Adinda Toppets (UZLeuven), Sabine Stordeur (KCE), Koen Van den Heede (KCE)
External experts:	Diégo Backaert (Thuiszorg Groep Backaert); Hilde Beele (UZ Gent); Daniëlle Declercq (UMC Sint-Pieter); Anne Hermand (Cliniques uiversitaires Saint-Luc, Bruxelles); Aurore Lafosse (Cliniques universitaires Saint-Luc, Bruxelles); Dominique Putzeys (CIPIQ-s); Evelien Touriany (Militair Ziekenhuis Koningin Astrid); Dirk Van De Looverbosch (CRA Zorgbedrijf Antwerpen); Katrien Vanderwee (O.L.V. van Lourdes ziekenhuis Waregem).
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LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
ACA	Available case analysis
ADL	Activity of daily living
AE	Adverse events
BMI	Body mass index
BUN	Blood urea nitrogen
CBC	Complete blood count
IHD	Ischemic heart disease
IQR	Interquartile range
ITT	Intention-to-treat analysis
LTC	Long-term care
MID	Minimal important difference
MMSE	Mini-mental state examination
NDT	Neurodevelopmental treatment
NR	Not reported
OR	Odds ratio
PSST	Pressure sore status tool
PU	Pressure ulcer
PUSH	Pressure ulcer scaling for healing
RD	Risk difference
RN	Registred nurse
RR	Relative risk
SCI	Spinal cord injury
SD	Standard deviation
SEM	Standard error of the mean

TAO	Topical antibiotic ointment
TIBC	Total iron binding capacity
USD	US Dollar

1. NUTRITION FOR TREATMENT

1.1. Review protocol

Table 1 – Protocol review question

Protocol	Nutrition for treatment
Review question	• What are the most clinically effective nutritional interventions for the treatment of pressure ulcers?
Population	• People of any age with existing pressure ulcers in any care setting
Intervention	• Nutritional interventions (supplementation or special diet) • Hydration • For treatment of pressure ulcers
Comparison	• Usual diet (including hospital diet) • Other supplementation • Other special diet
Outcomes	**Critical outcomes for decision-making:** • Time to complete healing (time to event data) • Rate of complete healing (continuous data) • Rate in change of size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer. • Proportion of patients completely healed within trial period **Important outcomes:** • Pain (wound-related) • Time in hospital (continuous data) • Patient acceptability of supplements – eg measured by compliance, tolerance, reports of unpalatability • Side effects (nausea, vomiting, diarrhoea) • 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 for treatment
	o Manchester Short Assessment of Quality of Life o EQ-5D o WHO-Quality of life BREF o Cardiff HRQoL tool o HUI o Pressure ulcer quality of life (Gorecki)
Study design	• 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 of patients who do not already have active pressure ulcers at time of enrolment • Studies with outcomes that do not involve pressure ulcers • 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. Must have active pressure ulcers at time of enrolment. • Intervention - Different types of nutritional supplementation will not be combined for meta-analysis • Comparison - any comparison which fits the inclusion criteria will be meta-analysed • 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. We will not meta-analyse studies where patients have multiple ulcer and the unit of analysis is pressure ulcer with studies where the unit of analysis

Protocol	Nutrition for treatment
	is patients. • 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 authors data. If there is a 10% differential or higher between the groups or if the missing data is higher than the event rate downgrade on risk of bias. If authors use ACA and ITT, ACA is preferable over ITT. • 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 • With and without nutritional deficiency • Different nutritional supplements • Hydrational strategies and nutritional interventions **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

1.2. Search strategy

1.2.1. Search filters

Table 2 – Search filters in OVID Medline

Search strategy	Nutrition for treatment		Results
Date	April 2013		
Database	Medline-Ovid		
Search strategy	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	Nutrition for treatment		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

Search strategy	Nutrition for treatment		Results
	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
	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
Notes			

Table 3 – Search filters in Embase

Search strategy	Nutrition for treatment		Results
Date	April 2013		
Database	Embase-OVID		
Search strategy	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

Search strategy	Nutrition for treatment		Results
	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
	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

Search strategy	Nutrition for treatment		Results
	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
	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
	51	((pool* or combined) adj2 (data or trials or studies or results)).ab.	28922
	52	cochrane.jw.	10982
	53	or/43-52	205807
	54	(26 or 53) not 42	1031869
	55	16 and 54	151

Search strategy	Nutrition for treatment		Results
	56	limit 55 to yr="2002 -Current"	105
Notes			

Table 4 – Search filters in CINAHL

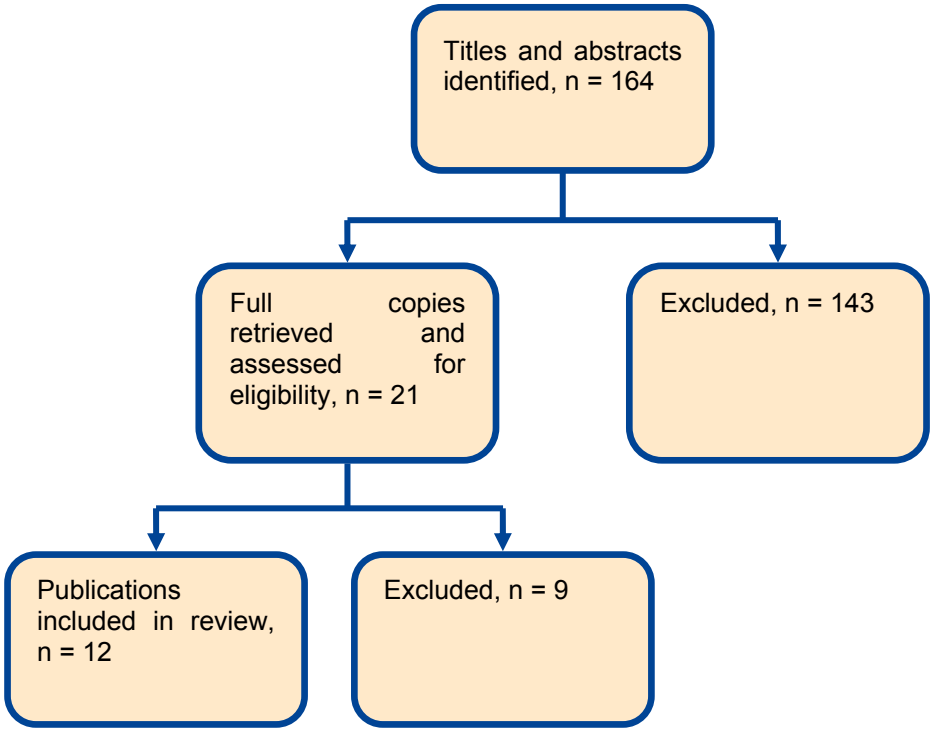
Search strategy	Nutrition for treatment		Results
	S10	s8 not s9	109
	S9	PT anecdote or PT audiovisual or PT bibliography or PT biography or PT book or PT book review or PT brief item or PT cartoon or PT commentary or PT computer program or PT editorial or PT games or PT glossary or PT historical material 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
	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	Nutrition for treatment		Results
Date	April 2013		
Database	Cochrane (- CDSR [3/2012]; DARE; Central [3/2012]; NHS EED; HTA)		
Search strategy	#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
Notes			

1.2.2. Selection of articles

Figure 1 – Flow diagram of clinical article selection for nutrition and hydration for treatment review



1.2.3. Excluded clinical studies

Table 6 – Studies excluded from the clinical review

Reference	Title	Reason for exclusion
STRATTON 2005	Enteral nutritional support in prevention and treatment of pressure ulcers: a systematic review and meta-analysis	Review.
BREWER 2004	The effectiveness of oral nutritional supplementation in the healing of pressure ulcers	Not an RCT.
MYERS 1990	Consistent wound care and nutritional support in treatment	Not included in Cochrane or old guideline. Nutritional supplementation was not clearly described.
STARKE 2011	Short-term individual nutritional care as part of routine clinical setting improves outcome and quality of life in malnourished medical patients	Not pressure ulcers
THIBAUT 2011	Acute management of nutritional demands after spinal cord injury	Systematic review which did not look at pressure ulcers.
RYPKEMA 2004	Cost-effectiveness of an interdisciplinary intervention in geriatric inpatients to prevent malnutrition	Cost-effectiveness study.
GRAY2003A	Does oral supplementation with vitamins A or E promote healing of chronic wounds	Review
YAMAMOTO 2009	Evaluation of nutrition in the healing of pressure ulcers: are the EPUAP nutritional guidelines sufficient to heal wounds?	Not an RCT – retrospective study.
HEYMAN 2008	Benefits of an oral nutritional supplement on pressure ulcer healing in long-term care residents	Not an RCT

1.3. Clinical evidence

No RCTs with interventions for hydration to treat pressure ulcers were found. For interventions for nutrition to treat pressure ulcers we found one Cochrane review[1] which included 4 randomised controlled trials (Taylor, 1974[2], Ter Riet, 1995[3], Chernoff, 1990[4], and Norris, 1971[5]). We have included these randomised controlled trials in the evidence review and have updated this Cochrane Review. Eight further randomised controlled trials were found (Desneves, 2005[6], Lee, 2006[7], Cereda, 2009[8], Van Anholt, 2010[9], Brewer, 1967[10], Benati, 2001[11] and Ohura, 2011[12]) and included. Another study found in the search looked specifically at the efficacy and safety of ornithine alpha ketogluatarate in heel pressure ulcers (Meaume, 2009[13]).

Most of the studies looked at different forms of supplementation in addition to the standard hospital diet versus the standard hospital diet alone. The supplements differed in their composition therefore we did not meta-analyse these studies together. There were two studies looking at ascorbic acid versus placebo which we meta-analysed under that comparison, although the populations were still different (nursing home and surgical patients).

Studies with ulcers of all stages were analysed separately from those with stages 2 and upwards (classification system is stated, where reported) and studies where patients were nutritionally deficient or non-nutritionally deficient were also separated.

1.3.1. Summary of included studies

Table 7 – Summary of studies included in the review

Study	Intervention/comparator	Population	Outcomes	Study length
Benati 2001[11]	normal hospital diet plus an oral supplementation with an iso-calorie and iso-protein solution enriched with arginine, vitamins and trace elements with antioxidant effect vs normal hospital diet plus oral supplementation with high protein calorie solution vs Normal hospital diet.	Patients with severe cognitive impairment and pressure ulcers. Reduced oral food intake.	Pressure sore status tool	2 weeks
Brewer 1967[10]	Oral zinc sulphate 220mgs (50mg zinc) t.i.d versus inert substance (Lactose)	Patients with spinal cord injuries and poorly healing pressure ulcers of various sizes, types, locations and duration (5 months to 2 years)	Proportion of patients completely healed; side effects	2-3 months
Cereda 2009[8]	Disease-specific nutritional treatment - standard hospital diet plus 400ml oral supplement (500kcal, 34g protein, 6g arginine, 500mg vitamin C, 18mg zinc) or tube fed 100ml high protein formula (20% energy from protein, enriched	Elderly residents of patients in long-term facilities with stage II, III or IV pressure ulcers (NPUAP 2007) – who were orally or tube fed.	Reduction in pressure ulcer area reduction in PUSH tool score at week 12; proportion of patients with complete healing; % reduction in pressure	12 weeks

	with arginine, zinc and vitamin C) versus standard protocol - hospital diet (16% energy from protein) without any additional supplement or tube fed standard formula energy and the infusion of appropriate volumes of a standard formula satisfied protein requirements.		ulcer area at 12 weeks; all cause mortality.	
Chernoff 1990[4]	Very high protein (25% of calories) formula versus high protein (16% of calories) formula	Long-term tube fed institutionalised patients with pressure ulcers	Proportion of patients with complete healing; % reduction in ulcer surface area.	8 weeks
Desneves 2005[6]	Standard hospital diet plus 2 tetrapaks of a defined arginine-containing supplement (500kcal, 21g protein, 0g fat, 500mg vitamin C, 30mg zinc and 9g arginine versus standard hospital diet plus 2 tetrapaks of high protein, high energy supplement (providing additional 500kcal, 18g protein, 0g fat, 72mg vitamin C and 7.5mg zinc) versus standard hospital diet.	Inpatients with stage 2,3 or 4 pressure ulcer. Diagnosis: dementia (n=1), cerebrovasular accident (n=6), spinal cord injury (n=2), parkinson's disease (n=1), chronic cardiac failure (n=2), fractured bones (n=3), pressure ulcers (alone) (n=1)	Reduction in PUSH tool scores.	3 weeks
Lee 2006[7]	Standard diet plus concentrated, fortified, collagen protein hydrolysate supplement versus standard diet plus placebo	Residents of long-term care facilities with pressure ulcers stage II, III or IV.	Reduction in mean PUSH tool score; % reduction in PUSH tool score	8 weeks
Norris 1971[5]	Oral zinc sulphate (200mg) capsules 3 times per day versus placebo	Patients in a hospital with chronic disease and geriatric problems with non-superficial pressure ulcers. Diagnosis: brain damage after head injury (n=1), senile	Mean reduction in pressure ulcer volume.	12 weeks treatment then crossed over for another 12 weeks

		dementia n=1), subdural hematoma (n=1), paraplegia (n=4), multiple sclerosis (n=2), cerebral thrombosis (n=1), poliomyelitis (n=1), quadriplegia (n=1), brain damage after cardiac arrest (n=1), rheumatoid arthritis, amputee (n=1)		
Ohura 2011[12]	Protein, fat, carbohydrate versus same nutrition as before trial	Tube fed patients with stage III to IV pressure ulcers. The majority of who were elderly.	Proportion of patients with complete healing within 12 weeks; reduction in pressure ulcers at 12 weeks; study-related adverse events.	12 weeks
Taylor 1974[2]	Basic hospital diet plus 500mg ascorbic acid twice daily versus basic hospital diet plus placebo	Surgical patients with pressure sores. Diagnosis fractured neck of femur n=9), rheumatoid arthritis (n=2), cerebrovascular accident (n=2), fractured pelvis (n=1), peripheral vascular disease (n=1), paraplegia (n=1), gastric ulcer (n=1), benign prostatic hypertrophy (n=1), diverticular disease (n=1), aortic aneurysm (n=1)	% surface reduction at one month; completely healed pressure sores; mean rates of healing (cm2 per week); all cause mortality.	One month
Ter Riet 1995[3]	Ascorbic acid supplementation	Patients from 11 nursing	Time to complete	12 weeks

	(500mg twice daily) as effervescent tablets versus identical placebo which contained 10mg of ascorbic acid	homes and 1 hospital with pressure ulcers (partial thickness skin loss or worse). Most patients had nutritional deficiency on admission.	healing; mean surface area reduction (cm2/week and %/week); proportion of patients with complete healing at 84 days; mean volume reduction (ml/week/%/ week); mean healing velocity (cm/week); all cause mortality	
Van Anholt 2010A[9]	Oral nutritional supplement 250kcal, 28.4g carbohydrates (45% energy), 20g protein (30% energy), 3g arginine, 7g fat (25% energy), 238mg vitamin A, 250mg vitamin C, 38mg vitamin E, 1.5mg carotenoids, 9mg zinc, 64ug selenium, 1.35mg copper, 200ug folic acid vs non-caloric, flavoured placebo	Non-malnourished patients at health care centres, hospitals and long-term care facilities, aged 18 to 90 years with stage III to IV pressure ulcers	Reduction in ulcer size per week; reduction in mean PUSH tool scores; incidence of diarrhoea, nausea and vomiting; all cause mortality	Maximum 8 weeks
Meaume 2009[13]	10g sachet of ornithine alpha-ketoglutarate versus one sachet of placebo	Elderly patients (geriatrics, internal medicine, physical medicine and rehabilitation, trauma, plastic surgery, cardiology, neurology and dermatology settings) who had pressure ulcers of the heel of stage II or II (NPUAP classification)	% reduction in pressure ulcer surface area; >90% reduction by week 6; rate of complete healing (cm2/day); all cause mortality	6 weeks.

Please note that the last study (Meaume, 2009)[13] included patients with heel ulcers only.

1.3.2. Clinical evidence GRADE-tables

Table 8 – Important difference for continuous outcomes – baseline values

Study	Treatment	Control
Pressure ulcer surface area mean cm^2 baseline values and standard deviations		
Cereda 2009 – protein, arginine, zinc	20.15 (11.13)	20.7 (14.7)
Van Anholt 2010 – protein, arginine	10.5 (2.3)	11.5 (2.5)
Meaume 2009 – alpha ketoglutarate	8.7 (6.7)	8.2 (8.9)
Median standard deviation: 7.8 x 0.5 = 3.9 MID for pressure ulcer surface area		
PUSH score mean baseline values and standard deviations		
Cereda 2009 – protein, arginine, zinc	13.5 (2.2)	14.0 (2.6)
Lee 2006 - protein	9.11 (4.15)	6.07 (2.65)
Desneves 2005 – arginine	9.4 (1.2)	8.7 (1.0)
Desneves 2005 – protein, vitamin C, zinc	8.0 (0.5)	8.7 (1.0)
Van Anholt 2010 – protein, arginine	11.5 (0.7)	11.4 (0.7)
Median standard deviation: 1.1 x 0.5 = 0.55 MID for pressure ulcer surface area		

Table 9 – 500kcal, 34g protein, 6g arginine, 500mg vit C, 18mg zinc and standard hospital diet vs standard hospital diet for preventing and treating pressure

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	500kcal, 34g protein, 6g arginine, 500mg vit C, 18mg zinc and standard hospital diet	Standard hospital diet	Relative (95% CI)	Absolute		
Proportion with complete healing – elderly LTC adults with stage II, III, IV ulcers[i] (unclear if nutritionally deficient)												
1Cereda (2009)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	1/13 (7.7%)	0/15 (0%)	Peto OR 8.62 (0.17 to 438.7)[f]	-	⊕OOO VERY LOW	Critical
								0%		-		
Mean % reduction in ulcer size (change scores) – elderly LTC adults with stage II, III, IV ulcers[i] (unclear if nutritionally deficient)												
1Cereda (2009)	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[e]	none	72% N=13	45% N=15	-	MD 27% P=0.05	⊕OOO VERY LOW	Critical
Mean reduction in ulcer size (cm2) (change scores) – elderly LTC adults with stage II, III, IV ulcers[i] (unclear if nutritionally deficient)												
1Cereda (2009)	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	serious[g]	14.5 (s.d 8.03) N=13	8.41 (s.d 5.59) N=15	-	MD 6.09 higher (0.89 to 11.29 higher)	⊕OOO VERY LOW	Critical
Mean reduction in PUSH scores (change scores) (0= complete healing, 17=greatest severity) (change scores) – elderly LTC adults with stage II, III, IV ulcers[i] (unclear if nutritionally deficient)												
1Cereda (2009)	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	Serious[d]	serious[h]	-6.1 (s.d 2.7) N=13	-3.3 (s.d 2.4) N=15	-	MD 2.8 lower (4.71 to 0.89 lower)	⊕OOO VERY LOW	Critical
								0%		-		

a Cereda (2009) Computer-generated randomisation list used but no details of allocation concealment of list. Drop-out higher than event rate for proportion with complete healing; b Confidence interval crossed both MID points (0.75 to 1.25 for dichotomous data and 0.5 x SD for continuous data). Limited number of events.; c Confidence interval crossed both MID points (0.75 to 1.25 for dichotomous data and 0.5 x SD for continuous data).; d Confidence interval crossed one MID point (0.75 to 1.25 for dichotomous data and 0.5 x SD for continuous data).; e No standard deviations given. Very small sample size.; f Peto-odds ratio was used as one arm had zero events.

g The Mann-Whitney U-test was used for nonhomogenous distribution of variance, but log transformation was not conducted. ; h Analysed using ANOVA for repeated measures but log transformation was not conducted.

i NPUAP 2007 classification of pressure ulcers.

Table 10 – 250kcal, 28.4g carbohydrates, 20g protein, 3g arginine, 7g fat, vitamins, minerals and standard hospital diet vs placebo and standard hospital diet for preventing and treating pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	250kcal, 28.4g carbohydrates, 20g protein, 3g arginine, 7g fat, vitamins, minerals and standard hospital diet	Standard hospital diet and placebo	Relative (95% CI)	Absolute		
Reduction in mean PUSH scores (change scores) – elderly non-malnourished adults with stage III-IV ulcers[h] (non-malnourished)												
1Van Anholt (2010)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Very serious[e]	None[f]	6 N=22	5.4 N=21	-	MD 0.6 P=0.011[g]	⊕OOO VERY LOW	Critical
Rate of mean reduction in ulcer size (cm^2/week) (change scores)– elderly non-malnourished adults with stage III-IV ulcers[h] (non-malnourished)												
1Van Anholt (2010)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Very serious[e]	None[f]	8.4cm^2/week[i] N=22	8.75cm^2/week[i] N=21 0.15cm^2/day after week 8	-	MD =0.35cm^2/week[i] P=0.006[g]	⊕OOO VERY LOW	Critical
Adverse events related to the product– elderly non-malnourished adults with stage III-IV ulcers[h] (non-malnourished)												
1Van Anholt (2010)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	9/22 (40.9%)	4/21 (19%)	RR 2.15 (0.78 to 5.92)	219 more per 1000 (from 42 fewer to 937 more)	⊕OOO VERY LOW	Important
								19.1%		220 more per 1000 (from 42 fewer to 940 more)		
Incidence of diarrhoea– elderly non-malnourished adults with stage III-IV ulcers[h] (non-malnourished)												
1Van Anholt (2010)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	6/22 (27.3%)	2/21 (9.5%)	RR 2.86 (0.65 to 12.64)	177 more per 1000 (from 33 fewer to 1000 more)	⊕OOO VERY LOW	Important
								9.5%		177 more per 1000 (from 33 fewer to 1000 more)		

Incidence of nausea– elderly non-malnourished adults with stage III-IV ulcers[h] (non-malnourished)												
1Van Anholt (2010)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	1/22 (4.5%)	1/21 (4.8%)	RR 0.95 (0.06 to 14.3)	2 fewer per 1000 (from 45 fewer to 633 more)	⊕OOO VERY LOW	Important
								4.8%		2 fewer per 1000 (from 45 fewer to 638 more)		
Incidence of vomiting– elderly non-malnourished adults with stage III-IV ulcers[h] (non-malnourished)												
1Van Anholt (2010)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	0/22 (0%)	1/21 (4.8%)	Peto OR 0.13 (0 to 6.51)	41 fewer per 1000 (from 48 fewer to 198 more)	⊕OOO VERY LOW	Important
								4.8%		41 fewer per 1000 (from 48 fewer to 199 more)		

a Van Anholt (2010) No details of allocation concealment or sequence generation. No details of blinding of outcome assessors. Recruitment stopped early due to lack of patients fulfilling inclusion criteria. High drop-out.

b Confidence interval crossed one MID point (0.75 to 1.25 for dichotomous data and 0.5 x SD for continuous data).

c Confidence interval crossed both MID points(0.75 to 1.25 for dichotomous data and 0.5 x SD for continuous data). Limited number of events.

d Confidence interval crossed both MID points (0.75 to 1.25 for dichotomous data and 0.5 x SD for continuous data).

e No standard deviations given. Small sample size.

f If data did not meet the assumption of normal distribution , they were log-transformed to enhance normality before statistical analysis (for pressure ulcer size).

g Study reported p value for treatment by time. P value for treatment by time^2 (curve fits: p</=0.016 for ulcer size (cm^2/week) and p</=0.033 for PUSH scores/week. Repeated-measures mixed models. Data adjusted for centre.

h EPUAP and NPUAP 2009 classification of pressure ulcers.

i Data estimated from graph.

j Mean difference calculated from estimated graph values.

Table 11 – 500kcal, 18g protein, 0g fat, 72mg vitamin C and 7.5mg zinc and standard hospital diet vs standard hospital diet for preventing and treating pressure

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	500kcal, 18g protein, 0g fat, 72mg vitamin C and 7.5mg zinc and standard hospital diet	Vs standard hospital diet	Relative (95% CI)	Absolute		
PUSH scores at week 3 (0=complete healing, 17=greatest severity) (Final scores) – elderly adults or spinal injury patients, stage 2, 3 or 4 ulcers[d] (unclear if nutritionally deficient)												
1Desneves (2005)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	serious[c]	6 (s.d 1.2) N= 5	7 (s.d 1.5) N= 6	-	MD 1 lower (2.6 lower to 0.6 higher)	⊕OOO VERY LOW	Critical

a Desneves (2005): No details of allocation concealment. No details of blinding of patients and those administering treatment but outcome assessors were blinded.

b Confidence interval crossed both MID points (0.75 to 1.25 for dichotomous data and 0.5 x SD for continuous data).

c Between-group comparisons were evaluated using the Mann-Whitney U-test but no log transformations conducted.

d Australian Wound Management Association Clinical Practice Guidelines classification of pressure ulcers.

Table 12 – 500kcal, 21g protein, 0g fat 500mg vitamin C, 30mg zinc and 9g arginine and standard hospital diet vs standard hospital diet for preventing and treating pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	500kcal, 21g protein, 0g fat 500mg vitamin C, 30mg zinc and 9g arginine and standard hospital diet	Standard hospital diet	Relative (95% CI)	Absolute		
PUSH scores at week 3 (0=complete healing, 17=greatest severity) (final scores) – elderly adults or spinal injury patients, stage 2, 3 or 4 ulcers[d] (unclear if nutritionally deficient)												
1Desneves (2005)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	Serious[b]	2.6 (s.d 0.6) N= 5	7 (s.d 1.5) N= 6	-	MD 4.4 lower (5.71 to 3.09 lower)	⊕OOO VERY LOW	Critical

a Desneves (2005): No details of allocation concealment. No details of blinding of patients and those administering treatment but outcome assessors were blinded.

b Between-group comparisons were evaluated using the Mann-Whitney U-test but no log transformations conducted.

c Australian Wound Management Association Clinical Practice Guidelines classification of pressure ulcers.

Table 13 – 500kcal 21g protein, 0g fat, 500mg vitamin C, 30mg zinc, 9g of arginine and standard hospital diet vs 500kcal 18g protein, 0g fat, 72mg vitamin C and 7.5mg zinc and standard hospital diet for preventing and treating pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	500kcal 21g protein, 0g fat, 500mg vitamin C, 30mg zinc, 9g of arginine and standard hospital diet	500kcal 18g protein, 0g fat, 72mg vitamin C and 7.5mg zinc and standard hospital diet	Relative (95% CI)	Absolute		
PUSH scores at week 3 (0=complete healing, 17=greatest severity) (final scores) – elderly adults or spinal injury patients, stage 2, 3 or 4 ulcers[c](unclear if nutritionally deficient)												
1Desneves (2005)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	Serious[b]	2.6 (s.d 0.6) N= 5	6 (s.d 1.2) N= 5	-	MD 3.4 lower (4.58 to 2.22 lower)	⊕OOO VERY LOW	Critical

a Desneves (2005): No details of allocation concealment. No details of blinding of patients and those administering treatment but outcome assessors were blinded.

b Between-group comparisons were evaluated using the Mann-Whitney U-test but no log transformations conducted.

c Australian Wound Management Association Clinical Practice Guidelines classification of pressure ulcers.

Table 14 – 4.38g protein, 2.23g fat, 15.62g carbohydrate, minerals and vitamins (per 100ml) and standard hospital diet vs standard hospital diet for preventing and treating pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Per 100ml - 4.38g protein, 2.23g fat, 15.62g carbohydrate, minerals and vitamins and standard hospital diet	Standard hospital diet	Relative (95% CI)	Absolute		
Proportion with complete healing- majority elderly, tube-fed patients with stage III to IV pressure ulcers[f] (unclear if nutritionally deficient)												
1Ohura (2011)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	7/21 (33.3%)	4/29 (13.8%)	RR 2.42 (0.81 to 7.21)	196 more per 1000 (from 26 fewer to 857 more)	⊕OOO VERY LOW	Critical
								13.8%		196 more per 1000 (from 26 fewer to 857 more)		

Mean reduction in ulcer size (cm2) (change scores)-majority elderly, tube-fed patients with stage III to IV pressure ulcers[f] (unclear if nutritionally deficient)												
1Ohura (2011)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none[d]	1.31 (s.d 0.24) N= 21	0.32 (s.d 0.2) N= 29	-	MD 0.99 higher (0.86 to 1.12 higher)[e]	⊕⊕OO LOW	Critical
Study-related adverse events –majority elderly, tube-fed patients with stage III to IV pressure ulcers[f] (unclear if nutritionally deficient)												
1Ohura (2011)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	8/29 (27.6%)	5/30 (16.7%)	RR 1.66 (0.61 to 4.47)	110 more per 1000 (from 65 fewer to 578 more)	⊕OOO VERY LOW	Important
								16.7%		110 more per 1000 (from 65 fewer to 579 more)		

a Ohura (2011): Unblinded study. High drop-out, differential >10% between arms.

b Confidence interval crossed one MID point (0.75 to 1.25 for dichotomous data and 0.5 x SD for continuous data).

c Confidence interval crossed both MID points (0.75 to 1.25 for dichotomous data and 0.5 x SD for continuous data).

d For size of pressure ulcer analyses were performed on log-transformed data, taking into consideration a lognormal distribution observed in the population at each time point.

e A graph and confidence intervals were reported in the study (which we assume to be log-transformed) so we calculated the point estimate and 95% confidence intervals.

f NPUAP classification of pressure ulcers.

Table 15 – Very high protein dietary formula (92 to 150gms/day) vs high protein dietary formula (57 to 90 gms/day) for preventing and treating pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Very high protein dietary formula (92 to 150gms/day)	High protein dietary formula (57 to 90 gms/day)	Relative (95% CI)	Absolute		
Proportion with complete healing – long-term tube-fed institutionalised patients with pressure ulcers (unclear if nutritionally deficient)												
1 Chernoff (1990)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	4/6 (66.7%)	0/6 (0%)	RR 9 (0.59 to 137.65)	-	⊕OOO VERY LOW	Critical
								0%		-		
Mean Surface Area Reduction (%) – long-term tube-fed institutionalised patients with pressure ulcers (unclear if nutritionally deficient)												
1Chernoff (1990)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	73% N=6	42% N=6	-	MD 31%	⊕OOO VERY LOW	Critical

a Chernoff (1990): Abstract. No details of sequence generation, allocation concealment or blinding. No details on baseline differences except ulcer size – the very high protein group ranged from 1.6cm^2 to 46.4cm^2 and 1.6cm^2 to 63.8cm^2 in the high protein group.

b Confidence interval crossed both MID points (0.75 to 1.25 for dichotomous data and 0.5 x SD for continuous data). Limited number of events.

c No standard deviations given. Very small sample size.

Table 16 – 1000mg ascorbic acid (500mg twice daily) and standard hospital diet vs placebo and standard hospital diet for preventing and treating pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	500mg ascorbic acid and standard hospital diet	Standard hospital diet and placebo	Relative (95% CI)	Absolute		
Proportion with complete healing – patients from 11 nursing homes and 1 hospital (most with nutritional deficiencies) with pressure ulcers (partial thickness skin loss or worse) and surgical patients (unclear if nutritionally deficient)[k]												
2 Ter Riet (1994); Taylor (1974)	randomised trials	very serious[a]	Serious inconsistency[d]	no serious indirectness	very serious[b]	none	23/53 (43.4%)[e]	25/55 (45.5%)[e]	RR 0.95 (0.62 to 1.47)	23 fewer per 1000 (from 173 fewer to 214 more)	⊕OOO VERY LOW	Critical
								39.4%		20 fewer per 1000 (from 150 fewer to		

										185 more)		
Time to complete healing (Better indicated by lower values) – patients from 11 nursing homes and 1 hospital with pressure ulcers (partial thickness skin loss or worse) (most with nutritional deficiencies)												
1 Ter Riet (1994)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	None[f]	N= 43	N= 45	-	HR 0.78 higher (0.39 to 1.54 higher)	⊕OOO VERY LOW	Critical
Mean % surface area reduction – surgical patients (unclear if nutritionally deficient)												
1 Taylor (1974)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	84 (s.d 2.4) N= 10	42.7 (s.d23.43) N= 10	-	MD 41.3 higher (20.51 to 62.09 higher)[g]	⊕OOO VERY LOW	Critical
Rate of mean reduction in ulcer size (cm2/week) – patients from 11 nursing homes and 1 hospital with pressure ulcers (partial thickness skin loss or worse) (most with nutritional deficiencies)												
1 Ter Riet (1994)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	serious[c]	none	0.21 N=43	0.27 N=45	-	MD -0.06 Adjusted difference: -0.02 (95% CI -0.20 to 0.16)[h]	⊕OOO VERY LOW	Critical
Rate of mean reduction in ulcer size (cm2/week) – surgical patients (unclear if nutritionally deficient)												
1 Taylor (1974)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[l]	None	2.47 N=10	1.45 N=10	-	MD 1.02	⊕OOO VERY LOW	Critical
Rate of mean reduction in volume (ml/week) – patients from 11 nursing homes and 1 hospital with pressure ulcers (partial thickness skin loss or worse) (most with nutritional deficiencies)												
1 Ter Riet (1994)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	serious[c]	Serious[i]	0 N=43	0.20 N=45	-	MD -0.20 Adjusted difference: -0.66 (95% CI -1.44 to 0.78)[f]	⊕OOO VERY LOW	Critical
Rate of % reduction in volume (%/week) – patients from 11 nursing homes and 1 hospital with pressure ulcers (partial thickness skin loss or worse) (most with nutritional deficiencies)												
1 Ter Riet (1994)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	serious[c,j]	Serious[i]	-3.39 N=43	16.71 N=45	-	-20.10 Adjusted difference: 35.33 (95% CI -11.31 to 81.91)	⊕OOO VERY LOW	Critical

Rate of mean healing velocity (cm/week) – patients from 11 nursing homes and 1 hospital with pressure ulcers (partial thickness skin loss or worse) (most with nutritional deficiencies)												
1 Ter Riet (1994)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	serious[c]	Serious[i]	0.12 N=43	0.19 N=45	-	-0.08 Adjusted difference -0.05 (95% CI -0.148 to 0.048)	⊕OOO VERY LOW	Critical

a Ter Riet (1994): Unclear allocation concealment. Control group had a greater number of large ulcers at baseline. High drop-out. Taylor (1974)(9): Quasi-randomised using year of birth. Inadequate allocation concealment.

b Confidence interval crossed both MID points (0.75 to 1.25 for dichotomous data and 0.5 x SD for continuous data).

c No standard deviations given.

d I^2 was 56% but p value was 0.13 so not significant. The populations differed as one study included nursing home patients and the other included surgical patients.

e Data was extracted from graphs in the Cochrane Review by Langer.

f Cox proportional hazards analysis in which wound survival ratio was adjusted for differences from baseline. Kaplan-Meier wound survival curves were done for all patients, p=0.84 log rank test, one tailed.

g We calculated the standard deviation from the standard error.

h We calculated 95% CI from 90% CI, which was presented in the paper.

i No log transformation of data and non-parametric tests used.

j Only 12 patients in the intervention group and 13 patients in the control group when this was measured.

k Ter Riet (1994): authors state that most patients had nutritional deficiency on admission. Taylor (1974)(9): does not mention if patients were nutritionally deficient.

l No standard deviations given. Small sample size.

Table 17 – Zinc sulfate vs placebo for preventing and treating pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Zinc sulfate	Placebo	Relative (95% CI)	Absolute		
Proportion with complete healing - zinc sulfate 220mg versus placebo (unclear if nutritionally deficient)												
1 Brewer (1967)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	serious[d]	1/6 (16.7%)	2/7 (28.6%)	RR 0.58 (0.07 to 4.95)	120 fewer per 1000 (from 266 fewer to 1000 more)	⊕OOO VERY LOW	Critical
								28.6%		120 fewer per 1000 (from 266 fewer to 1000 more)		
Mean reduction in pressure ulcer volume (ml) - zinc sulfate 200mg three times per day versus placebo – patients in a hospital with chronic disease and geriatric problems with non-superficial pressure ulcers (unclear if nutritionally deficient)												
1 Norris (1971)	randomised trials	very serious[c]	no serious inconsistency	no serious indirectness	very serious[b]	serious[d]	10.1 (s.d 9) N= 10	6 (s.d 17.5) N= 10	-	MD 4.1 higher (8.1 lower to 16.3 higher)	⊕OOO VERY LOW	Critical

a Brewer (1967): No details of sequence generation and unclear allocation concealment. No details of baseline values.

b Confidence interval crossed both MID points (0.75 to 1.25 for dichotomous data and 0.5 x SD for continuous data).

c Norris (1971): No details of sequence generation. High drop-out.

d No log transformations and no non-parametric tests used.

Table 18 – Concentrated, fortified, collagen protein hydrolysate vs placebo for preventing and treating pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Concentrated, fortified, collagen protein hydrolysate	Placebo	Relative (95% CI)	Absolute		
Mean reduction in PUSH scores (final scores) – elderly adults or spinal injury patients, stage 2, 3, or 4 ulcers[f] (unclear if nutritionally deficient overweight)												
1 Lee (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	serious[b]	serious[e]	3.55 (s.d 4.66) N= 44	3.22 (s.d 4.11) N= 27	-	MD 0.33 higher (1.74 lower to 2.4 higher)	⊕OOO VERY LOW	Critical
% reduction in PUSH tool score (change scores) – elderly adults or spinal injury patients, stage 2, 3, or 4 ulcers[f] (unclear if nutritionally deficien overweight)												
1 Lee (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	serious[d]	none	60% N=44	48% N=27	-	MD 12% P<0.05	⊕OOO VERY LOW	Critical

a Inadequate sequence generation, first patient was randomised by flip of coin, following patients were alternated between the two groups. No allocation concealment. High drop-out.

b Confidence interval crossed one MID point (0.75 to 1.25 for dichotomous data and 0.5 x SD for continuous data).

c Confidence interval crossed both MID points (0.75 to 1.25 for dichotomous data and 0.5 x SD for continuous data). Limited number of events.

d No standard deviations given.

e ANOVA with repeated measures was used to compare pressure ulcer healing. No log transformation and no non-parametric tests used.

f NPUAP 2005 classification for pressure ulcers.

Table 19 – Ornithine alpha-ketoglutarate vs placebo for preventing and treating pressure ulcer

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	10g Ornithine alpha-ketoglutarate	Placebo	Relative (95% CI)	Absolute		
Rate of complete healing (cm2/day) – elderly patients who had pressure ulcers of the heel of stage II or III[g] (unclear if nutritionally deficient)												
1 Meaume (2009)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	serious[b]	none	0.07 (s.d 0.11) N= 85	0.04 (s.d 0.08) N= 75	-	MD 0.03 higher (0 to 0.06 higher)	⊕OOO VERY LOW	Critical
Mean % reduction in ulcer size – elderly patients who had pressure ulcers of the heel of stage II or III[g] (unclear if nutritionally deficient) – log transformed data												
1 Meaume (2009)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious	None[f]	59.5 (s.d 71.4) N= 85	54 (s.d 69) N= 75	-	Simple analysis: MD 5.5 higher (16.28 lower to 27.28 higher) Ancova analysis p=0.477	⊕OOO VERY LOW	Critical
Mean surface area reduction (cm2) – elderly patients who had pressure ulcers of the heel of stage II or III[g] (unclear if nutritionally deficient)												
1 Meaume (2009)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious	None[f]	2.3 (s.d 4.2) N= 85	1.7 (s.d 1.7) N= 75	-	MD 0.6 higher (0.37 lower to 1.57 higher)	⊕OOO VERY LOW	Critical
90% reduction by week 6– elderly patients who had pressure ulcers of the heel of stage II or III[g] (unclear if nutritionally deficient)												
1 Meaume (2009)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Very serious[c]	none	23.4% N=85	13% N=75	OR 0.49 (CI 0.16 to 14.6)[e]	-	⊕OOO VERY LOW	Critical

a Very high drop-out in both arms. Due to problems in recruitment the study was opened up to other centres so some centres had 2 patients and randomisation balanced by blocks of four. Baseline differences. Missing data higher than event rate. ; b Confidence interval crossed one MID point. ; c Confidence interval crossed both MID points.

d value reported by study.; e Odds ratio reported by study. ; f ANCOVA used. Non-parametric tests detected between-group differences (p=0.044) which were confirmed by parametric tests after log-transformation to normalise distribution (p=0.027 for group comparisons).; g NPUAP classification of pressure ulcers.

Benati (2001)[11] met the inclusion criteria for the review but it had incomplete outcome reporting and so no results were able to be extracted from this paper.

1.3.3. Forest plots

Figure 2 – 500kcal, 34g protein, 6g arginine, 500mg vit C, 18mg zinc and standard hospital diet vs standard hospital diet – proportion with complete healing

Study or Subgroup	Supplement Events	Total	SHD Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Cereda, 2009	1	13	0	15	100.0%	8.62 [0.17, 438.70]
Total (95% CI)		**13**		**15**	**100.0%**	**8.62 [0.17, 438.70]**
Total events	1		0			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.07 (P = 0.28)

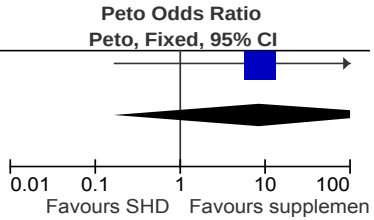


Figure 3 – 500kcal, 34g protein, 6g arginine, 500mg vit C, 18mg zinc and standard hospital diet vs standard hospital diet –mean reduction in ulcer size cm2 (change scores)

Study or Subgroup	Supplement Mean	SD	Total	SHD Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Cereda, 2009	14.5	8.03	13	8.41	5.59	15	100.0%	6.09 [0.89, 11.29]
Total (95% CI)			**13**			**15**	**100.0%**	**6.09 [0.89, 11.29]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.29 (P = 0.02)

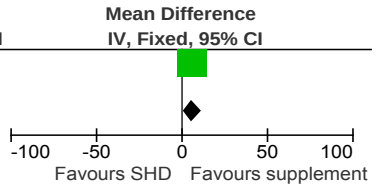


Figure 4 – 500kcal, 34g protein, 6g arginine, 500mg vit C, 18mg zinc and standard hospital diet vs standard hospital diet –mean reduction in PUSH scores (change scores)

Study or Subgroup	Supplement Mean	SD	Total	SHD Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Cereda, 2009	-6.1	2.7	13	-3.3	2.4	15	100.0%	-2.80 [-4.71, -0.89]
Total (95% CI)			**13**			**15**	**100.0%**	**-2.80 [-4.71, -0.89]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.88 (P = 0.004)

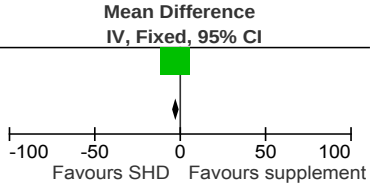


Figure 5 – 500kcal, 34g protein, 6g arginine, 500mg vit C, 18mg zinc and standard hospital diet vs standard hospital diet –all cause mortality

Study or Subgroup	Supplement Events	Supplement Total	SHD Events	SHD Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Cereda, 2009	2	15	0	15	100.0%	7.94 [0.47, 133.26]
Total (95% CI)		**15**		**15**	**100.0%**	**7.94 [0.47, 133.26]**
Total events	2		0			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.44 (P = 0.15)

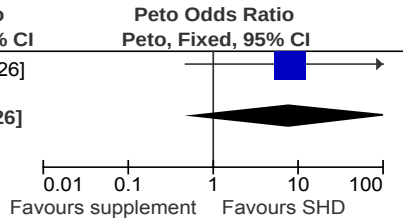


Figure 6 – 250kcal, 28.4g carbohydrates, 20g protein, 3g arginine, 7g fat, vitamins, minerals and standard hospital diet vs standard hospital diet and placebo – adverse events related to the product

Study or Subgroup	Supplement Events	Supplement Total	SHD Events	SHD Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Van Anholt, 2010	9	22	4	21	100.0%	2.15 [0.78, 5.92]
Total (95% CI)		**22**		**21**	**100.0%**	**2.15 [0.78, 5.92]**
Total events	9		4			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.48 (P = 0.14)

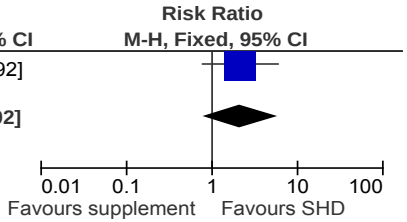


Figure 7 – 250kcal, 28.4g carbohydrates, 20g protein, 3g arginine, 7g fat, vitamins, minerals and standard hospital diet vs standard hospital diet and placebo – Incidence of diarrhea

Study or Subgroup	Supplement Events	Supplement Total	SHD Events	SHD Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Van Anholt, 2010	6	22	2	21	100.0%	2.86 [0.65, 12.64]
Total (95% CI)		**22**		**21**	**100.0%**	**2.86 [0.65, 12.64]**
Total events	6		2			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.39 (P = 0.16)

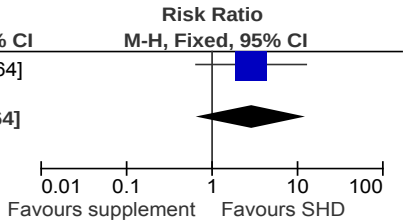


Figure 8 – 250kcal, 28.4g carbohydrates, 20g protein, 3g arginine, 7g fat, vitamins, minerals and standard hospital diet vs standard hospital diet and placebo – Incidence of nausea

Study or Subgroup	Supplement Events	Supplement Total	SHD Events	SHD Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Van Anholt, 2010	1	22	1	21	100.0%	0.95 [0.06, 14.30]
Total (95% CI)		**22**		**21**	**100.0%**	**0.95 [0.06, 14.30]**
Total events	1		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.03 (P = 0.97)

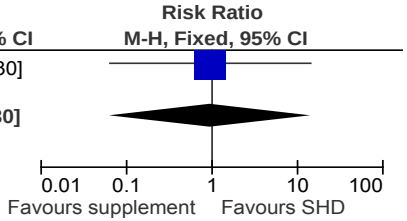


Figure 9 – 250kcal, 28.4g carbohydrates, 20g protein, 3g arginine, 7g fat, vitamins, minerals and standard hospital diet vs standard hospital diet and placebo – Incidence of vomiting

Study or Subgroup	Supplement Events	Supplement Total	SHD Events	SHD Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Van Anholt, 2010	0	22	1	21	100.0%	0.13 [0.00, 6.51]
Total (95% CI)		**22**		**21**	**100.0%**	**0.13 [0.00, 6.51]**
Total events	0		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.02 (P = 0.31)

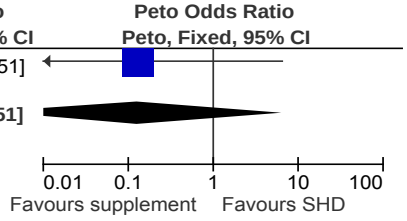


Figure 10 – 500kcal, 18g protein, 0g fat, 72mg vitamin C, 7.5 mg zinc and standard hospital diet vs standard hospital diet – PUSH scores at week 3

Study or Subgroup	Supplement Mean	Supplement SD	Supplement Total	SHD Mean	SHD SD	SHD Total	Weight	Mean Difference IV, Fixed, 95% CI
Desneves, 2005	6	1.2	5	7	1.5	6	100.0%	-1.00 [-2.60, 0.60]
Total (95% CI)			**5**			**6**	**100.0%**	**-1.00 [-2.60, 0.60]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.23 (P = 0.22)

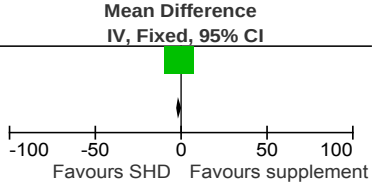


Figure 11 – per 100ml 4.38g protein, 2.23g fat, 15.62g carbohydrate, minerals and vitamins and standard hospital diet vs standard hospital diet – proportion with complete healing

Study or Subgroup	Supplement Events	Total	SHD Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Ohura, 2011	7	21	4	29	100.0%	2.42 [0.81, 7.21]
Total (95% CI)		**21**		**29**	**100.0%**	**2.42 [0.81, 7.21]**
Total events	7		4			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.58 (P = 0.11)

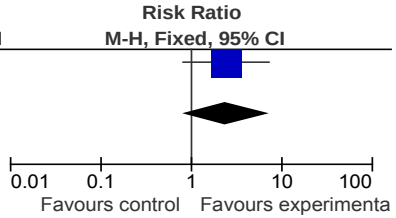


Figure 12 – per 100ml 4.38g protein, 2.23g fat, 15.62g carbohydrate, minerals and vitamins and standard hospital diet vs standard hospital diet – mean reduction in ulcer size (cm^2)

Study or Subgroup	Supplement Mean	SD	Total	SHD Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Ohura, 2011	1.31	0.24	21	0.32	0.2	29	100.0%	0.99 [0.86, 1.12]
Total (95% CI)			**21**			**29**	**100.0%**	**0.99 [0.86, 1.12]**

Heterogeneity: Not applicable
Test for overall effect: Z = 15.42 (P < 0.00001)

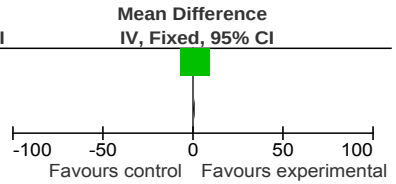


Figure 13 – per 100ml 4.38g protein, 2.23g fat, 15.62g carbohydrate, minerals and vitamins and standard hospital diet vs standard hospital diet – study-related adverse events

Study or Subgroup	Supplement Events	Total	SHD Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Ohura, 2011	8	29	5	30	100.0%	1.66 [0.61, 4.47]
Total (95% CI)		**29**		**30**	**100.0%**	**1.66 [0.61, 4.47]**
Total events	8		5			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.99 (P = 0.32)

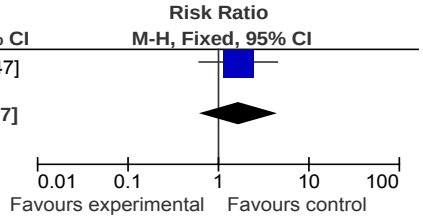


Figure 14 – 500mg ascorbic acid and standard hospital diet vs standard hospital diet and placebo – time to complete healing

Study or Subgroup	log[]	SE	Weight	IV, Fixed, 95% CI
ter Riet 1995	-0.2485	0.3481	100.0%	0.78 [0.39, 1.54]
Total (95% CI)			**100.0%**	**0.78 [0.39, 1.54]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.71 (P = 0.48)

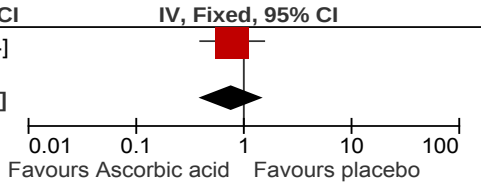


Figure 15 – Zinc sulphate 200mg vs placebo – mean reduction in pressure ulcer volume (ml)

	Zinc sulfate			Placebo				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Norris 1971	10.1	9	10	6	17.5	10	100.0%	4.10 [-8.10, 16.30]
Total (95% CI)			**10**			**10**	**100.0%**	**4.10 [-8.10, 16.30]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.66 (P = 0.51)

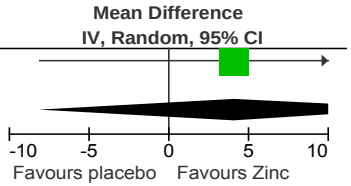


Figure 16 – Concentrated, fortified, collagen protein hydrolysate vs placebo – mean reduction in PUSH scores

	Supplement			Placebo				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Lee, 2006	3.55	4.66	44	3.22	4.11	27	100.0%	0.33 [-1.74, 2.40]
Total (95% CI)			**44**			**27**	**100.0%**	**0.33 [-1.74, 2.40]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.31 (P = 0.76)

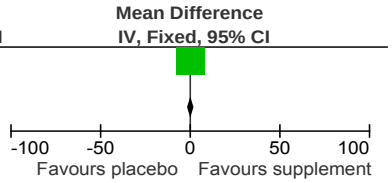


Figure 17 – Concentrated, fortified, collagen protein hydrolysate vs placebo – all cause mortality

	Supplement		Placebo			Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Lee, 2006	1	56	1	33	100.0%	0.59 [0.04, 9.11]
Total (95% CI)		**56**		**33**	**100.0%**	**0.59 [0.04, 9.11]**
Total events	1		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.38 (P = 0.71)

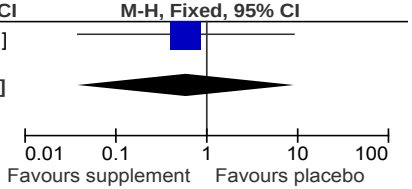


Figure 18 – Ornithine alpha-ketoglutarate vs placebo – time to complete healing

Study or Subgroup	Ornithine alpha Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Meaume, 2009	0.07	0.11	85	0.04	0.08	75	100.0%	0.03 [0.00, 0.06]
Total (95% CI)			**85**			**75**	**100.0%**	**0.03 [0.00, 0.06]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.99 (P = 0.05)

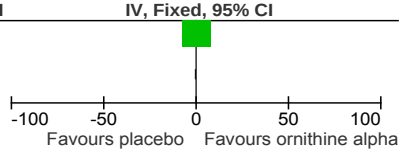


Figure 19 – Ornithine alpha-ketoglutarate vs placebo – mean% reduction in ulcer size

Study or Subgroup	Ornithine alpha Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Meaume, 2009	59.5	71.4	85	54	69	75	100.0%	5.50 [-16.28, 27.28]
Total (95% CI)			**85**			**75**	**100.0%**	**5.50 [-16.28, 27.28]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.50 (P = 0.62)

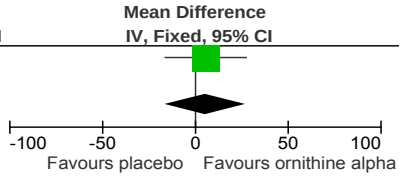
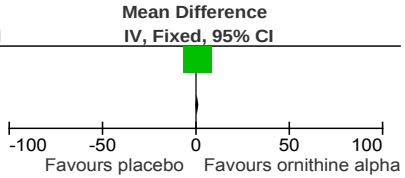


Figure 20 – Ornithine alpha-ketoglutarate vs placebo – mean surface area reduction (cm^2)

Study or Subgroup	Ornithine alpha Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Meaume, 2009	2.3	4.2	85	1.7	1.7	75	100.0%	0.60 [-0.37, 1.57]
Total (95% CI)			**85**			**75**	**100.0%**	**0.60 [-0.37, 1.57]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.21 (P = 0.23)



1.3.4. Clinical evidence tables

Table 20 – TERRIET1995

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Ter Riet (1995) Title: Randomised clinical trial of ascorbic acid in the treatment of pressure ulcers Journal: J. Clinical Epidemiol, 1995, 48(12), 1453-1460 Study type: multi-centre blinded randomised controlled trial – factorial design Sequence generation: randomisation in stratum, using random permuted blocks size 4, prepared with help of a computer program. Allocation concealment: unclear Blinding: tablets were identical; investigators, nursing staff (and physiotherapists), and patients were blinded to treatment allocation.	Patient group: patients from 11 nursing homes and 1 hospital with pressure ulcers (partial thickness skin loss or worse). Most patients had nutritional deficiencies on admission. All patients Randomised N=88 ITT N:88 Per protocol N:63 Drop-outs: 25 There were 3 deaths and 1 withdrawal in the intervention group and 5 deaths and 2 withdrawals in the control group. 7 patients died and 2 withdrew before effect measurement at 6 weeks. One died and 1 withdrew after 6 weeks follow-up.	Group 1: ascorbic acid supplementation (500mg twice daily), effervescent tables. Group 2: identical placebo containing 10mg of ascorbic acid Factorial design study and ultrasound was the second intervention under study. Randomly allocated to one of the four treatment groups (high Asorbic Acid – ultrasound; high Asorbic Acid – sham ultrasound; low Ascorbic Acid – ultrasound; low Ascorbic Acid – sham ultrasound) after pre-stratification on nursing home and muscle involvement (yes/no). The results of the ultrasound were reported elsewhere and the trial was designed on the assumption that the	Outcome 1: wound closure probability per unit time (closure rate)	Cox proportional hazards analysis: HR 0.78 (90% precision interval 0.44 to 1.39) ITT	Funding: Grant from the Netherlands Organisation for Scientific Research (NWO). Limitations: unclear allocation concealment. The control group had a greater number of large ulcers at baseline and a high drop-out. Additional outcomes: overall visual mark, wound survival time,
			Outcome 2:mean surface reduction (cm2/wk) [mean absolute healing rate]	Group 1: 0.21 cm2/week Group 2: 0.27 cm2/week Difference: -0.06cm2/week No standard deviations reported	
			Outcome 2:mean surface reduction (%/wk)	Group 1: 13.88 Group 2: 22.85 Intervention minus control -8.97 Adjusted difference (PI 90% precision interval): -3.13 (-13.66 to 7.39) ITT	
			Outcome 3: proportion healed at 84 days	Group 1: 17/43 Group 2: 22/45 Relative risk: 0.81 95% CI: 0.50 to 1.30 This was calculated by Cochrane Reviewer's from a graph (Langer 2003)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Success of blinding checked at 2 and 12 weeks. Addressing incomplete outcome data: They mention drop-outs and reasons for it but do not say which group had missing data. Type of analysis: ITT and per protocol. The authors state that they did a sensitivity analysis where trend of each drop out was extrapolated using the same group Statistical analysis: Kaplan-Meier to calculate wound survival times and Cox proportional hazards analysis to calculate the ratio of the wound closure probabilities per unit time. Baseline differences: the control group had a greater proportion of patients with very large ulcers which might be a prognostic disadvantage in	Three patietns were excluded from the analyses pertaining to wound surface areas. One patient was found to be ineligible. Group 1 Randomised N: 43 ITT N:43 Per protocol N:35 Dropouts: 8 Wound status: bad 34.9%, normal 58.1%, good 7.0%. Nutritional status: bad 69.8%, normal 30.2% Vitamin C: </=2mg/l 25.6%, 2-4mg/l 37.2%, >4mg/l 37.2%. Mobility: bad 16.3%, normal 60.5%. Subcutaneous cushioning: bad 16.3%, normal 83.7%. Care level: bad 37.2%, normal 62.8% Concomitant diseases: bad 20.9%, normal 79.1%, overall pressure	effect of AA supplementation was not modified by ultrasound. Patients were on water beds and repositioned once every 3 hours. Flotation pads were provided if patients were sat up. Patients received wound care once (or exceptionally twice) daily. Debridement was performed when indicated. Ulcers were covered with paraffin and hydrophilic gauze. Topical antibiotics were left to the treating physician but discouraged by authors of study.	Outcome 4: mean volume reduction (ml/week)	Group 1: 0 ml/week Group 2: 0.20 ml/week Difference: -0.20ml/week	
			Outcome 4: mean volume reduction (%/wk)	Group 1: -3.39 Group 2: 16.71 Intervention minus control -20.10 Adjusted difference (PI 90% precision interval): 35.33 (-74.58 to 3.91)	
			Outcome 5: mean healing velocity (cm/wk)	Group 1: 0.12 Group 2: 0.19 Intervention minus control -0.08 Adjusted difference (PI 90% precision interval): -0.05 (-0.13 to 0.03)	
			Outcome 6: mean clinical change where improvements (surface reduction, healing velocity, volume reduction) scored on a scale from 100 to +100%:	Group 1: 17.89%/week Group 2: 26.08%/week Difference: -8.19%/week	
			Outcome 7: all	Group 1: 3/43 (6.98%)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
survival analysis. Prognostic baseline covariates grouped in cogent clusters and used in the analysis to control for confounders. Baseline similarity for these cluster variables was good for five of eight clusters, leaving some room for confounding. The authors used the clusters in a multivariate analysis to correct for potential confounding and found that the adjusted differences were close to the crude ones. Study power/sample size: n=88, no sample size calculations given Setting: 11 nursing homes and 1 hospital in the South of the Netherlands Length of study: 12 weeks Categorisation of PUs: not stated, says that recruited patients with	ulcer status 65.1%, normal 34.9% Group 2 Randomised N: 45 ITT N:45 Per protocol N: 28 Dropouts: 17 Wound status: bad 33.3%, normal 48.9%, good 17.8% Nutritional status: bad 69.8%, normal 30.2%. Vitamin C: </=2mg/l 26.7%, 2-4mg/l 24.4%, >4mg/l 48.9% Mobility: bad 42.2%, normal 57.8% Subcutaneous cushioning: bad 22.2%, normal 77.8% Care level: bad 33.3%, normal 66.7%. Concomitant diseases: bad 20.0%, normal 80.0%. Overall pressure ulcer status: bad 77.8%, normal 22.2%		cause mortality	Group 2: 5/45 (11.1%) RR: 0.63 95% CI: 0.16 to 2.47	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
pressure ulcers with partial thickness skin loss or worse. Assessment of PUs: Slides were made and projected and wound contours drawn and scanned into computer, where surface area was calculated by computer programme. If possible ulcer volumes were measured by Berg et al (1990)'s method. Multiple ulcers: would use ulcers located on the trunk first and second would choose most serious PU.	Inclusion criteria: pressure ulcers with partial thickness skin loss or worse. If there were multiple ulcers they preferred ulcers located on the trunk and then chose the most serious one. Exclusion criteria: difficulties with swallowing or frequent vomiting, osteomyelitis in the ulcer area, idiopathic hemochromatosis, thalassemia major, sideroblastic anemia, Cushing's syndrome or disease, pregnancy, radiotherapy in the ulcer area, and the use of antineoplastic agents or systemic glucocorticosteroids. A high probability to drop out within the 12-week follow-up period (terminally ill patients, patients for whom surgical treatment of the ulcer – other than				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	debridement – had been planned) also led to exclusion; patients who were already taking vitamin C supplements in excess of 50mg/day; patients with grade II ulcers (partial thickness skin loss) could participate only if de-epithelialisation had persisted for at least 7 days without interruption; patients with leg ulcers had to have a positive history of pressure on that site to be eligible.				

Table 21 – NORRIS1971

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Norris 1971 Title: The effect of oral zinc sulphate therapy on decubitus ulcers Journal: J. Am Geriatr. Soc. 1971, 19(9), 793-797 Study type: double-blinded crossover RCT. Study quality: Sequence generation: no details of how generated Allocation concealment: tablets were packaged in separate containers by the hospital pharmacy and labelled Zincate A and Zincate B. The physicians and the nursing staff did not know the exact contents of these capsules until completion. Blinding: identical appearing capsules Addressing incomplete	Patient group: patients with decubitus ulcers All patients Randomised N=14 Completed N=3 Drop-outs: 11 - ulcer healed (2); died (7); transferred to surgery (1); discharged home (1). 6 of these 11 patients were in the study for 12-16 weeks. 10/14 received zinc sulphate for 4-12 weeks and 8 received only placebo for 4-12 weeks. Patients who received placebo for less than 4 weeks following 12 weeks of zinc sulphate were not included in the calculations for the control group due to 'probably spillover effect from the zinc therapy. Age range: 26-88 years M/F: 9/5 Group 1	Group 1: oral zinc sulphate (200mg) capsules 3 times per day. Group 2: placebo	Outcome 1: mean net change of ulcer volume	Group 1: 10.1ml (s.d 9ml) (10 patients) Group 2: 6.0ml (s.d 17.5ml) (10 patients) T value in comparing the means: NS (0.7</=p</=0.8) Weighted Mean Difference: 4.1ml 95%CI: -8.10 to 16.30, p=0.5	Funding: C.R Canfield and Company (supplied the zinc sulphate and defraying incidental costs). Limitations: Very small study. No details of sequence generation and a high drop-out rate. Many patients died (7) but do not know which arm of the crossover this occurred. Crossover study but no washout period. Additional outcomes:

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
outcome data: gives details of reasons patients dropped out but unclear which arm of trial when discontinued. Type of analysis: did not use ITT analysis, but assessed volume in 10 patients receiving oral zinc sulfate therapy for 4-12 weeks and in 8 receiving placebo for 4-12 weeks. Statistical analysis: no tests mentioned Baseline differences: N/A Study power/sample size: very small (14 patients) Setting: The Chronic Disease Hospital of Baltimore City Hospitals (a 320 bed unit for the care of patients with chronic disease and those with geriatric problems) Study length: 24	Randomised N: 7 Completed: unclear Dropouts: unclear Group 2 Randomised N: 7 Completed N: unclear Dropouts: unclear Inclusion criteria: all hospital patients with decubitus ulcers Exclusion criteria: those with neoplastic disease or those in the terminal phase of their illness; case with superficial ulcers or deep sinus tracts excluded because the authors thought that the volume measurements would be inaccurate. Patients had: brain damage after head injury (1), senile dementia (1), subdural hematoma (1), paraplegia (4), multiple				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
weeks (12 weeks then crossed over for another 12 weeks) Categorisation of ulcers: not reported Assessment of ulcers: Volume assessed by filling ulcers with a rapidly-setting alginate hydrocolloid (Jeltrate). After solidification ulcer volume determined by immersing Jeltrate impression in a graduated cylinder and measuring the displacement of water in millimeters (adaptation of Pories et al method)	sclerosis (2), cerebral thrombosis (1), poliomyelitis (1), quadriplegia (1), brain damage after cardiac arrest (1), rheumatoid arthritis; amputee (1).				

Table 22 – TAYLOR 1974

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Taylor 1974 Title: Ascorbic acid supplementation in the	Patient group: surgical patients with a pressure sore. All patients	Group 1: basic hospital diet plus 500mg ascorbic acid (twice daily).	Outcome 1: mean % (SE) reduction in area at one month	Group 1: 84% (SE 7.60) Group 2: 42.7% (SE 7.41) Relative risk: Weighted Mean Difference 41.30	Funding: Joint Research Board of the Institute of Child Health and

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
treatment of pressure sores Journal: Lancet, 1974, 2(7880), 544-546. Study type: double-blind quasi-randomised controlled trial Study quality: Sequence generation: allocated to treatment groups A or B according to their year of birth. Allocation concealment: no details Blinding: identical white tablets were used. The data were analysed by an independent blinded observer. Addressing incomplete outcome data: no details given on drop-outs. Type of analysis: not reported Statistical analysis: no mention of statistical	Randomised N=20 Completed N= 18 Drop-outs: 2 (patients died – one in each group) Diagnosis: 9 had fractured neck of femur, 2 had rheumatoid arthritis or cerebrovascular accident, and one patient had fractured pelvis, peripheral vascular disease, paraplegia, gastric ulcer, benign prostatic hypertrophy, diverticular disease and aortic aneurysm. Gender: 8 males and 12 females. Age mean (range): 74.5 years (54-88 years). Group 1 Randomised N: 10 Completed N: 9 Dropouts: 1 Age (mean): not reported separately Other baseline data: not	Group 2: basic hospital diet plus placebo.		95% CI: 34.72 to 47.88 p<0.005	the Hospital for Sick Children, and the Department of Health and Social Security. Limitations: quasi-randomised using year of birth. No details allocation concealment. Additional outcomes:
			Outcome 2: completely healed pressure sores	Group 1: 6/9 (66.67%) ACA, 6/10 ITT Group 2:3/9 (33.33%) ACA, 3/10 ITT Relative risk: 2.00 95% CI: 0.68 to 5.85	
			Outcome 3: mean rates of healing	Group 1: 2.47 cm2 per week Group 2: 1.45 cm2 per week Relative risk: 95% CI:	
			Outcome 4: all cause mortality	Group 1: 1/10 Group 2: 1/10 Relative risk: 1.00 95% CI: 0.07 to 13.87	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
tests. Baseline differences: no differences Study power/sample size: very small (20 patients), no sample size calculation. Setting: Surgical ward UK Categorisation of PUs: not reported Assessment of PUs: areas assessed by one of the researchers clinically, by pressure-area tracings and by weekly photographic assessment. Study length: one month	reported separately Group 2 Randomised N: 10 Completed N: 9 Dropouts: 1 Age (mean): not reported separately Other baseline data: not reported separately Inclusion criteria: surgical patients with a pressure sore. Exclusion criteria: not stated.				

Table 23 – DESNEVES2005

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Desneves 2005 Title: Treatment with supplementary arginine, vitamin C	Patient group: Inpatients from aged care or spinal injury wards with either stage 2,3 or 4 pressure ulcer.	Group 1: Standard hospital diet plus 2 tetrapaks of a defined arginine-containing supplement (providing an additional 500kcal, 21g protein, 0g fat, 500mg	Outcome 1: improvement in pressure ulcer healing (change in PUSH tool scores from	Group 1: -1.7 (baseline: 8.7 (1.0) and week 3: 7.0 (1.5) Group 2: -2.0 (baseline 8.0 (0.5) and week 3: 6.0 (1.2) Group 3: -6.8 (baseline: 9.4	Funding: Research grant from the Windermere Foundation Ltd.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
and zinc in patients with pressure ulcers: a randomised controlled trial Journal: Clin. Nutr. 2005, 24(6), 979-987. Study type: randomised controlled trial Study quality: Sequence generation: randomly assigned into one of 3 groups sequentially by order recruited. Sequence determined before trial by list of random numbers generated by a computer program) in numerical order. Allocation concealment: no details Blinding: No details of blinding of patients and those administering treatments. Pressure ulcer assessors blinded. Addressing incomplete outcome data:	All patients Randomised N: 16 Completed N: 13 Drop-outs: 3 Age (range): 37-92 years. BMI (range): 16.4-28.1kg/m2 Group 1 Randomised N: 6 Completed N:5 Dropouts: 1 (died after completion of assessment at week 2) Age (mean and SEM): 6.30 (SEM 9.9) BMI (kg/m2 and SEM): 24.4 (1.0) Weight (kg and SEM): 63.0 (2.6) Males/females: 4/2 Diagnosis: Dementia: 0 Cerebrovascular accident:3 Spinal cord injury:1	vitamin C, 30mg zinc and 9g arginine. (diet C). Group 2: Standard hospital diet plus 2 tetrapaks of high-protein, high-energy supplement (providing additional 500kcal, 18g protein, 0g fat, 72mg vitamin C and 7.5mg zinc) (diet B). Group 3: Standard hospital diet (diet A) Pressure ulcer care including turning schedules, bed and mattress type and dressings were kept constant during the study period.	baseline) Outcome 2: Outcome 3: Outcome 4:	(1.2) and week 3: 2.6 (0.6) P<0.05 (diet C compared to diet A or B) Group 1: Group 2: Relative risk: 95% CI: Group 1: Group 2: Relative risk: 95% CI: Group 1: Group 2: Relative risk: 95% CI:	Limitations: Very small study. No details of allocation concealment or blinding of patients or those administering treatment. Did not screen for malnutrition at start of study but transthyretin levels were normal which the authors say suggest they were not severely malnourished. Additional outcomes: actual dietary intake, changes in body weight, blood biochemistry, dietary compliance.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
adequate Type of analysis: not reported Statistical analysis: within-group changes using the Friedman test with between-group comparisons using the Mann-Whitney U-test. Differences in baseline measures tested by one-way ANOVA. Repeated-measures ANOVA testing used to calculated differences in weight changes and biochemical parameters Baseline differences: BMI significantly lower for Diet C compared to Diet A or B. Study power/sample size: small. No sample size calculation given. Setting: Inpatients in Australia Length of study: 3 weeks Categorisation of PUs:	Parkinson's disease:0 Chronic cardiac failure:0 Fractured bones: 1 Pressure ulcers (alone):1 Initial stage of pressure ulcer: Stage 2: 4 Stage 3:2 Stage 4:0 Pressure ulcer location: Heel: 2 Sacrum:1 Perineal:1 Ischium:0 Ankle:1 Toe:1 Group 2 Randomised N: 5 Completed N:5 Dropouts:1 (died after completion of assessment at week 2) Age (mean and SEM): 75.6 (5.9) BMI (kg/m2 and SEM):25.6 (0.8)				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Staging according to the Australian Wound Management Association Clinical Practice Guidelines. Assessment of diary intake: daily food and fluid record Assessment of PUs: PUSH tool.	Weight (kg and SEM): 68.8 (5.8) Males/females: 3/2 Diagnosis: Dementia: 1 Cerebrovascular accident:1 Spinal cord injury:0 Parkinson's disease:0 Chronic cardiac failure:2 Fractured bones: 1 Pressure ulcers (alone):0 Initial stage of pressure ulcer: Stage 2: 5 Stage 3:0 Stage 4:0 Pressure ulcer location: Heel: 2 Sacrum:1 Perineal:0 Ischium:1 Ankle:1 Toe:0 Group 3: Randomised N: 5				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	Completed N:5 Dropouts:1 (discharged after completion of assessment at week 2) Age (mean and SEM): 83.2 (1.1) BMI (kg/m2 and SEM): 20.6(1.5) Weight (kg and SEM): 59.5 (8.7) Males/females: 3/2 Diagnosis: Dementia:0 Cerebrovascular accident:2 Spinal cord injury:1 Parkinson's disease:1 Chronic cardiac failure:0 Fractured bones: 1 Pressure ulcers (alone):0 Initial stage of pressure ulcer: Stage 2: 3 Stage 3:1 Stage 4:1 Pressure ulcer location: Heel: 1				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	Sacrum:3 Perineal:0 Ischium:1 Ankle:0 Toe:0 Inclusion criteria: Inpatients on aged care or spinal injury wards with stage 2, 3 or 4 pressure ulcer. Exclusion criteria: Clinical suspicion or diagnosis of osteomyelitis as it can cause skin ulcers with a different aetiology to pressure ulcers; patients with diabetes mellitus, individuals receiving enteral or parenteral nutrition support or individuals prescribed hydroxyurea or greater than 10mg of steroids/day as these factors inhibit wound healing.				

Table 24 – CEREDA2009

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Cereda 2009 Title: Disease-specific, versus standard, nutritional support for the treatment of pressure ulcers in institutionalised older adults: a randomised controlled trial Journal: J. Am. Geriatr. Soc, 2009, 57(8), 1395-1402. Study type: multicentre RCT Study quality: Sequence generation: computer-generated randomisation list. Allocation concealment: no details. Blinding: nurse and pressure ulcer assessor were blinded to the interventions. Addressing incomplete outcome data: adequate, 2 patients in the treatment group died and the final	Patient group: elderly participants with stage II, III and IV pressure ulcers of recent onset (<1 month history). All patients Randomised N: 30 Completed N: 28 Drop-outs: 2 patients Group 1 Randomised N: 15 Dropouts: 2 patients died within first 4 weeks of follow-up period (days 15 and 22) Completed N=13 Age (mean+/-sd):82.2+/-9.6 BMI g/m2 (mean+/-sd):20.8+/-3.2 Oral feeding:tube feeding: 4:9 Diagnoses, n: Vascular dementia: 4 Alzheimer's disease: 3 Cerebrovascular	Group 1: Disease-specific nutritional treatment - standard hospital diet plus 400mL oral supplement (500kcal, 34g protein, 6g arginine, 500mg vitamin C, 18mg zinc or tube fed 1000mL high-protein formula (20% energy from protein, enriched with arginine, zinc and vitamin c). Group 2: standard hospital diet (16% energy from protein) without any additional supplement or tube fed standard formula (standard formula satisfied protein requirements) Both groups received nutritional support of at least 30kcal/kg per day regardless of feeding method – no modification was made for patients receiving above this prior to the study. Additional wound care for both groups: reduction in pressure, turning and repositioning program	Outcome 1: pressure ulcer healing (mean reduction in pressure ulcer area) at week 12 (mean +/- s.d) mm2	Group 1: -1450 +/- 803 Group 2: -841 +/- 559 MD: p<0.005	Funding: No direct funding, Nutricia provided the supplements. Limitations: study is very small. No details of allocation concealment of the randomisation list. Additional outcomes: Change score for PUSH. Notes: nutritional intervention can only be considered effective if it produces a reduction of 20% to 40% in the PPU in the first 4 weeks (Frias 2004) Have taken
			Outcome 2: pressure ulcer healing (PUSH score) at week 12 (mean+/-s.d)	Group 1: 7.4+/-3.4 Group 2: 10.7+/-3.4 Relative risk: 95% CI: P<0.05	
			Outcome 3: complete healing	Group 1: 1/13 (7.7%) ACA Group 2: 0/15 (0%) ACA Relative risk (Peto odds ratio): 8.62 95% CI: 0.17 to 438.70	
			Outcome 4: % reduction in pressure ulcer area at 12 weeks	Group 1: 72% Group 2: 45% P=0.05	
			Outcome 5: all cause mortality	Group 1: 2/15 Group 2: 0/15 Peto OR 7.94 (0.47 to 133.26)	

analysis consisted of 28 patients which did not include these 2 patients. Type of analysis: ACA Statistical analysis: Differences in proportions were assessed with the Chi-square or fisher exact test; Comparisons of between–group and within–group s were performed using unpaired and paired student t-tests. Mann-Whitney U-test was used for nonhomogenous ANOVA. Baseline differences: no significant differences except 10 in the treatment group and 5 in the control group had more than one lesion (p=0.03) Study power/sample size: very small sample size (28 patients), no sample size calculation given. Setting: long-term facilities in Como, Italy Length of study:12 weeks follow-up	accident: 4 Psychiatric disorders: 2 MS: 0 Pressure ulcers, n: Stage II:2 Stage III:4 Stage IV:7 Group 2 Randomised N: 15 Dropouts: 0 Completed N=15 Age (mean+/-sd):81.4+/-9.9 BMI g/m2 (mean+/-sd):23.1+/-5.0 Oral feeding:tube feeding: 6:9 Diagnoses, n: Vascular dementia: 5 Alzheimer's disease: 2 Cerebrovascular accident: 5 Psychiatric disorders: 2 MS: 1 Pressure ulcers: Stage II:3 Stage III:4 Stage IV:8 Inclusion criteria:	(dynamic air mattress or gel cushion). Topical treatments, antibiotic therapy, systemic therapy. Total dietary adherence: Treatment group: 94.7% Control group: 94.3% All patients reached 85% or greater proposed cut-off.		results for week 12 but was reported at different time points.

Categorisation of PUs: NPUAP staging system Assessment of PUs: Pressure Ulcer Scale for Healing (PUSH) tool and area measurement	residents in long-term care aged 65 and older; stage II, III or IV lesions as assessed according to NPUAP staging system; patients fed orally and by feeding tubes. Exclusion criteria: presence of acute illness (e.g infection) or chronic disease (eg diabetes mellitus, peripheral vascular disease, autoimmune or neoplastic disorders) possibly affecting the nutritional intervention and healing process, positive culture from pressure ulcer swab sampling, use of immunosuppressive therapies, development of the lesion more than 1 month before evaluation, and lack of dietary adherence (<85% of prescription).				

Table 25 – MEAUME2009

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Meaume 2009	Patient group: hospitalised or	Group 1: one 10g sachet of ornithine alpha-ketoglutarate	Outcome 1: wound area	Group 1: -2.3+/-4.2cm2 Group 2: -1.7+/-1.cm2	Funding: grant from CHIESI

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Title: Efficacy and safety of ornithine alpha-ketoglutarate in heel pressure ulcers in elderly patients: results of a randomised controlled trial Study type: multi-centre double-blinded RCT Sequence generation: randomised in blocks of four, randomisation codes generated by using computer. A randomisation no. attributed to chronological order of entry of patients into the double-blind period within each investigational site. Allocation concealment: adequate Blinding: placebo had similar aspect and taste. Investigators and assessors were blinded. Addressing incomplete	outpatient elderly patients All patients Randomised N=165 ITT N: 160 Drop-outs: 72 Group 1 Randomised N: 89 ITT N: 85 (see analysis details) Completed N: 45 Dropouts:44 Age (mean):80.8+/-8.8 years (ITT) Sex (m/f): 34.1/65.9 BMI: 27.1+6.5 Ulcer area (cm2): mean 8.7+/-6.7 Median: 6.6 Min-Max: 0.71-39.05 Log-transformed ulcer area: 0.816+/-0.349 >8 area </=12cm2: 18.8% Group 2	Group 2: one sachet of placebo Both sachets given during or after lunch, preferably in 200ml of water or mixed with food. Other ulcer management included mechanical debridement, cleaning, heel elevation, dressings, heel offloading with a suspension boot, management of pain with analgesics and topical corticosteroids and topical antibacterials for excessive granulation tissue. Compliance tested with by collecting treatment kits.	changes at week 6	p=0.006	France and Italy. Limitations: well-reported trial with clear details of methodology. Study powered for 70 in each arm which was met for studies randomised but there was a very high drop-out rate in both arms. Due to difficulties in patient recruitment the study was opened to many more centres than initially planned and 2 or 3 of the centres recruited no more than 2 patients while randomisation was balanced by blocks of four. Randomisation did not balance baseline pressure ulcer
			Outcome 2:% regression in wound area	Group 1:-59.5+/-71.4% Group 2:-54.0+/-69% Relative risk: p=0.477	
			Outcome 3: >90% regression by week 6	Group 1:23.4% Group 2:13.0% OR: 0.49 95% CI: 0.16/1.46	
			Outcome 4: adverse events in patients	Group 1: 13/85 Group 2: 7/75	
			Outcome 5: severe adverse events in patients (all were considered unrelated to study treatment by investigators)	Group 1: 13/85 Group 2: 15/75	
			Outcome 6: Mortality (unrelated to drug):	Group 1: 5/89 (5.6%) Group 2: 3/76 (3.9%) Relative risk: 1.42 95% CI: 0.35 to 5.76	
			Outcome 7: Rate of complete	Group 1: -0.07 +/- 0.11cm2/day	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
outcome data: adequate Type of analysis: ITT on efficacy analyses – who take at least one dose of study medication and who had at least one post-treatment evaluation. LOCF applied to deal with missing efficacy time-points. Statistical analysis: ANCOVA (age, history of lesion and patients weight as covariates). Baseline differences: more males in OKG than placebo group; significant difference in ulcer area. Study power/sample size: power calculations 70 patients per group based on previous studies of OKG in pressure ulcer treatment. Setting: 67 investigational centres in six European	Randomised N: 76 ITT N:70 (see analysis details) Completed N:43 Dropouts:33 Age (mean):80.5+/-9.6 Sex (m/f): 52.6/47.4, p=0.017 BMI: 26.7+5.9 Ulcer area (cm2): mean 8.2+/-8.9 Median: 3.9, p=0.044 Min-Max: 0.23-48.14 Log-transformed ulcer area: p=0.027 >8 area </=12cm2, p=0.001 Inclusion criteria: males or females over age of 60 years; heel pressure ulcer (NPUAP stage II or III) occurring after accidental immobilisation; ulcer in process of recovery with early signs of granulation tissue (at least 10% of red tissue on colour scale).		healing at week 6 (cm2/day)	Group 2: - 0.04 +/- 0.08 cm2/day P=0.007	characteristics and ulcer area distribution deviated from normal distribution as healing is strongly related to baseline ulcer are the abnormal distribution was a major bias so was subgrouped. Additional outcomes: particular adverse events.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
countries. Study length: 6 weeks Categorisation of PUs: NPUAP Assessment of PUs: assessed once a week for 6 weeks.	Exclusion criteria: patients confined to bed 24 hours a day before the episode triggering development of the pressure ulcer; pressure ulcer entirely covered by necrosis or fibrin, infected ulcer; poorly controlled type I or II diabetes, dialysed patient, active neoplastic disease; parenteral nutrition; serum albumin <22g/l; advanced peripheral arterial occlusive disease [[ABPI (ankle brachial pressure index)ranging between 0.80 and 1.3 with presence of distal pulses]				

Table 26 – OHURA2011

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Ohura 2011 Title: Evaluation of	Patient group: tube-fed patients with stage III-IV pressure ulcers	Group 1: received calories according to the range of Basal Energy Expenditure	Outcome 1: Number of pressure ulcers	Group 1: 7/21 (33.3%) Group 2: 4/29 (13.8%) Relative risk: 2.42	Funding:The Health and Labor Sciences

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
effects of nutrition intervention on healing of pressure ulcers and nutritional states (randomised controlled trial) Journal: Wound Repair Regen, 2011, 19(3), 330-336. Study type: open randomised controlled trial Study quality: Sequence generation: Minimisation used Allocation concealment: minimisation method in the central enrolment centre. Blinding: none (open) Addressing incomplete outcome data: authors specified which group and the reason for exclusion. These were not included in the analysis. Statistical analysis: Wilcoxon's rank sum test (0.15 significance	(NPUAP classification) in the sacral, occygeal, trochanteric or calcaneal region. All patients Randomised N=60 No. completed: 50 Drop-outs: 10 Group 1 Randomised N: 30 Dropouts: 9 No. completed: 21 Age (mean and range): 81.4+/-8.13 (62-95) Sex (m/f): 6/15 BMI (mean +/-SD) and range: 18.60+/-4.04 (14.0-32.3) Group 2 Randomised N: 30 Dropouts: 1 No. completed: 29 Age (mean and range): 80.6+/-8.91 (58-95) Sex (m/f): 10/19	(BEE, calculated from the Harris-Benedict equation) x active factor 1.1 x stress factor 1.3-1.5. Group 2: same nutrition management as before trial. Both groups prior to study underwent a preparation period of 10 days or less to adjust to a switch in their feeding formula to Racol - this formula contained protein 4.38g, fat 2.23g, and carbohydrate 15.62g, all per 100mL of product. The ratio of omega 3 to omega 6 essential fatty acids is 1:3 in this formula, which also includes Cu 125ug, and Zn 0.64mg. The day when the calories supplied by the feeding formula reached the pre-specified value was defined as the start of the intervention period. Patients treated according to the Guidelines for Local Treatment of Pressure Ulcers. Only wound	healed within 12 weeks Outcome 2: changes in size of pressure ulcers over time (at 12 weeks) Outcome 3: study-related adverse events	95% CI: 0.81 to 7.21 Group 1: 1.32 (0.24) Group 2: 0.32 (0.2) MD 0.99 95% CI: 0.86 to 1.12 Group 1:8/29 ITT minus one who did not have treatment. Group 2:5/30 ITT Relative risk: 1.66 95% CI: 0.61 to 4.47	Research Grants (Comprehensive Research on Aging and Health) Limitations: no blinding. High differential drop-out . Additional outcomes (list additional outcomes reported in paper but not recorded in this table): changes in size of pressure ulcers at 8 weeks and at ten weeks. Also changes in size of pressure ulcers over time (stratified by median)

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
level, two-sided). ANOVA for efficacy parameters. Fisher's exact test for adverse events. For size of pressure ulcers analyses were performed on log-transformed data. Baseline differences: no significant differences Study power/sample size: small, no sample size calculation Setting: Japan. Study length: 10 days preparation, 12 weeks intervention period. When pressure ulcer resolved patient was removed from the study. Categorisation of PUs: NPUAP staging system Assessment of PUs: diagnosis and healing process determined based on NPUAP classification and DESIGN tool for	BMI (mean +/-SD) and range:17.11+/-2.56 (10.9-20.9) Inclusion criteria: albumin (Alb) 2.5-3.5g/dL, OH scale 8.5 or lower and Braden scale 9-17. Exclusion criteria: current condition or history of serious liver or renal disorder, severe diabetes mellitus, arteriosclerosis obliterans, or a malignant tumor (within the past 5 years); patients with unmanageable severe general condition or unevaluable pressure ulcer wounds (existence of necrotic tissue in 20% or more of the wound surface, wound before sharp debridement, 2cm or more in depth of the undermining, multiple pressure ulcers and wound infection).	dressing materials in general were used in this study. Use of therapeutic ointments limited to agents such as bucladesine sodium or alprostadil alfadex, antibacterial agents. Use of trafermin was prohibited. All patients used the ADVAN pressure release mattress and body position was changed every 2 hours daily. Study representative and nursing staff went round all wards to ensure consistency of nursing and care. Nursing staff were trained in how to eliminate body pressure and shear force for each patient using the 'Hand touching method'.			

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
evaluation (Japanese evaluation tool for pressure ulcers: depth, exudates, size, inflammation/infection, granulation tissue, necrotic tissue and undermining) as well as the size (length x width) and depth of pressure ulcers. The Braden scale and the OH scale were also used for observation.					

Table 27 – LEE2006

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Lee 2006 Title: Pressure ulcer healing with a concentrated, fortified, collagen protein hydrolysate supplement: a randomised controlled trial	Patient group: residents of long-term care facilities with stage II, III or IV pressure ulcers All patients Randomised N: 89 Drop-outs: 18 (11 had AEs including 2 deaths), 5 left facilities before	Group 1: standard care plus a concentrated, fortified, collagen protein hydolysate supplement Group 2: standard care plus placebo.	Outcome 1: PUSH tool scores at 8 weeks (a measurement of pressure ulcer healing) mean +/- s.d	Group 1: 3.55 +/-4.66 Group 2: 3.22 +/-4.11 MD 0.33 95% CI: -1.74 to 2.4 P<0.05	Funding: medical nutrition USA and one of authors is consultant for this company. Limitations: small sample size. Not clear which group had adverse
			Outcome 2: % reduction in PUSH tool score	Group 1: 60% Group 2: 48% MD 12%	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Study type: double-blinded multicentre RCT Sequence generation: the first patient in each building was randomised to red or white group by research assistant using the flip of a coin. Following assignments were made by alternating between the two groups. Allocation concealment: no details of who held the randomisation schedule. Blinding: Placebo was a noncaloric liquid indistinguishable from the study produce in colour, taste and texture. The placebo and intervention packaged in identical opaque white, unit-dose bottles differentiated by a numeric code and a red dot or no dot on the label. Staff were	end of trial, 2 died from causes unrelated to the study) No. completed: 71 Group 1 Randomised N: 56 Completed N: 44 Dropouts: 12/56 (21.5%) Age (mean): no details Weight (lbs) mean (SD): 157 (39.2) BMI (kg/m2) mean (SD): 27 (8.8) Kilocalories (kcal): 1381 (484.1) Protein (g): 55 (18) BUN (mg/dL): 25.2 (15.81) Creatinine (mg/dL): 0.94 (0.469) Group 2 Randomised: N= 33 Completed: 27 Dropouts: 6/33 (18%) Age (mean): no details Weight (lbs) mean (SD):		(change scores) Outcome 3: all cause mortality	P<0.05 Group 1: 1/56 (1.8%) Group 2: 1/33 (3%) Relative risk: 0.59 95% CI: 0.04 to 9.11	events and drop-outs. Additional outcomes: wound healing over time (mean push tool score) at weeks 0,2,4 and 6.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
unaware of the numeric code or the meaning of the colours. Addressing incomplete outcome data: analysed all who completed study. Authors state how many discontinued and reason but do not state from which group they dropped out from. Baseline differences: no significant differences. Study power/sample size: small, no sample size calculation given. Statistical analysis: Chi-square was conducted to compare frequency of PU stage by groups. T-test to compare mean supplement intake per group. ANOVA with repeated measures calculated to compare PU healing in the treatment and control groups. Setting: LTC facilities,	160 (55.4) BMI (kg/m2) mean (SD): 27 (7.9) Kilocalories (kcal): 1279 (520.9) Protein (g): 47 (29.4) BUN (mg/dL): 21 (16.36) Creatinine (mg/dL): 0.88 (0.498) Authors state that there were no significant differences between the 2 groups on the baseline characteristics (weight, BMI, kilocalories, protein, blood urea nitrogen and creatinine). Inclusion criteria: patients from long term care facilities with stage II, III or IV pressure ulcers. They were selected from a convenience sample from 23 LTC facilities in New York, New Jersey, Ohio and Indiana;				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
New York, New Jersey, Ohio and Indiana Study length: 8 weeks Categorisation of PUs: NPUAP staging system Assessment of pressure ulcer healing – PUSH tool used by nurses trained in the use of the tool	Exclusion criteria: terminal diagnosis, hospice care, a protein-restricted diet due to renal insufficiency, active metabolic or gastrointestinal diseases that might interfere with nutrient absorption, distribution, metabolism, or excretion (eg Crohn's disease, bowel resection, ileus, or dumping syndrome), food allergies, use of corticosteroids or antibiotics for wound infection.				

Table 28 – VAN ANHOLT2010A

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Van Anholt 2010A Title: Specific nutritional support accelerates pressure ulcer healing and	Patient group: non-malnourished patients with stage III or IV pressure ulcers	Group 1: 200ml of the specific ONS (200mL high energy supplement (250kcal, 28.4g carbohydrates, 20g protein, 3g arginine, 7g fat, 238mg vitamin A, 250 mg	Outcome 1: reduction in pressure ulcers size by time (8 weeks – study period)	Group 1: 8.4 cm2/week Group 2: 8.75 cm2/week Treatment by time: P=0.006 RMMM treatment by time2: p=0.016	Funding:Nutricia Advanced Medical Nutrition Limitations:

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
reduces wound care intensity in non-malnourished patients Journal: Nutrition, 2010, 26(9), 867-872 Study type: multicountry, randomised, controlled, double-blind, parallel group trial Study quality: Sequence generation: no details, states randomly allocated. Allocation concealment: no details. Blinding: placebo was similar in taste and appearance. Addressing incomplete outcome data: In case of drop-outs the parameters of the remaining time-points were set at 'missing'. Type of analysis: intention to treat. Statistical analysis: Repeated-measures mixed models	All patients Randomised N=47 Drop-outs: 4 before consuming anything but does not say from which group, so ITT number 43. Group 1 Randomised N: 22 Completed N: 17 Dropouts: 5 Age (mean): 76.2+/-3.2 Males/females: 8/14 Body weight (kg):66.3+/-4.5 BMI (kg/m2): 23.7+/-1.0 Ulcer location: Heel:8 Ischium:2 Sacrum:8 Trochanter:4 Ulcer size (cm2):10l5+/-2.3 Ulcer stage: Stage 3:17 Stage 4:5 PUSH tool (total	vitamin C, 38mg vitamin E, 1.5mg carotenoids, 9mg zinc, 64ug selenium, 1.35mg copper, 200ug folic acid) three times per day plus regular diet and standard wound care Group 2: non-caloric control product three times per day plus regular diet and standard wound care Standard nutrition diets and wound care were maintained according to the locally used protocols.	Outcome 2:PUSH scores by time (8 weeks – study period)	Group 1: 6 Group 2: 5.4 MD: 0.6 Treatment by time: P=0.011 RMMM treatment by time2: p=0.033	inclusion to study stopped early due to limited availability of patients who fulfilled the inclusion criteria. It was underpowered (100 subjects was originally required). Additional outcomes (list additional outcomes reported in paper but not recorded in this table): compliance, total number of dressings applied; Average time spent per week applying dressings; Tissue types (granulated, necrotic, closed, epithelial); gastrointestinal tolerance (varied
			Outcome 3: adverse events related to the product	Group 1: 9/22 (40.9%) Group 2: 4/21 (19%) RR 2.15 95% CI: 0.78 to 5.92	
			Outcome 4: incidence of diarrhoea	Group 1: 6/22 (27.3%) Group 2: 2/21 (9.5%) RR 2.86 95% CI: 0.65 to 12.64	
			Outcome 5: incidence of nausea	Group 1: 1/22 (4.5%) Group 2: 1/21 (4.8%) RR 0.95 95% CI: 0.06 to 14.3	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
(RMMM) used to compare changes in time between treatments. Data adjusted for center and baseline by including these as covariates in analysis. Baseline measurements and blood parameters analysed by ANOVA. Fisher's exact test for categorical variables. Baseline differences: no statistically significant differences Selective reporting: Study power/sample size: small (47 randomised) Setting: 8 health care centres, hospitals and long-term care facilities in four countries (Czech Republic, Belgium, The Netherlands, and Curacao). Study length: 8 weeks Assessment of PUs: healing: measured maximum length and	score):11.5+/-0.7 Group 2 Randomised N: 21 Completed N: 15 Dropouts: 6 Age (mean): 73.0+/-3.3 Males/females:11/10 Body weight (kg):75.6+/-5.3 BMI (kg/m2): 25.8+/-1.1 Ulcer location: Heel:8 Ischium:0 Sacrum:8 Trochanter:5 Ulcer size (cm2):11.5+/-2.5 Ulcer stage: Stage 3: 14 Stage 4:7 PUSH tool (total score):11.4+/-0.7 Inclusion criteria: aged 18 to 90 years; at least one stage III to IV				from zero to four per time point in the study).

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
width of ulcer with a ruler. Assuming surface area had an ellipse form they calculated the formula: length/2x width/2 x 3.14 [15.24]. If multiple pressure ulcers the local investigator selected one representative ulcer to be assessed throughout the study. The Pressure Ulcer Scale for Healing (PUSH tool) was used as a secondary parameter. Assessment of other parameters: volume consumed recorded in a diary. Tolerance (gastrointestinal) was assessed weekly by standardised questionnaires.	pressure ulcer according to the revised EPUAP classification system; receiving standard care and a standard (institutional) diet without nutritional supplements for at least 2 weeks before the study; Exclusion criteria : malnourished patients as indicated by a BMI below 18.5kg/m2 for patients 18 to 70 years old or a BMI below 21kg/m2 for those older than 70 years; severe medical conditions, non-pressure-related ulcers (e.g diabetic ulcers), life expectancy shorter than 6 months; receiving palliative care; use of corticosteroids and/or dietary restrictions e.g a protein-restricted diet. 4 drop-outs before consuming anything (1 death, 1 hospitalisation, 1 exceeding inclusion criteria for BMI, 1				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	withdrawal of informed consent). A further 11 dropped out (5 from ONS arm and 6 from CTRL arm – 1 withdrew consent, 1 due to exclusion criteria, 2 diarrhoea and or dyspepsia; 1 IHD, 3 lost to follow-up /discharged; 2 stroke recurrence, 1 taste of control). There were no details on which group the dropouts came from except 2 diarrhoea/diarrhoea and dyspepsia were in the ONS group and were judged to be related to the study product. In the control group 2 subjects discontinued due to serious (non-related) AEs (death due to cerebral vascular accident and stroke recurrence).				

Table 29 – CHERNOFF1990

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Chernoff 1990 Title: The effect of a high protein formula (replete) on decubitus ulcer healing in long term fed institutionalised patients. Journal: J. Am Diet Assoc. 1990, 90, A-130. Study type: RCT - Abstract Sequence generation: no details Allocation concealment: no details Blinding: no details Addressing incomplete outcome data: no details Type of analysis: no details Statistical analysis: no details Baseline differences: no details Study power/sample	Patient group: institutionalised tube feeding dependent patients with decubitus ulcers. All patients Randomised N: 12 Drop-outs: not reported Males/females: 5/7 Mean age: 7 1.5 years (range 6-88) Group 1 Randomised N: 6 Completed N: not reported Dropouts: not reported Ulcer size at baseline (range): 1.0cm2 to 46.4cm2 Group 2 Randomised N: 6 Completed N: not reported Dropouts: not reported Ulcer size at baseline	Group 1: very high protein (25% of calories) commercially available polymeric dietary formula. Group 2: high protein (16% of calories) commercially available polymeric dietary formula.	Outcome 1: ulcer completely healed Outcome 2: decrease in ulcer size (%)	Group 1: 4/6 (66.7%) Group 2: 0/6 (0%) Relative risk: 9 95% CI: 0.59 to 137.65 Group 1: 73% Group 2: 42% MD: 31%	Funding: no details Limitations: abstract. Pilot study of only 12 patients. No details on randomisation, allocation concealment or blinding. Additional outcomes:

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
size: very small Study length: 8 weeks monitoring Categorisation of PUs: no details Assessment of PUs: no details	(range): 1.6cm2 to 63.8cm2 Inclusion criteria: no details Exclusion criteria: no details				

Table 30 – BENATI2001

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Benati 2001 Title: Impact on pressure ulcer healing of an arginine-enriched nutritional solution Journal: Archives of gerontology and geriatrics, suppl 7, 43-47. Study type: RCT Sequence generation: no details Allocation concealment: no	Patient group: inpatients with severe cognitive impairment and pressure ulcers. They also had a reduced oral food intake. All patients Randomised N=16 Drop-outs: 0 Age (range): 72 to 91 Activities of daily living (ADL) scores (range): 0 to 3.	Group 1: normal hospital diet plus oral supplementation 2x200ml aliquots/day of a high protein calorie supplementary feeding (providing an extra 500Kcal and approximately 37g of protein each day) (group B) Group 2: normal hospital diet plus an oral supplementation 2x200ml aliquots/day of a high protein calorie supplementary feeding (providing an extra 500Kcal and approximately 37g of protein each day) plus	Outcome 1: Individual PSST scores	GRAPH of PSST score but no further outcome reporting	Funding: no details Limitations: no details of sequence generation, allocation concealment or blinding. No details of baseline differences. Short study duration. Incomplete outcome reporting of the

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
details Blinding: no details Addressing incomplete outcome data: no drop outs. Type of analysis: no details Statistical analysis: no details Baseline differences: no details except gender Study power/sample size: very small no sample size calculation Setting: hospital Study length: 15 days Categorisation of PUs: Assessment of PUs: Pressure sore status tool (PSST) at 0,5,10 and 15 days	Group 1 (group B): Randomised N: 5 Dropouts: 0 Age (mean): not reported Sex (m/f): 3/2 Group 2 (group C) Randomised N: 6 Dropouts: 0 Age (mean): not reported Sex (m/f): 2/4 Group 2 (group A) Randomised N: 5 ITT N: NR Dropouts: 0 Age (mean): NR Sex (m/f): 4/1 Inclusion criteria: severe cognitive impairment (mini mental state examination, MMSE, Folstein et al, 1975) score </=15 out of 30; pressure ulcers.	arginine (7.5g/day), zinc (25mg) and antioxidants. (group C) Group 3: normal hospital diet (group A) Other treatments: all patients layed on an alternating pressure air mattress. Pressure ulcer treatment was standardized with advanced protocols.			only outcome reported. Very small sample size. Additional outcomes (list additional outcomes reported in paper but not recorded in this table): none.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
	Exclusion criteria: patients who were unlikely to benefit from nutritional supplementation.				

Table 31 – BREWER1967

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Brewer 1967 Title: The effect of oral zinc sulphate on the healing of decubitus ulcers in spinal cord injured patients Journal: Proceedings of the annual clinical spinal cord injury conference, 16, 70-72. Sequence generation: selection of capsule was made on a random basis. Allocation concealment: two types of capsules prepared by the Pharmacy but no more	Patient group: patients with spinal cord injuries and poorly healing pressure ulcers of various size, types, locations and duration (5 months to over 2 years). All patients Randomised N: 14 Completed N: 13 Drop-outs: 1 Group 1 Randomised N: 7 Completed N: 6 Dropouts: 1	Group 1: oral zinc sulphate 220mgs (50mg zinc) t.i.d Group 2: inert substance (Lactose) t.i.d.	Outcome 1: proportion of patients completely healed	Group 1: 1/6 (16.7%) Group 2: 2/7 (28.6%) RR 0.58 95% CI: 0.07 to 4.95	Funding: no details Limitations: Very small study. No details of sequence generation and unclear allocation concealment. No details of baseline values. Additional outcomes: there was an equal number of transient gastrointestinal upsets (nausea
			Outcome 2: side effects – discontinued due to upper gastrointestinal distress (although the patient was noted to have x-ray evidence of a pre-existing prolapse of gastric mucosa into the duodenum)	Group 1: 1/7 Group 2: 0/7	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
details. Blinding: double-blinded but no details. Addressing incomplete outcome data: one patient was not able to remain on zinc sulphate. Type of analysis: not reported Statistical analysis: none Baseline differences: no details except that ulcers were various sizes, types, locations and durations (5 months to over 2 years). Study power/sample size: very small. No power calculation Setting: no details Length of study: 2-3 months. Categorisation of PUs: not reported Assessment of PUs: not reported Multiple ulcers: not mentioned.	Group 2 Randomised N: 7 Completed N: 7 Dropouts: 0 Inclusion criteria: not stated Exclusion criteria: not stated				and loose stools) – but no figures given. No significant changes in white blood counts, hemoglobins, hematocrits, total proteins, albumins, BUN, or creatinine before, during and after zinc sulphate. NB the authors state that when dealing with trace elements in micrograms there are multiple sources of contamination and therefore error. Therefore the figures are much higher than the laboratory controlled normal range of values.

2. RE-DISTRIBUTING DEVICES FOR TREATMENT

2.1. Review protocol

Table 32 – Protocol review question

Protocol	Re-distributing devices
Review question	• What are the most clinically effective pressure re-distributing devices for the treatment of pressure ulcers?
Population	• People of any age with existing pressure ulcers in any care setting
Intervention	• Mattresses/overlays o Standard foam mattresses (needs to be identified) o Alternative foam mattresses/ overlays (e.g. convoluted foam, cubed foam) o Specialised foam mattresses o Gel-filled mattresses/ overlays o Fibre-filled mattresses/ overlays o Air-filled mattresses/ overlays o Water-filled mattresses/ overlays o Bead-filled mattresses/ overlays o AP mattresses/ overlays (air-filled sacs which inflate and deflate) o Low-air-loss mattresses o Operating-table overlays o Sheepskins (synthetic/natural) • Beds o Air-fluidised beds o Low-air-loss beds – patients are supported on a series of air sacs through which warmed air passes o Air flotation beds o Bead-filled beds

Protocol	Re-distributing devices
	• Seating o Standard Chair o Tilt in space o Pressure relieving chairs o Cushions ▪ foam-filled cushions ▪ gel-filled cushions ▪ fluid-filled cushions ▪ air/dry flotation cushions ▪ alternating pressure cushions ▪ tilt-in-space ▪ Wheelchair support surfaces • Other o Pillows o Postural support o Limb protectors: pads and cushions of different forms to protect bony prominences As treatment strategies
Comparison	• Each other • No intervention
Outcomes	**Critical outcomes for decision-making:** • Time to complete healing (time to event data) • Rate of healing (continuous data) • Rate of change in size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer. • Proportion of patients completely healed within trial period

Protocol	Re-distributing devices
	Important outcomes: • Pain (wound-related) • Time in hospital (continuous data) • Patient acceptability of supplements – eg measured by compliance, tolerance • Side effects • 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 o Pressure ulcer quality of life (Gorecki)
Study design	• High quality systematic reviews of RCTs and/or RCTs only. • Crossover trials will be meta-analysed together with parallel trials • 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)
Exclusion	• Studies of patients who do not already have active pressure ulcers at time of enrolment • Studies with outcomes that do not involve pressure ulcers • 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 those specified in the strata. Must have

Protocol	Re-distributing devices
	active pressure ulcers at time of enrolment. • Intervention – different types of devices 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 unblended 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. We will not meta-analyse studies where patients have multiple ulcers and the unit of analysis is pressure ulcer with studies where the unit of analysis is patients. • 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 authors data. If there is a 10% differential or higher between the groups or if the missing data is higher than the event rate downgrade on risk of bias. If authors use ACA and ITT, ACA is preferable over ITT. • 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 • Adjunctive therapies

2.2. Search strategy

2.2.1. Search filters

Table 33 – Search filters in OVID Medline

Search strategy	Re-distributing devices			Results
Date	04/2013			
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

Search strategy	Re-distributing devices		Results
	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
	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

Search strategy	Re-distributing devices		Results
	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.	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

Search strategy	Re-distributing devices		Results
	70	limit 69 to yr="2010 -Current"	49
Notes			

Table 34 – Search filters in Embase

Search strategy	Re-distributing devices		Results
Date	04/2013		
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

Search strategy	Re-distributing devices	Results
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
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

Search strategy	Re-distributing devices	Results
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.	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

Table 35 – Search filters in CINAHL

Search strategy	Re-distributing devices		Results
Date	04/2013		
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

Search strategy	Re-distributing devices		Results
	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			

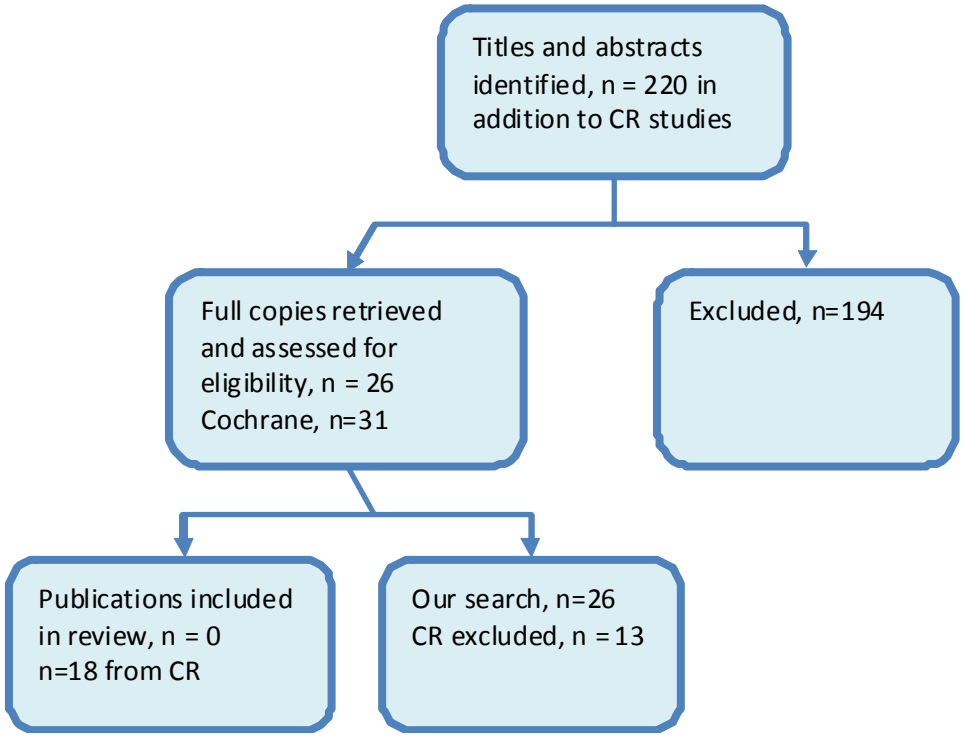
Table 36 – Search filters in Cochrane

Search strategy	Re-distributing devices		Results
Date	04/2013		
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

Search strategy	Re-distributing devices		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
Notes			

2.2.2. Selection of articles

Figure 21 – Flow diagram of clinical article selection for what are the most clinically effective pressure redistributing devices for the treatment of pressure ulcers?



2.2.3. Excluded clinical studies

Table 37 – Studies excluded from the clinical review

Reference	Reason for exclusion
Bennett 1998	Authors did not report treatment data: "too few patients with existing pressure ulcers were treated for too short a period of time to assess the effect of low-air-loss hydrotherapy on pressure sore healing"
De Roche 2004	Ulcers had been surgically closed and, therefore, were post-surgical wounds
Finnegan 2008	Ulcers had been surgically closed and, therefore, were post-surgical wounds
Gardner 2008	Not investigating pressure ulcer treatment. Outcome measure of interface pressure.
Hardin 2000	Not an RCT, measured interface pressure and included a retrospective chart audit
Lazzara 1991	Participants did not have existing pressure ulcers
Marchand 1993	Retrospective chart audit
Meyers 2008	Study did not investigate the treatment of pressure ulcers
Prebio 2005	Unclear of baseline number of pre-existing pressure ulcers
Rosenthal 1996	Study investigated interface pressures
Rosenthal 2003	Treatment outcomes were inadequately reported. Process of randomisation may have introduced bias
Stoneberg 1986	Participants did not have existing pressure ulcers
Timmons 2008	Not an RCT, but a product review
Hayes 2010	Abstract
Anon 2011B	Abstract
Mistiaen 2010B	Prevention not treatment. Economic paper
Rafter 2011	Not an RCT
Demarre 2010	Prevention not treatment
McInnes 2012	Prevention not treatment

Moysidis 2011	Prevention not treatment
Iyun 2012	Not an RCT
Demarre 2010	Prevention not treatment
Mistiaen 2010A	Prevention not treatment. Abstract
Michaluk 2010	Not an RCT
Sprigle 2010	Prevention not treatment
Brienza 2010	Prevention not treatment
House 2010	Not an RCT
Lotan 2010	Not an RCT
Malbrain 2010	Study included patients with and without pressure ulcers. Only 9 patients had pressure ulcers.
Van Leen 2011	Prevention not treatment
Donnelly 2011	Prevention not treatment
Milne 2011	Abstract
Koerner 2011	Abstract
Stone 2011	Abstract
Mistiaen 2010c	Prevention not treatment
Tang 2010	Abstract
Jan 2011	Not an RCT
Mastrangelo 2010	Abstract
Soares 2012A	Not an RCT

2.3. Clinical evidence

A Cochrane Review[14] for support surfaces for treating pressure ulcers was retrieved from the search and we used this as the basis for our review. It included 18 randomised controlled trials.[15-31] No further RCTs were found to update it.

Various types of devices were used to redistribute pressure, and the Cochrane categorised them as low-tech (non-powered) constant low pressure support surfaces, high-tech support surfaces and other support surfaces.[14]

2.3.1. Summary of included studies

Table 38 – Summary of included studies in the review

Study	Intervention/comparison	Population	Outcomes	Length of study
Allman 1987[15]	Air-fluidised therapy (CLINITRON) repositioned every 4 hours vs conventional treatment (including 2-hourly turns, heel and elbow protectors, alternating-pressure mattresses	Surgical patients aged 18 or over with pressure ulcers of all stages – Shea staging system.	Median change in total surface area of ulcers; improvement in condition of pressure ulcer; pain response.	Mean 13 days follow-up (range 4-77 days)
Branom 2001[16]	PressureGuard CFT (Constant Force Therapy) (non-powered mattress) vs LAL mattress	Inpatients from long term and sub-acute care centre specialising in ventilator-dependent patients and those with extensive wound care needs. Bedridden patients with a pressure ulcer at grade 3 or 4 on trunk or pelvis (classification system not reported)	Meeting the goals of wound treatment as determined by medical team (including wound closure, maintenance of condition and preparation for flap; The rate of wound healing over 8 weeks;	8-week follow-up
Caley 1994[32]	LAL bed (Monarch, Mediscus) vs LAL overlay	Acute care patients with existing pressure ulcers	Median change in ulcer area	Average 24-day follow-up
Clark 1998[17]	ProActive 2 cushion (Pegasus) (cushion for day chairs and wheelchairs, seating automatically adjusts to patient's weight) Vs ROHO cushion (dry flotation system) All patients had a Pegasus Airwave	Elderly patients in 2 acute care hospitals and 2 nursing homes. Grade 2 ulcers or above, classification system not reported.	Number of ulcers healed completely; rate of healing (cm2/day); rate of healing (cm3/day)	Average 58.6 days (ProActive and 43.73 days (ROHO)

	System in bed.			
Day 1993[18]	Air suspension bed (Therapulse, Kinetic concepts); Foam mattress overlay (Geomatt, SpanAmerica) Wound care standardised for 2 groups	Hospitalised, adult patients with existing grade 2-4 pressure ulcer – NPUAP classification system.	Mean ulcer size (initial minus end) divided into grade 2 and grade 3/4 ulcers; mean comfort scores	7-day follow-up
Devine 1995[19]	Alternating-pressure mattress (Nimbus I) (Modular, with rows of figure-of-eight shaped cells; two sets of cells are inflated and deflated over 10 min cycle) vs alternating-pressure mattress (Pegasus Airwave) (Double layer mattress with a 3-cell alternating cycle lasting 7.5 minutes). All patients were subject to the standard hospital protocol for wound dressing; details of this were not provided	Elderly patients in hospital with ulcers of grade 2 or above – classification system not specified.	Complete healing at 4 weeks; comfort; median rate of reduction in area (cm2/day); withdrawal rates by group and reasons for withdrawal	4-week follow-up
Evans 2000[20]	Alternating-pressure mattress replacement system (APMRS) (Nimbus 3) vs alternating-pressure mattress replacement system (APMRS) for hospital patients (P.Biwave, P.Airwave.P.Cairwave or AlphaXCell) or alternating-pressure mattress overlay (AlphaXCell or Quattro) for nursing home patients. Turning and wound care standardised for 2 groups.	Hospital and nursing patients, over 65 years with either grade 2 or 3 ulcer (classification system not reported), or grade 2 ulcer and difficulty to reposition in bed, unable to tolerate 30 degree tilt, unable to move in bed, in bed for >20 h/24 h, >108kg and bed-bound, undergone spinal anaesthetic.	Absolute and relative reduction in wound surface area; comfort	2-week follow-up period
Ferrell 1993[22]	LAL bed (KINAIR) vs 10cm convoluted foam overlay on top of standard foam mattress Both groups had similar co-interventions as per standard care i.e. mobilisation as much as possible; 2-hourly turning during waking	Elderly nursing home residents with multiple medical problems, and with trunk or trochanter pressure ulcers. Grade 2 ulcers or above (Shea	Rate of healing; wound surface area was traced twice/week on plastic film and area measured using planimetry; ulcers completely healed (covered with epithelium)	Median follow-up of 33 days (LAL group) and 40 days (foam mattress)

	hours; avoidance of head-of-bed elevation; avoidance of dragging patients on sheets; nutritional support; infection control	grading system)		
Groen 1999[23]	Foam replacement mattress (3 layers of polyurethane foam designated as comfort, load-distributing and support layers) vs Secutex water mattress (placed on top of standard hospital mattress, 3 PVC sections holding 26L water each, with heating element). Standard turning protocol (every 2-3 hour) for both groups	Nursing home patients, >59 years old with pressure ulcer on trunk of grade 3 (superficial cutaneous or subcutaneous necrotic) or grade 4 (deep subcutaneous necrotic) – no classification system reported.	Proportion with healed ulcers at 4 weeks; mean pressure ulcer severity score at 4 weeks	4-week follow-up
Keogh 2001[24]	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 old; Waterlow score of 15-25; tissue damage no greater than grade 1 (EPUAP grading system)	Proportion with healed grade 1 ulcers	5-10 days follow-up
Makhsous 2009[33]	Wheelchair cushion equipped with an individualised cyclic pressure-relief protocol vs regular wheelchair cushions Treatment was specific to patient and a variety of wound care modalities applied when required (topical wound dressings eg wound gel, hydrocolloid, alginate, foam and moisture barrier) also silver antimicrobial dressings and Negative Pressure Wound Therapy.	Wheelchair users with SCI (paraplegia or tetraplegia) with existing stage II or III pressure ulcers (classification system not specified) in the sacral and/or ischial area	Healing of pressure ulcers; healing rate of pressure ulcers; PUSH score improvement; % surface area healing; % PUSH score improvement	30 days follow-up
Mulder 1994[25]	Air suspension bed (Therapulse, Kinetic concepts) (a pulsating air suspension therapy – cushions alternatively inflate and deflate but classed as LAL rather than AP	Nursing home patients with grade 3-4 pressure ulcers (International Association of Enterostomal Therapists	Wound closure; pressure ulcer improvement (pressure ulcer reduced by one grade or more, including healed completely)	Maximum 12-weeks' follow-up or until ulcers healed, whichever came first

	vs convoluted foam mattress overlay. Wound care and repositioning standardised for both groups	staging system).		
Munro 1989[26]	Air-fluidised bed (Clinitron) vs standard care. The bed/mattress in the standard care group was not described. Sheepskins or gel pads were placed beneath ulcer areas. Standard care involved positioning and massage.	Male patients with grade 2 or 3 pressure ulcers (classification system not specified), expected to remain in hospital for at least 15 days.	Change in mean ulcer area (mm2); patients' perception of pain; patient satisfaction.	15-day follow-up
Nixon 2006[27]	Alternating-pressure overlay within 24 hours of admission vs alternating-pressure mattress within 24 hours of admission	Patients at least 55 years old, from vascular, orthopaedic, medical or care of the elderly wards with an expected length of stay at least 7 days and Braden score of 1 or 2, or an existing grade 2 pressure ulcer (grading system not specified)	Proportion of patients developing a new pressure ulcer of grade 2 or worse; time to development of new pressure ulcers; proportion of participants developing a new pressure ulcer within 30 days; healing of existing pressure ulcers; patient acceptability; adverse events.	30-day follow-up
Osterbrink 2005[28]	Repose device vs small cell vs large cell	Participants recruited from aged care facility, acute care hospitals and home care setting, over 18 years old, with at least 1 grade 2 pressure ulcer at any bony prominence (EPUAP classification). If recruited from hospital, must have been nursed on care of the elderly, neurological or surgical units.	Wound healing success; weekly changes in wounds (ulcer size, grade, wound bed, edge appearance and local wound treatment).	Follow-up time as long as clinical circumstances allowed. Maximum duration 42 days
Russell 2000[29]	2 types of alternating cell mattress systems with pressure-relieving cushions: Huntleigh Nimbus 3 with Aura cushion and 4-hourly	Patients from care of the elderly units with pressure ulcer of ≥grade 2	Ulcer healing: all types, and divided into heel and sacral ulcers	18-month follow-up

	turning vs Pegasus Cairwave Therapy System with Proactive 2 seating cushion and 8-hourly turning.	(Torrance classification system). Average age 83.9 and 84.6 years in the 2 groups.	at 12 and 18 months	
Russell 2003[30]	Alternating-pressure, multicell mattress with 10 minute cycle time (Nimbus 3) vs fluid overlay mattress (RIK static) All patients had standard 4-hourly re-positioning, but could have additional turning at the patient's request	Patients with grade 1 or 2 pressure ulcers (EPUAP classification) admitted to hospital. Mean age 80 years. Baseline Waterlow scores 21.8 and 21.3 in groups 1 and 2 respectively and baseline Burton scores 14.6 and 14.2.	Improved ulcer response; length of hospital stay	Length of follow-up unclear, but presumably until discharge from enrolment hospital
Strauss 1991[31]	Home air-fluidised therapy (CLINITRON) when grade 3 or 4 ulcers present, plus the consultative and technical services of a visiting nurse specialist vs conventional or standard therapy, patient specific and prescribed (n=50), but included alternating –pressure pads, air-filled mattresses, water-filled mattresses, high density foam pads	People: with at least 1 grade 3 or 4 pressure ulcer (Shea classification); who would probably require future hospitalisation for the pressure ulcer; with severely limited mobility; for who home air-fluidised therapy was a practical option, likely to comply, live at least 1 year; aged 16 years or over	Pressure ulcers classified by blinded observers as improved; unchanged; worse; or not accessible; pressure ulcer-related hospitalisations and costs/patient; pressure ulcer-related hospital days/patient.	36-week follow-up

2.3.2. Clinical evidence GRADE-tables

2.3.2.1. Low-tech constant pressure devices

Table 39 – Clinical evidence profile: Water mattress overlay vs low-tech mattress for treating pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Water mattress overlay	Low-tech mattress	Relative (95% CI)	Absolute		
Proportion with healed ulcers at 4 weeks – grade 3 ulcers (no classification system specified), nursing home patients, 4-week follow-up												
1Groen (1999)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	27/60 (45%)	29/60 (48.3%)	RR 0.93 (0.63 to 1.37)	34 fewer per 1000 (from 179 fewer to 179 more)	⊕OOO VERY LOW	Critical
								48.3%		34 fewer per 1000 (from 179 fewer to 179 more)		
Percentage reduction in pain – (change values)– grade 3 ulcers (no classification system specified), nursing home patients, 4-week follow-up												
1Groen (1999)	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	Very serious[c]	none	35.9%	16.2%	-	-	⊕OOO VERY LOW	Important

a Groen (1999) no details of randomisation method; unclear allocation concealment; no blinding of outcome assessors; insufficient reporting of incomplete outcome data; no details of type of analysis; selective reporting; no grading system specified.

b Confidence interval crossed both MID points.

c Not enough data to analyse in Revman.

d Baseline differences in pain at start of trial (40% in water mattress overlay group and 20% for low-tech mattress group).

2.3.2.2. High-tech pressure devices

Table 40 – Low-air-loss bed vs low-tech foam mattress overlay for treating pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Low-air-loss bed	Foam mattress overlay	Relative (95% CI)	Absolute		
Proportion with pressure ulcers completely healed (meta-analysed) – Shea grade 2 ulcers or above and IAET staging system stage III and IV ulcers – elderly nursing home patients												
2 Mulder (1994); Ferrell (1993)	randomised trials	very serious[a,c]	no serious inconsistency	no serious indirectness	serious[b]	none	31/74 (41.9%)	22/59 (37.3%)	RR 1.25 (0.84 to 1.86)	93 more per 1000 (from 60 fewer to 321 more)	⊕OOO VERY LOW	Critical
								31.5%		79 more per 1000 (from 50 fewer to 271 more)		
Proportion with pressure ulcers completely healed - Shea grade 2 ulcers or above, elderly nursing home patients, mean 36 days follow-up[g]												
1Ferrell (1993)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	serious[b]	none	26/43 (60.5%)	19/41 (46.3%)	RR 1.3 (0.87 to 1.96)	139 more per 1000 (from 60 fewer to 445 more)	⊕OOO VERY LOW	Critical
								46.3%		139 more per 1000 (from 60 fewer to 444 more)		
Proportion with pressure ulcers completely healed - International Association of Enterostomal Therapists staging system stage III and IV ulcers, nursing home patients, 12 weeks follow-up[7]												
1Mulder (1994)	randomised trials	very serious[c]	no serious inconsistency	no serious indirectness	very serious[d]	none	5/31 (16.1%)	3/18 (16.7%)	RR 0.97 (0.26 to 3.58)	5 fewer per 1000 (from 123 fewer to 430 more)	⊕OOO VERY LOW	Critical
								16.7%		5 fewer per 1000 (from 124 fewer to 431 more)		
Pressure ulcers reduced by one grade or more including healed completely - International Association of Enterostomal Therapists staging system stage III and IV ulcers, nursing home patients, 12-weeks follow up												
1Mulder (1994)	randomised trials	very serious[c]	no serious inconsistency	no serious indirectness	very serious[d]	none	10/31 (32.3%)	5/18 (27.8%)	RR 1.16 (0.47 to 2.86)	44 more per 1000 (from 147 fewer to 517 more)	⊕OOO VERY	Critical

								27.8%		44 more per 1000 (from 147 fewer to 517 more)	LOW	
Rate of healing (mm2/day) median (25th, 75th percentiles) - Shea grade 2 ulcers or above, nursing home patients, mean 36 days follow-up												
1 Ferrell (1993)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[f]	serious[i]	9.0 (4.0, 19.8)	2.5 (0.5 to 6.5)	P=0.0002	-	⊕OOO VERY LOW	Critical
Mean change in ulcer size (final values)– NPUAP stage II ulcers, hospitalised patients, 7 days follow-up												
1 Day (1993)	randomised trials	very serious[e]	no serious inconsistency	no serious indirectness	serious[b]	Serious[h]	7.3 (s.d 2.4) N= 25	5.3 (s.d 2.1) N=23	-	MD 2 higher (0.73 to 3.27 higher)	⊕OOO VERY LOW	Critical
Mean change in ulcer size (final values) – NPUAP stage III and IV ulcers, hospitalised patients, 7 days follow-up												
1 Day (1993)	randomised trials	very serious[e]	no serious inconsistency	no serious indirectness	no serious	Serious[h]	37.1 (s.d 8.1) N=17	12.4 (s.d 3.5) N=12	-	MD 24.7 higher (20.37 to 29.03 higher)	⊕OOO VERY LOW	Critical
Mean comfort scores (perception of comfort) (Better indicated by lower values) – NPUAP stage II to IV ulcers, hospitalised patients, 7 days follow-up												
1Day (1993)	randomised trials	very serious[e]	no serious inconsistency	no serious indirectness	no serious imprecision	none	4.1 (s.d 1.3) N=20	3.7 (s.d 1.3) N=19	T[37]=0.91 p>0.05	MD 0.4 higher (0.42 lower to 1.22 higher)	⊕⊕OO LOW	Critical

a Ferrell (1993) study terminated at interim analysis as difference much larger than expected. Unclear sequence generation and blinding; insufficient reporting of incomplete outcome data. Higher drop-out than event rate for proportion completely healed outcome. ; b Confidence interval crossed one MID point.; c Mulder (1994) no details of randomisation method; unclear allocation concealment and blinding; unclear which group drop-outs came from; not all of the pre-specified outcomes were reported; ulcer size not reported at baseline. Insufficient reporting of incomplete outcome data; High drop-out than event rate for proportion completely healed outcome.; d Confidence interval crossed both MID points.; e Day (1993) unclear randomisation, allocation concealment and blinding, insufficient reporting of incomplete outcome data, not all of the pre-specified outcomes were analysed. Did not report initial ulcer sizes.; f Not enough data to put in Revman.; g The Cochrane review did not conduct meta-analysis as the outcomes were measured in different ways. Ferrell (1993) used tracing of the epithelial border of the ulcer on plastic film and then the are measured using a polar planimeter. The wounds were assessed using the four-point Shea scale and the Sessing scale (similar to Shea scale, but was undergoing development at time of the study), which has 7 verbal descriptions of ulcers including colour, presence of granulation tissue, evidence of infection, drainage, odour and eschar. Mulder (1994) assessed wound surface area by photoplanimetry. Ulcer volume = ulcer length x width x depth (of deepest ulcer point). The wounds were assessed using the International Association of Enterostomal Therapists staging system. Only stage III and IV ulcers were included in this study. ; h The baseline had a larger difference than the difference between the final values therefore the results should be viewed with caution. No log transformation of data. ; i Non-parametric test (Wilcoxon rank-sum) used but no log transformation of data.

Table 41 – Low-air-loss bed vs low-air-loss overlay

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Low-air-loss bed	Low-air-loss overlay	Relative (95% CI)	Absolute		
Median change in ulcer area (cm2) – acute care patients, mean 24 day follow-up												
1 Caley (1994)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	3.9 cm^2	1.9 cm^2	P=0.060	-	⊕OOO VERY LOW	Critical
Mean changes in pressure ulcer surface area– acute care patients, mean 24 day follow-up												
1 Caley (1994)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	10.2 cm^2	3.8 cm^2	-	-	⊕OOO VERY LOW	Critical

a Very little data provided (median change in area and range); unclear (and unlikely) that the outcome assessment was blind to treatment group. No description of co-interventions except skincare protocol applied to both groups; Insufficient reporting of incomplete outcome data; high drop-out.

b No data available to analyse in Revman.

Table 42 – Air-fluidised therapy (AFT) vs standard/conventional therapies for treating pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Air-fluidised bed	Standard care	Relative (95% CI)	Absolute		
Proportion with 50% reduction in total surface area – Shea all stages, surgical patients, mean 13 days follow-up												
1Allman (1987)	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	9/31 (29%)	8/34 (23.5%)	RR 1.23 (0.54 to 2.8)	54 more per 1000 (from 108 fewer to 424 more)	⊕OOO VERY LOW	Critical
								23.5%		54 more per 1000 (from 108 fewer to 423 more)		
Proportion with improvement in pressure ulcers – Shea stage 3 or 4 ulcers, patients at home, 36 weeks follow-up												
1Strauss (1991)	randomised trials	very serious[c,i]	no serious inconsistency	no serious indirectness	Serious[d]	none	19/22 (86.4%)[o]	9/13 (69.2%)[o]	RR 1.25 (0.84 to 1.86)	173 more per 1000 (from 11 fewer to 595 more)	⊕OOO VERY LOW	Critical
								69.2%		173 more per 1000 (from 11 fewer to 595 more)		
Proportion with improvement[j] in pressure ulcers – Shea all stages, surgical patients, mean 13 days follow-up												
1Allman (1987)	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	Serious[d]	none	22/31 (71%)	16/34 (47.1%)	RR 1.51 (0.99 to 2.3)	240 more per 1000 (from 5 fewer to 612 more)	⊕⊕OO LOW	Critical
								47.1%		240 more per 1000 (from 5 fewer to 612 more)		
Proportion with improvement in pressure ulcers – Shea all stages (surgical and patients at home) – meta-analysed												
2 Allman (1987); Strauss (1991)	randomised trials	Serious[a,c]	no serious inconsistency	no serious indirectness	Serious[d]	none	41/53 (77.4%)[o]	25/47 (53.2%)[o]	RR 1.4 (1.04 to 1.88)	213 more per 1000 (from 21 more to 468 more)	⊕⊕OO LOW	Critical
								58.1%		232 more per 1000 (from 23 more to 511 more)		
Change in mean ulcer area (mm2) – stage 2 or 3 ulcers (not specified which classification system), hospital patients, 15 days follow-up (final values)												
1Munro (1989)	randomised	very	no	serious	no serious	Very serious[k]	Serious[l]	1158mm^2	2051mm^2	-	p=0.05	⊕OOO VERY	Critical

	trials	serious[e]	inconsistency	indirectness							LOW	
Change in total surface area (median, range) cm2– Shea all stages, surgical patients, mean 13 days follow-up												
1Allman (1987)	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	Very serious[f]	Serious[m]	-1.2 (-38.0 to +15.5)	+0.5 (-55.1 to +94.7)	-	Difference (median): -1.7cm2 (95% CI -9.2cm2 to -0.6cm2)	⊕OOO VERY LOW	Critical
Patient satisfaction (Better indicated by higher values) – stage 2 or 3 ulcers (not specified which classification system), hospital patients, 15 days follow-up												
1Munro (1989)	randomised trials	very serious[e,h]	no serious inconsistency	no serious indirectness	no serious imprecision	none	57.5 (s.d 6.1) N= 8	48.6 (s.d 12.3) N=10	-	MD 8.9 higher (0.18 to 17.62 higher)	⊕⊕OO LOW	Critical
Increase in comfort– Shea all stages, surgical patients, mean 13 days follow-up												
1Allman (1987)	randomised trials	very serious[a,h]	no serious inconsistency	no serious indirectness	Serious[d]	none	8/13 (61.5%)	3/14 (21.4%)	RR 2.87 (0.96 to 8.55)	401 more per 1000 (from 9 fewer to 1000 more)	⊕OOO VERY LOW	Critical
Reduction in comfort– Shea all stages, surgical patients, mean 13 days follow-up												
1Allman (1987)	randomised trials	very serious[a,h]	no serious inconsistency	no serious indirectness	very serious[b]	none	1/13 (7.7%)	6/14 (42.9%)	RR 0.18 (0.02 to 1.30)	351 fewer per 1000 (from 420 fewer to 129 more)	⊕OOO VERY LOW	Critical
Time in hospital (Better indicated by lower values) – Shea stage 3 or 4 ulcers, patients at home, 36 weeks follow-up												
1Strauss (1991)	randomised trials	very serious[c]	no serious inconsistency	no serious indirectness	very serious[b]	none	11.5 (s.d 8.8) days N= 47	21.5 (s.d 23.8) days N= 50	-	MD 10 lower (161.64 lower to 141.64 higher)	⊕OOO VERY LOW	Important
Median length of stay in hospital after randomisation– Shea all stages, surgical patients, mean 13 days follow-up												
1Allman (1987)	randomised trials	serious[a]	no serious inconsistency	no serious indirectness	Very serious[f]	none	16 days	15 days	-	-	⊕OOO VERY LOW	Important
Reduction in pain[g]– Shea all stages, surgical patients, mean 13 days follow-up												
1Allman (1987)	randomised trials	very serious[a,h]	no serious inconsistency	no serious indirectness	Serious[d]	none	8/13 (61.5%)	4/14 (28.6%)	RR 2.15 (0.85 to 5.48)	329 more per 1000 (from 43 fewer to 1000 more)	⊕OOO VERY LOW	Important

Increase in pain[g]– Shea all stages, surgical patients, mean 13 days follow-up													
1Allman (1987)	randomised trials	very serious[a,h]	no serious inconsistency	no serious indirectness	very serious[b]	none	0/13 (0%)	3/14 (21.4%)	Peto OR 0.12 (0.01 to 1.31)	183 fewer per 1000 (from 212 fewer to 49 more)	⊕OOO VERY LOW	Important
								21.4%		182 fewer per 1000 (from 212 fewer to 49 more		
								35.2%		109 fewer per 1000 (from 218 fewer to 81 more)		

a Allman (1987): unclear allocation concealment; baseline difference and size of ulcer at baseline not reported.

b Confidence interval crossed both MID points.

c Strauss (1991): unclear allocation concealment; insufficient reporting of incomplete outcome data; ulcer size at baseline not reported. High drop-out rate.

d Confidence interval crossed one MID point.

e Munro (1989): Unclear allocation concealment; no information regarding sample size calculations, randomisation method, blinding, baseline characteristics or extent of follow-up. No raw data presented in the paper; insufficient reporting of incomplete outcome data.

f Not able to analyse data in Revman.

g Change in pain intensity from baseline (from asking patients to score 0 to 5 on words to describe pain (none, mild, discomforting, distressing, horrible or excruciating).

h Patient self-reported outcomes.

i Improvement was assessed by an independent nurse reviewer's assessment of the patients' pressure sore. There was no definition of improvement.

j Improvement was defined as those pressure ulcers that had healed, much improved, or a little improved. Non-improvement included those that were unchanged, a little worse, or much worse. This was assessed by an investigator and a plastic surgeon independently from photographs.

k Change scores given by study but not able to analyse data in Revman as no standard deviations given.

l The ulcer size (diameter) at day 1 had a larger difference between the groups than the difference between the ulcer sizes at day 15. No log transformation of data.

m Non-parametric test s used but no log transformation of data.

n Less than half the participants completed questionnaire.

o Strauss: Independent nurse reviewer's assessment of the patients' pressure sore, the data was given for both reviewers and we have amalgamated the results for the 35 patients who were assessed.

Table 43 – Alternating-pressure mattress vs alternating-pressure mattress for treating pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Alternating-pressure mattress	Alternating-pressure mattress	Relative (95% CI)	Absolute		
Proportion of patients with pressure ulcers completely healed – grade 2 and above (grading system not specified), elderly patients, 4-week follow-up – Nimbus 1 vs Pegasus Airwave												
1Devine (1995)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	10/16 (62.5%)	5/14 (35.7%)	RR 1.75 (0.79 to 3.89)	268 more per 1000 (from 75 fewer to 1000 more)	⊕OOO VERY LOW	Critical
								35.7%		268 more per 1000 (from 75 fewer to 1000 more)		
Proportion with decrease in pressure ulcer size– grade 2 and above (grading system not specified), elderly patients, 4-week follow-up– Nimbus 1 vs Pegasus Airwave												
1Devine (1995)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[d]	none	4/16 (25%)	6/14 (42.9%)	RR 0.58 (0.21 to 1.65)	180 fewer per 1000 (from 339 fewer to 279 more)	⊕OOO VERY LOW	Critical
								42.9%		180 fewer per 1000 (from 339 fewer to 279 more)		
Proportion with increase in pressure ulcer size– grade 2 and above (grading system not specified), elderly patients, 4-week follow-up– Nimbus 1 vs Pegasus Airwave												
1Devine (1995)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[d]	none	2/16 (12.5%)	3/14 (21.4%)	RR 0.58 (0.11 to 3.00)	90 fewer per 1000 (from 191 fewer to 429 more)	⊕OOO VERY LOW	Critical
								21.4%		90 fewer per 1000 (from 190 fewer to 428 more)		
Median rate of reduction in surface area (cm/day) – grade 2 and above (grading system not specified), elderly patients, 4-week follow-up– Nimbus 1 vs Pegasus Airwave												
1Devine (1995)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[e]	Serious[h]	0.089cm^2/day	0.107cm^2/day	Difference 0.018 cm2 (95% CI 0.179 to 0.143) P=0.92	-	⊕OOO VERY LOW	Critical

Median absolute reduction in wound surface area per day – grade 2 and above (grading system not specified), elderly hospital and nursing patients, 2 week follow-up – Nimbus 3 vs P.Biwave, P.Airwave, P. Cairwave or AlphaXCell) or alternating-pressure mattress overlay (AlphaXCell or Quattro)												
1 Evans (2000)	randomised trials	very serious[f]	no serious inconsistency	no serious indirectness	very serious[e]	serious[h]	0.12cm ^{2} (range 0 to 0.21cm^2)	0.08cm^2 (range 0.04 to 0.33cm^2)	P=0.570	-	⊕OOO VERY LOW	Critical
Median relative reduction in wounds surface area– grade 2 and above (grading system not specified), elderly hospital and nursing patients, 2 week follow-up– Nimbus 3 vs P.Biwave, P.Airwave, P. Cairwave or AlphaXCell) or alternating-pressure mattress overlay (AlphaXCell or Quattro)												
1 (2000)	randomised trials	very serious[f]	no serious inconsistency	no serious indirectness	very serious[e]	serious[h]	2.44% (range 0-7.14%)	1.34% (range 1.11-2.88%)	P=0.570	-	⊕OOO VERY LOW	Critical
Median absolute reduction in wound surface are per day– grade 2 and above (grading system not specified), elderly hospital and nursing patients, 2 week follow-up– Nimbus 3 vs P.Biwave, P.Airwave, P. Cairwave or AlphaXCell) or alternating-pressure mattress overlay (AlphaXCell or Quattro)												
1 Evans (2000)	randomised trials	very serious[f]	no serious inconsistency	no serious indirectness	very serious[e]	serious[h]	0.11cm^2 (range 0.04 to 0.41cm^2)	0.05cm^2 (range 0-0.48cm^2)	P=0.570	-	⊕OOO VERY LOW	Critical
Median relative reduction in wounds surface area – grade 2 and above (grading system not specified), elderly hospital and nursing patients, 2 week follow-up– Nimbus 3 vs P.Biwave, P.Airwave, P. Cairwave or AlphaXCell) or alternating-pressure mattress overlay (AlphaXCell or Quattro)												
1 Evans (2000)	randomised trials	very serious[f]	no serious inconsistency	no serious indirectness	very serious[e]	serious[h]	1.57% (range 0.45-5%)	0.99% (range 0-2.54%)	P=0.570	-	⊕OOO VERY LOW	Critical
Comfort – hospital patients– grade 2 and above (grading system not specified), elderly hospital and nursing patients, 2 week follow-up– Nimbus 3 vs P.Biwave, P.Airwave, P. Cairwave or AlphaXCell) or alternating-pressure mattress overlay (AlphaXCell or Quattro)												
1 Evans (2000)	randomised trials	very serious[f,g]	no serious inconsistency	no serious indirectness	very serious[e]	none	5 (very comfortable)	4 (comfortable)	P=0.006	-	⊕OOO VERY LOW	Critical
Comfort – nursing home patients– grade 2 and above (grading system not specified), elderly hospital and nursing patients, 2 week follow-up– Nimbus 3 vs P.Biwave, P.Airwave, P. Cairwave or AlphaXCell) or alternating-pressure mattress overlay (AlphaXCell or Quattro)												
1 Evans (2000)	randomised trials	very serious[f,g]	no serious inconsistency	no serious indirectness	very serious[e]	none	5 (very comfortable	4 (comfortable)	P=0.002	-	⊕OOO VERY LOW	Critical

Comfort – grade 2 and above (grading system not specified), elderly patients, 4-week follow-up– Nimbus 1 vs Pegasus Airwave												
1Devine (1995)	randomised trials	very serious[a,g]	no serious inconsistency	no serious indirectness	very serious[e]	none	Median 8/10	Median 8/10	-	-	⊕OOO VERY LOW	Critical

a Devine (1995): no blinding of outcome assessors; baseline differences (more people incontinent of urine in Nimbus group, more people catheterised in Airwave group) and baseline ulcer size not reported; drop-out higher than event rate; very small sample size.

b Confidence interval crossed one MID point.

d Confidence interval crossed both MID points.

e Not enough data available to analyse in Revman.

f Evans (2000): method of randomisation not reported, unclear allocation concealment; large proportion of patients did not complete follow-up (11/20 in nursing home group and 75% of hospital group); very small sample size.

g Patient self-reported outcomes.

h No log transformation of data.

Table 44 – Alternating-pressure mattress overlay vs alternating-pressure mattress for treating pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Alternating-pressure mattress overlay**	**Alternating-pressure mattress**	**Relative (95% CI)**	**Absolute**		
Proportion with pressure ulcers completely healed– grade 2 and above (classification system not specified), elderly patients, 30 day follow-up												
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	20/59 (33.9%)	19/54 (35.2%)	RR 0.96 (0.58 to 1.6)	14 fewer per 1000 (from 148 fewer to 211 more)	⊕OOO VERY LOW	Critical
								35.2%		14 fewer per 1000 (from 148 fewer to 211 more)		
absolute change in surface area (cm2) - change values (Better indicated by higher values) – grade 2 and above (classification system not specified), elderly patients, 30 day follow-up												
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	1 (SD 2.3)	2 (SD 6.1)	-	MD 1 lower (3.14 lower to 1.14	⊕OOO VERY	Critical

							N=33	N=36		higher)	LOW	
% change in surface area (change values) (Better indicated by higher values) – grade 2 and above (classification system not specified), elderly patients, 30 day follow-up												
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	-35 (SD 605.5) N=33	34.4 (SD 108.6) N=36	-	MD 69.4 lower (279.01 lower to 140.21 higher)	⊕OOO VERY LOW	Critical
Pressure ulcer improvement– grade 1 or 2 pressure ulcers (EPUAP classification system), elderly patients, follow-up period not specified												
1 Russell (2003)	randomised trials	very serious[d]	no serious inconsistency	no serious indirectness	no serious	none	56/75 (74.7%)	60/83 (72.3%)	RR 1.03 (0.86 to 1.25)	22 more per 1000 (from 101 fewer to 181 more)	⊕⊕OO LOW	Critical
								72.3%		22 more per 1000 (from 101 fewer to 181 more)		
Worsening of pressure ulcers– grade 1 or 2 pressure ulcers (EPUAP classification system), elderly patients, follow-up period not specified												
1 Russell (2003)	randomised trials	very serious[d]	no serious inconsistency	no serious indirectness	very serious[b]	none	16/75 (21.3%)	22/83 (26.5%)	RR 0.8 (0.46 to 1.41)	53 fewer per 1000 (from 143 fewer to 109 more)	⊕OOO VERY LOW	Critical
								26.5%		53 fewer per 1000 (from 143 fewer to 109 more)		
Time to healing (median time) days												
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[e]	none	20 days (12 to not estimable)	20 days (10 to not estimable)	-	P=0.86 log-rank test	⊕OOO VERY LOW	Important
Time in hospital (mean) – grade 1 or 2 pressure ulcers (EPUAP classification system), elderly patients, follow-up period not specified												
1 Russell (2003)	randomised trials	Very serious[d]	no serious inconsistency	no serious indirectness	very serious[e]	none	22.17 days	20.05 days	-	p=0.23	⊕OOO VERY LOW	Important

Patient acceptability (requested changes for comfort or other device-related reasons) – grade 2 and above (classification system not specified), elderly patients, 30 day follow-up												
1 Nixon (2006)	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	230/989 (23.3%)	186/982 (18.9%)	RR 1.23 (1.03 to 1.46)	44 more per 1000 (from 6 more to 87 more)	⊕⊕OO LOW	Important
								18.9%		43 more per 1000 (from 6 more to 87 more)		
Proportion of patients with negative comments on mattress motion– grade 2 and above (classification system not specified), elderly patients, 30 day follow-up												
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	328/929 (35.3%)	285/891 (32%)	RR 1.1 (0.97 to 1.26)	32 more per 1000 (from 10 fewer to 83 more)	⊕OOO VERY LOW	Important
								32%		32 more per 1000 (from 10 fewer to 83 more)		
Proportion of patients with positive comments for mattress motion– grade 2 and above (classification system not specified), elderly patients, 30 day follow-up												
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious	none	272/929 (29.3%)	263/891 (29.5%)	RR 0.99 (0.86 to 1.14)	3 fewer per 1000 (from 41 fewer to 41 more)	⊕⊕OO LOW	Important
								29.5%		3 fewer per 1000 (from 41 fewer to 41 more)		
Proportion of patients commenting negatively on getting into/out of bed– grade 2 and above (classification system not specified), elderly patients, 30 day follow-up												
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	serious[c]	none	124/929 (13.3%)	127/891 (14.3%)	RR 0.94 (0.74 to 1.18)	9 fewer per 1000 (from 37 fewer to 26 more)	⊕⊕OO LOW	Important
								14.3%		9 fewer per 1000 (from 37 fewer to 26 more)		
Patients commenting negatively on movement in bed– grade 2 and above (classification system not specified), elderly patients, 30 day follow-up												
1 Nixon	randomised	very	no serious	no serious	no serious	none	290/929	260/891	RR 1.07	20 more per 1000 (from 20 fewer to	⊕⊕OO	Important

(2006)	trials	serious[a]	inconsistency	indirectness	imprecision		(31.2%)	(29.2%)	(0.93 to 1.23)	67 more)	LOW	
								29.2%		20 more per 1000 (from 20 fewer to 67 more)		
Proportion of patients commenting positively on movement in bed– grade 2 and above (classification system not specified), elderly patients, 30 day follow-up												
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	25/929 (2.7%)	27/891 (3%)	RR 0.89 (0.52 to 1.52)	3 fewer per 1000 (from 15 fewer to 16 more)	⊕OOO VERY LOW	Important
								3%		3 fewer per 1000 (from 14 fewer to 16 more)		
Proportion of patients commenting on temperature as hot/warm– grade 2 and above (classification system not specified), elderly patients, 30 day follow-up												
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	67/929 (7.2%)	50/891 (5.6%)	RR 1.29 (0.9 to 1.83)	16 more per 1000 (from 6 fewer to 47 more)	⊕OOO VERY LOW	Important
								5.6%		16 more per 1000 (from 6 fewer to 46 more)		
Proportion of patients commenting on sweaty/sticky temperature– grade 2 and above (classification system not specified), elderly patients, 30 day follow-up												
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	32/929 (3.4%)	23/891 (2.6%)	RR 1.33 (0.79 to 2.26)	9 more per 1000 (from 5 fewer to 33 more)	⊕OOO VERY LOW	Important
								2.6%		9 more per 1000 (from 5 fewer to 33 more)		

Proportion of patients commenting on cold/cool temperature– grade 2 and above (classification system not specified), elderly patients, 30 day follow-up											
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	11/929 (1.2%)	11/891 (1.2%)	RR 0.96 (0.42 to 2.2)	0 fewer per 1000 (from 7 fewer to 15 more)	⊕OOO VERY LOW	Important
								1.2%		0 fewer per 1000 (from 7 fewer to 14 more)		
Mattress not working/not working properly– grade 2 and above (classification system not specified), elderly patients, 30 day follow-up											
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	16/929 (1.7%)	18/891 (2%)	RR 0.85 (0.44 to 1.66)	3 fewer per 1000 (from 11 fewer to 13 more)	⊕OOO VERY LOW	Important
								2%		3 fewer per 1000 (from 11 fewer to 13 more)		
Hard to tuck sheet under/sheets come off or gather/mattress cover slips– grade 2 and above (classification system not specified), elderly patients, 30 day follow-up											
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	19/929 (2%)	6/891 (0.7%)	RR 3.04 (1.22 to 7.57)	14 more per 1000 (from 1 more to 44 more)	⊕OOO VERY LOW	Important
								0.7%		14 more per 1000 (from 2 more to 46 more)		
Mattress/bed too high– grade 2 and above (classification system not specified), elderly patients, 30 day follow-up											
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	72/929 (7.8%)	48/891 (5.4%)	RR 1.44 (1.01 to 2.05)	24 more per 1000 (from 1 more to 57 more)	⊕OOO VERY LOW	Important
								5.4%		24 more per 1000 (from 1 more to 57 more)		

Mattress slippy– grade 2 and above (classification system not specified), elderly patients, 30 day follow-up												
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	9/929 (1%)	4/891 (0.4%)	RR 2.16 (0.67 to 6.98)	5 more per 1000 (from 1 fewer to 27 more)	⊕OOO VERY LOW	Important
								0.5%		6 more per 1000 (from 2 fewer to 30 more)		
Mattress too soft/edges soft or slope– grade 2 and above (classification system not specified), elderly patients, 30 day follow-up												
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	19/929 (2%)	29/891 (3.3%)	RR 0.63 (0.35 to 1.11)	12 fewer per 1000 (from 21 fewer to 4 more)	⊕OOO VERY LOW	Important
								3.3%		12 fewer per 1000 (from 21 fewer to 4 more)		
Not able to use backrest– grade 2 and above (classification system not specified), elderly patients, 30 day follow-up												
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	4/929 (0.4%)	2/891 (0.2%)	RR 1.92 (0.35 to 10.45)	2 more per 1000 (from 1 fewer to 21 more)	⊕OOO VERY LOW	Important
								0.2%		2 more per 1000 (from 1 fewer to 19 more)		
Mattress-related fall												
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	0/828 (0%)	4/891 (0.4%)	Peto OR 0.14 (0.02 to 1.03)	4 fewer per 1000 (from 4 fewer to 0 more)	⊕OOO VERY LOW	Important
								0.5%		4 fewer per 1000 (from 5 fewer to 0 more)		
Mattress-related suspected contact dermatitis– grade 2 and above (classification system not specified), elderly patients, 30 day follow-up												
1 Nixon	randomised	very	no serious	no serious	very serious[b]	none	0/929	1/891	Peto OR 0.13	1 fewer per 1000 (from 1 fewer to 6	⊕OOO	Important

(2006)	trials	serious[a]	inconsistency	indirectness			(0%)	(0.1%)	(0 to 6.54)	more)	VERY LOW	
								0.1%		1 fewer per 1000 (from 1 fewer to 6 more)		
Mattress-related climbed over/fell through cot sides– grade 2 and above (classification system not specified), elderly patients, 30 day follow-up												
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	2/929 (0.2%)	1/891 (0.1%)	RR 1.92 (0.17 to 21.12)	1 more per 1000 (from 1 fewer to 23 more)	⊕OOO VERY LOW	Important
								0.1%		1 more per 1000 (from 1 fewer to 20 more)		
Mattress deflation during transfer– grade 2 and above (classification system not specified), elderly patients, 30 day follow-up												
1 Nixon (2006)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	0/929 (0%)	1/891 (0.1%)	Peto OR 0.13 (0 to 6.54)	1 fewer per 1000 (from 1 fewer to 6 more)	⊕OOO VERY LOW	Important
								0.1%		1 fewer per 1000 (from 1 fewer to 6 more)		

a Nixon (2006): No blinding; The drop-out was higher than the event rate. The outcomes of patient acceptability and side effects were for the study as a whole rather than those who had pressure ulcers.

b Confidence interval crossed both MID points.

c Confidence interval crossed one MID point

d Russell (2003):no blinding; unclear allocation concealment and insufficient reporting of incomplete outcome data.

e Not enough data to analyse in Revman.

f Non-validated assessment of outcome.

Table 45 – Air-filled devices vs alternating pressure mattress for treating pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Air-filled devices	Alternating-pressure mattress	Relative (95% CI)	Absolute		
Proportion of patients with healed pressure ulcer – grade 2 ulcer or above (EPUAP classification system), elderly patients, maximum follow-up 42 days												
1Osterbrink (2005)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	7/34 (20.6%)	1/26 (3.8%)	RR 5.35 (0.7 to 40.84)	167 more per 1000 (from 12 fewer to 1000 more)	⊕OOO VERY LOW	Critical
								3.9%		170 more per 1000 (from 12 fewer to 1000 more)		

a Osterbrink (2005): unclear randomisation method, allocation concealment, blinding; insufficient reporting of incomplete outcome data; baseline ulcer size not reported.

b Confidence interval crossed both MID points and limited number of events.

2.3.2.3. Other support surfaces

Table 46 – Profiling bed vs foam mattress for treating pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Profiling bed	Foam mattress	Relative (95% CI)	Absolute		
Proportion with healed grade 1 ulcers – any grade of pressure ulcers, surgical or medical patients, 5-10 days follow-up												
1Keogh (2001)	randomised trials	Very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	4/4 (100%)	2/10 (20%)	RR 3.96 (1.28 to 12.24)	592 more per 1000 (from 56 more to 1000 more)	⊕OOO VERY LOW	Critical
								20%		592 more per 1000 (from 56 more to 1000 more)		

a Keogh (2001): unclear blinding; not all of the study's pre-specified outcomes were reported; not all patients had pressure ulcers (only 14 had existing pressure ulcers), so small sample size and uneven distribution, with only 4 in the experimental group. Grade 1 ulcers analysed only. No addressing of incomplete outcome data. High drop out from study and do not know how many of those who dropped-out had existing pressure ulcers at start of the trial.

b Limited number of events.

Table 47 – Constant force mattress versus low-air-loss mattress

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Constant force mattress	LAL mattress	Relative (95% CI)	Absolute		
Mean % rate of closure per week – grade 3 or 4 ulcers (classification system not specified), long-term or subacute inpatients from wards specialising in ventilator-dependent or extensive wound care needs, at 8 week follow-up												
1Branom (2001)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	serious[b]	serious[c]	9 (s.d 4.8) N= 10	5 (s.d 3.7) N= 8	-	MD 4 higher (0.07 to 7.93 higher)	⊕OOO VERY LOW	Critical

a Randomisation inadequate; unclear allocation concealment and blinding; no details of incomplete outcome data, type of analysis, ulcer sizes at baseline and classification of pressure ulcers. Very small sample size.

b Confidence interval crossed one MID point.

c No log transformation of data.

Table 48 – Alternating-pressure cushion vs dry flotation cushion for treating pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Alternating-pressure cushion	Dry flotation cushion	Relative (95% CI)	Absolute		
Proportion with pressure ulcers completely healed – grade 2 ulcers or above, elderly patients, mean 51 days follow-up												
1Clark (1998)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	3/14 (21.4%)	5/11 (45.5%)	RR 0.47 (0.14 to 1.56)	241 fewer per 1000 (from 391 fewer to 255 more)	⊕OOO VERY LOW	Critical
								45.5%		241 fewer per 1000 (from 391 fewer to 255 more)		
Rate of healing (cm^2/day) – grade 2 ulcers or above, elderly patients, mean 51 days follow-up												
1Clark (1998)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	Serious[d]	0.13 (SD 0.37)	0.27 (SD 0.56)	-	MD 0.14 lower (0.52 lower to 0.24 higher)	⊕OOO VERY LOW	Critical

Rate of healing (cm^3/day) – grade 2 ulcers or above, elderly patients, mean 51 days follow-up												
1Clark (1998)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	Serious[d]	0.56 (SD 0.86)	0.49 (SD 0.86)	-	MD 0.07 higher (0.61 lower to 0.75 higher)	⊕OOO VERY LOW	Critical
% change in area per day– grade 2 ulcers or above, elderly patients, mean 51 days follow-up												
1Clark (1998)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	Serious[d]	2.56 (SD 7.86)	5.71 (SD 5.57)	-	MD 3.15 lower (8.42 lower to 2.12 higher)	⊕OOO VERY LOW	Critical
% change in volume per day– grade 2 ulcers or above, elderly patients, mean 51 days follow-up												
1Clark (1998)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Very serious[b]	Serious[d]	1.00 (SD 1.83)	0.68 (SD 0.86)	-	MD 0.32 higher (0.76 lower to 1.4 higher)	⊕OOO VERY LOW	Critical

a Clark (1998): unclear details of randomisation; unblinded observer; grading system of ulcers not specified. High drop-out.

b Confidence interval crossed both MID points.

c Confidence interval crossed one MID point.

d No log transformation of data.

e Limited number of events.

Table 49 – Alternating-pressure cushion vs alternating-pressure cushion for treating pressure ulcers

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Alternating-pressure mattress	Alternating-pressure mattress	Relative (95% CI)	Absolute		
Proportion of pressure ulcers completely healed – grade 2 and above (Torrance classification system), elderly patients, 18 months follow-up – Nimbus 3 with Aura cushion and 4-hourly turning vs Pegasus Cairwave Therapy System with Proactive 2 seating cushion and 8-hourly turning												
1Russell (2000)	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	65/71 (91.5%)	65/70 (92.9%)	RR 0.99 (0.9 to 1.09)	9 fewer per 1000 (from 93 fewer to 84 more)	⊕⊕⊕O MODERATE	Critical
								92.9%		9 fewer per 1000 (from 93 fewer to 84 more)		
Mean time in hospital (for those who completed the trial) – grade 2 and above (Torrance classification system), elderly patients, 18 months follow-up– Nimbus 3 with Aura cushion and 4-hourly turning vs Pegasus Cairwave Therapy System with Proactive 2 seating cushion and 8-hourly turning												
1Russell (2000)	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	21.6 days N=57	21.7 days N=55	-	-	⊕OOO VERY LOW	Important

a Russell (2000): no details of randomisation method; unclear allocation concealment.

b Not enough data available to analyse in Revman.

c Confidence interval crossed both MID points.

Table 50 – Wheelchair cushion with equipped with individualised cyclic pressure-relief protocol vs standard wheelchair cushion[b]

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Adjusted automated wheelchair	Standard wheelchair	Relative (95% CI)	Absolute		
Pressure ulcer closure (cm^2)[c] – stage 2 or 3 ulcers (classification system not specified), paraplegic or tetraplegic wheelchair users, 30 days follow-up												
1Makhsous (2009)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	78.5 (s.d 74.4) N=22	12.49 (s.d 52.0) N=22	P<0.001	MD 66.01 higher (28.08 to 103.94 higher)	⊕⊕OO LOW	Critical
Pressure ulcer closure rate (cm^2/day)[c] – stage 2 or 3 ulcers (classification system not specified), paraplegic or tetraplegic wheelchair users, 30 days follow-up												
1Makhsous (2009)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	2.17 (s.d 1.46) N=220	2.3 (s.d 2.04) N=22	P<0.001	MD 1.94 higher (0.89 to 2.99 higher)	⊕⊕OO LOW	Critical
PUSH score improvement[c] – stage 2 or 3 ulcers (classification system not specified), paraplegic or tetraplegic wheelchair users, 30 days follow-up												
1Makhsous (2009)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	2.5 (s.d 2.3) N=22	0.7 (s.d 1.1) N=22	P=0.001	MD 1.8 higher (0.73 to 2.87 higher)	⊕⊕OO LOW	Critical
% surface area reduction[c] – stage 2 or 3 ulcers (classification system not specified), paraplegic or tetraplegic wheelchair users, 30 days follow-up												
1Makhsous (2009)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	45.0 (s.d 22.0) N=22	10.2 (s.d 34.9) N=22	P<0.001	MD 34.8 higher (17.78 to 51.82 higher)	⊕⊕OO LOW	Critical
% PUSH score improvement[c] – stage 2 or 3 ulcers (classification system not specified), paraplegic or tetraplegic wheelchair users, 30 days follow-up												
1Makhsous (2009)	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	21.9 (s.d 24.6) N=22	5.8 (s.d 9.2) N=22	P=0.003	MD 16.1 higher (5.13 to 27.07 higher)	⊕⊕OO LOW	Critical

a Makhsous (2010): no details of sequence generation, allocation concealment or blinding. Small sample size.

b Patients had Spinal Cord Injury and so would not be able to reposition themselves.

c Change scores were presented in the paper.

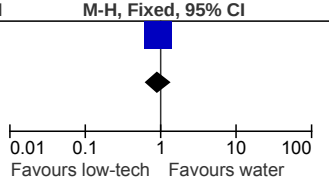
2.3.3. Forest plots

2.3.3.1. Water mattress overlay vs low-tech mattress

Figure 22 – Proportion with pressure ulcers completely healed

Study or Subgroup	Water mattress overlay Events	Total	Low-tech mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Groen 1999	27	60	29	60	100.0%	0.93 [0.63, 1.37]
Total (95% CI)		**60**		**60**	**100.0%**	**0.93 [0.63, 1.37]**
Total events	27		29			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.37 (P = 0.71)



2.3.3.2. Low-air-loss bed vs foam mattress overlay

Figure 23 – Proportion with pressure ulcers completely healed

Study or Subgroup	Low-air-loss bed Events	Total	Foam mattress overlay Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Ferrell 1993	26	43	19	41	100.0%	1.30 [0.87, 1.96]
Total (95% CI)		**43**		**41**	**100.0%**	**1.30 [0.87, 1.96]**
Total events	26		19			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.28 (P = 0.20)

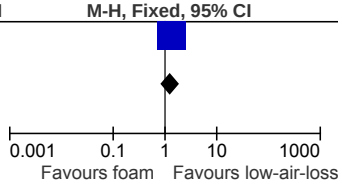


Figure 24 – Proportion with pressure ulcers completely healed

Study or Subgroup	Low air-loss bed Events	Total	Foam mattress overlay Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Mulder 1994	5	31	3	18	100.0%	0.97 [0.26, 3.58]
Total (95% CI)		**31**		**18**	**100.0%**	**0.97 [0.26, 3.58]**
Total events	5		3			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.05 (P = 0.96)

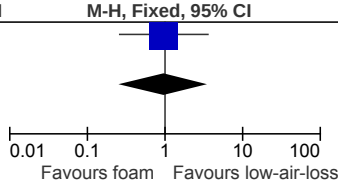


Figure 25 – Proportion with pressure ulcers completely healed (meta-analysed)

Study or Subgroup	LAL bed Events	Total	Foam mattress overlay Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Ferrell 1993	26	43	19	41	83.7%	1.30 [0.87, 1.96]
Mulder 1994	5	31	3	18	16.3%	0.97 [0.26, 3.58]
Total (95% CI)		**74**		**59**	**100.0%**	**1.25 [0.84, 1.86]**
Total events	31		22			

Heterogeneity: Chi² = 0.19, df = 1 (P = 0.66); I² = 0%
Test for overall effect: Z = 1.10 (P = 0.27)

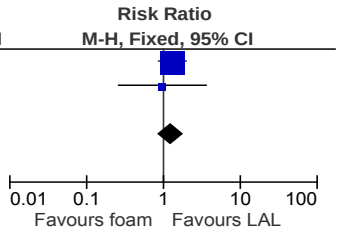


Figure 26 – Pressure ulcers reduced by one grade or more including healed completely

Study or Subgroup	Low-air-loss bed Events	Total	Foam mattress overlay Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Mulder 1994	10	31	5	18	100.0%	1.16 [0.47, 2.86]
Total (95% CI)		**31**		**18**	**100.0%**	**1.16 [0.47, 2.86]**
Total events	10		5			

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

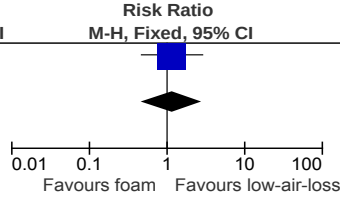


Figure 27 – Change in ulcer size of stage II ulcers (final values)

Study or Subgroup	Low-air-loss bed Mean	SD	Total	Foam mattress overlay Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Day 1993	7.3	2.4	25	5.3	2.1	23	100.0%	2.00 [0.73, 3.27]
Total (95% CI)			**25**			**23**	**100.0%**	**2.00 [0.73, 3.27]**

Heterogeneity: Not applicable
Test for overall effect: Z = 3.08 (P = 0.002)

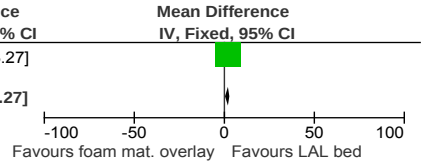


Figure 28 – Change in ulcer size of stage III and IV ulcers (final values)

Study or Subgroup	LAL bed Mean	SD	Total	Foam mattress overlay Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Day 1993	37.1	8.1	17	12.4	3.5	12	100.0%	24.70 [20.37, 29.03]
Total (95% CI)			**17**			**12**	**100.0%**	**24.70 [20.37, 29.03]**

Heterogeneity: Not applicable
Test for overall effect: Z = 11.18 (P < 0.00001)

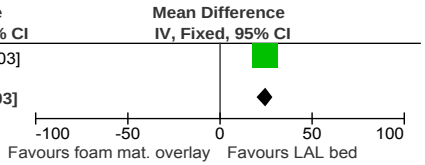
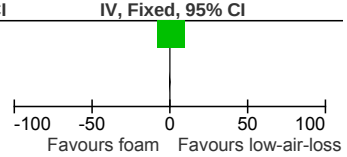


Figure 29 – Mean comfort score

Study or Subgroup	Low-air-loss bed Mean	SD	Total	Foam mattress overlay Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Day 1993	4.1	1.3	20	3.7	1.3	19	100.0%	0.40 [-0.42, 1.22]
Total (95% CI)			**20**			**19**	**100.0%**	**0.40 [-0.42, 1.22]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.96 (P = 0.34)



2.3.3.3. *Air-fluidised bed vs standard care*

Figure 30 – Proportion with 50% reduction in pressure ulcers total surface area

Study or Subgroup	Air-fluidised bed Events	Total	Standard care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Allman 1987	9	31	8	34	100.0%	1.23 [0.54, 2.80]
Total (95% CI)		**31**		**34**	**100.0%**	**1.23 [0.54, 2.80]**
Total events	9		8			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.50 (P = 0.61)

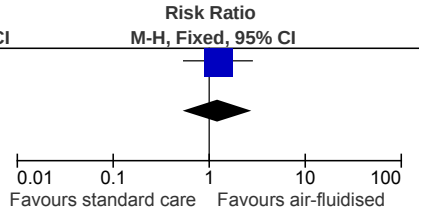


Figure 31 – Proportion with improvement in pressure ulcers

Study or Subgroup	Air-fluidised bed Events	Total	Standard care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Strauss 1991	19	22	9	13	100.0%	1.25 [0.84, 1.86]
Total (95% CI)		**22**		**13**	**100.0%**	**1.25 [0.84, 1.86]**
Total events	19		9			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.09 (P = 0.28)

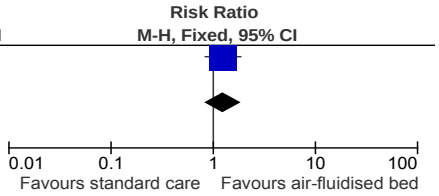


Figure 32 – Proportion with improvement in pressure ulcers

Study or Subgroup	Air-fluidised bed Events	Total	Standard care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Allman 1987	22	31	16	34	100.0%	1.51 [0.99, 2.30]
Total (95% CI)		**31**		**34**	**100.0%**	**1.51 [0.99, 2.30]**
Total events	22		16			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.91 (P = 0.06)

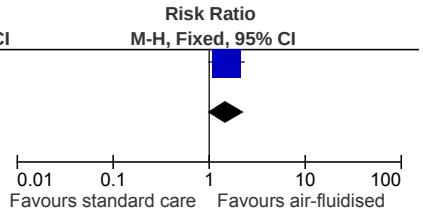


Figure 33 – Proportion with improvement in pressure ulcers

Study or Subgroup	Air-fluidised bed Events	Total	Standard care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Allman 1987	22	31	16	34	57.4%	1.51 [0.99, 2.30]
Strauss 1991	19	22	9	13	42.6%	1.25 [0.84, 1.86]
Total (95% CI)		**53**		**47**	**100.0%**	**1.40 [1.04, 1.88]**
Total events	41		25			

Heterogeneity: Chi² = 0.44, df = 1 (P = 0.51); I² = 0%
Test for overall effect: Z = 2.20 (P = 0.03)

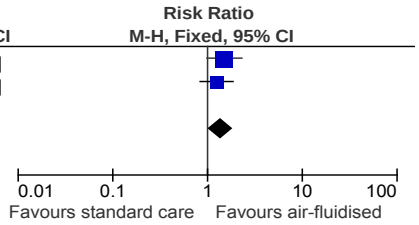


Figure 34 – Patient satisfaction

Study or Subgroup	Air-fluidised bed Mean	SD	Total	Standard care Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Munro 1989	57.5	6.1	8	48.6	12.3	10	100.0%	8.90 [0.18, 17.62]
Total (95% CI)			**8**			**10**	**100.0%**	**8.90 [0.18, 17.62]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.00 (P = 0.05)

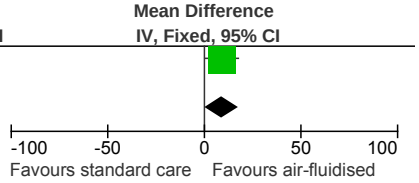


Figure 35 – Increase in comfort

Study or Subgroup	Air-fluidised bed Events	Total	Standard care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Allman 1987	8	13	3	14	100.0%	2.87 [0.96, 8.55]
Total (95% CI)		**13**		**14**	**100.0%**	**2.87 [0.96, 8.55]**
Total events	8		3			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.89 (P = 0.06)

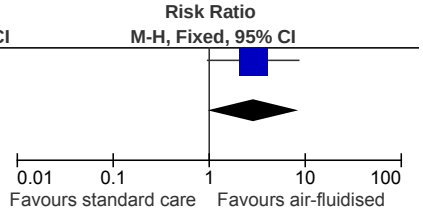


Figure 36 – Reduction in comfort

Study or Subgroup	Air-fluidised bed Events	Total	Standard care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Allman 1987	1	13	6	14	100.0%	0.18 [0.02, 1.30]
Total (95% CI)		**13**		**14**	**100.0%**	**0.18 [0.02, 1.30]**
Total events	1		6			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.70 (P = 0.09)

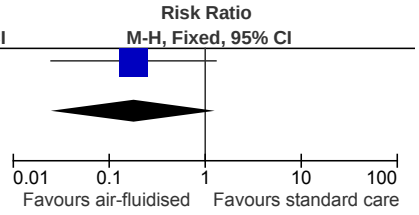


Figure 37 – Reduction in pain

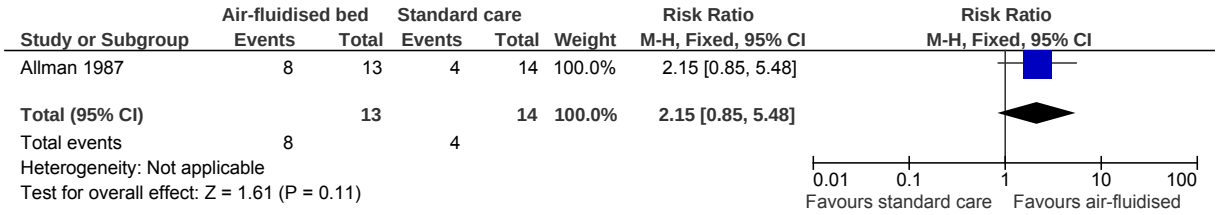


Figure 38 – Increase in pain

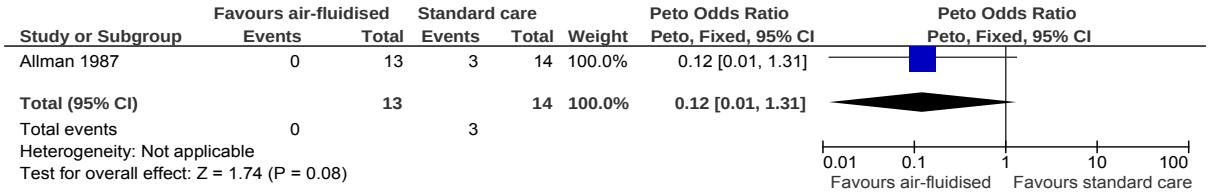
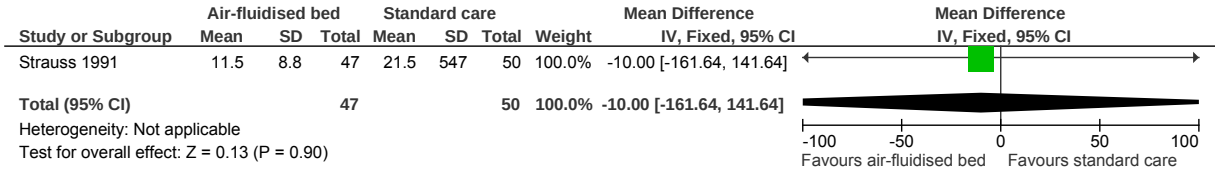


Figure 39 – Time in hospital



2.3.3.4. Alternating-pressure mattress vs alternating-pressure mattress

Figure 40 – Proportion with pressure ulcers completely healed

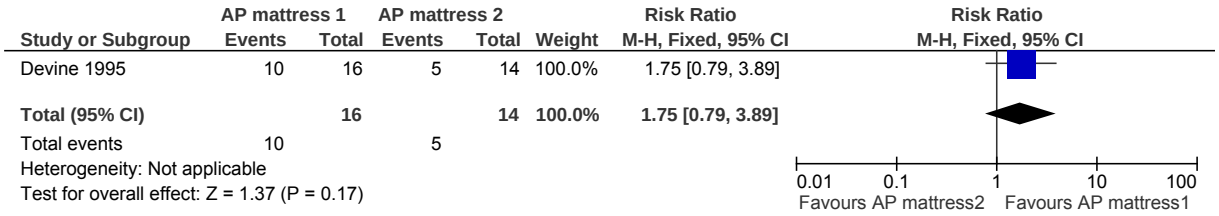


Figure 41 – Decrease in pressure ulcer size

Study or Subgroup	AP mattress 1 Events	Total	AP mattress 2 Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Devine 1995	4	16	6	14	100.0%	0.58 [0.21, 1.65]
Total (95% CI)		**16**		**14**	**100.0%**	**0.58 [0.21, 1.65]**
Total events	4		6			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.01 (P = 0.31)

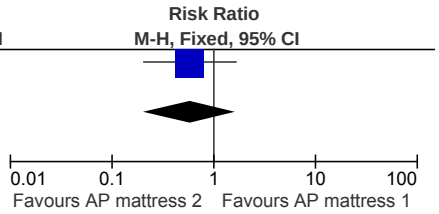
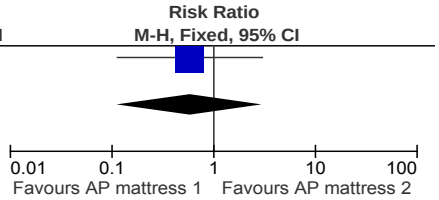


Figure 42 – Increase in pressure ulcer size

Study or Subgroup	AP mattress 1 Events	Total	AP mattress 2 Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Devine 1995	2	16	3	14	100.0%	0.58 [0.11, 3.00]
Total (95% CI)		**16**		**14**	**100.0%**	**0.58 [0.11, 3.00]**
Total events	2		3			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.64 (P = 0.52)



2.3.3.5. Alternating-pressure mattress overlay vs alternating-pressure mattress

Figure 43 – Proportion with pressure ulcers completely healed

Study or Subgroup	AP overlay Events	Total	AP mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Nixon 2006	20	59	19	54	100.0%	0.96 [0.58, 1.60]
Total (95% CI)		**59**		**54**	**100.0%**	**0.96 [0.58, 1.60]**
Total events	20		19			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.14 (P = 0.89)

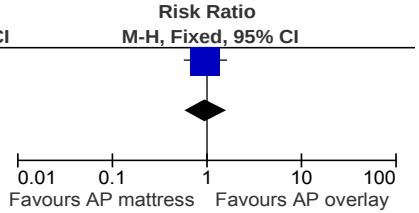


Figure 44 – Absolute change in surface area (cm2) – change values

Study or Subgroup	AP overlay Mean	SD	Total	AP mattress Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Nixon 2006	1	2.3	33	2	6.1	36	100.0%	-1.00 [-3.14, 1.14]
Total (95% CI)			**33**			**36**	**100.0%**	**-1.00 [-3.14, 1.14]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.92 (P = 0.36)

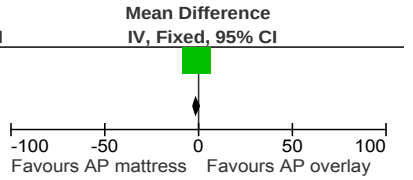


Figure 45 – % change in surface area – change values

Study or Subgroup	AP overlay Mean	SD	Total	AP mattress Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Nixon 2006	-35	605.5	33	34.4	108.6	36	100.0%	-69.40 [-279.01, 140.21]
Total (95% CI)			**33**			**36**	**100.0%**	**-69.40 [-279.01, 140.21]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.65 (P = 0.52)

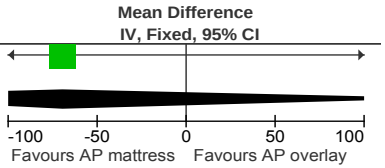


Figure 46 – Pressure ulcer improvement

Study or Subgroup	AP mattress overlay Events	Total	AP mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Russell 2003	56	75	60	83	100.0%	1.03 [0.86, 1.25]
Total (95% CI)		**75**		**83**	**100.0%**	**1.03 [0.86, 1.25]**
Total events	56		60			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.34 (P = 0.74)

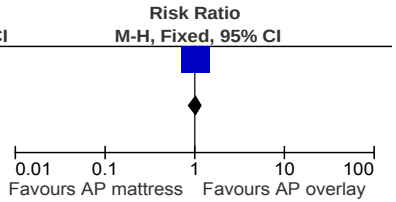


Figure 47 – Worsening of pressure ulcers

Study or Subgroup	AP mattress overlay Events	Total	AP mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Russell 2003	16	75	22	83	100.0%	0.80 [0.46, 1.41]
Total (95% CI)		**75**		**83**	**100.0%**	**0.80 [0.46, 1.41]**
Total events	16		22			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.76 (P = 0.45)

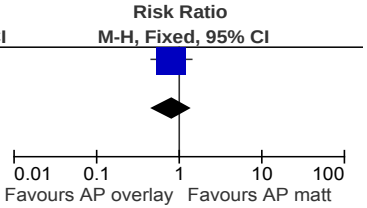


Figure 48 – Patient acceptability (requested changes for comfort or other device-related reasons)

Study or Subgroup	AP mattress Events	Total	AP mattress overlay Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Nixon 2006	230	989	186	982	100.0%	1.23 [1.03, 1.46]
Total (95% CI)		**989**		**982**	**100.0%**	**1.23 [1.03, 1.46]**
Total events	230		186			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.34 (P = 0.02)

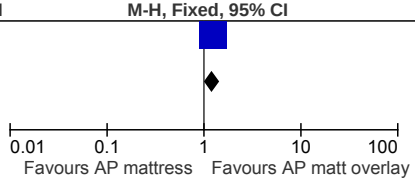


Figure 49 – Proportion of patients with negative comments on mattress motion

Study or Subgroup	AP overlay Events	Total	AP mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Nixon 2006	328	929	285	891	100.0%	1.10 [0.97, 1.26]
Total (95% CI)		**929**		**891**	**100.0%**	**1.10 [0.97, 1.26]**
Total events	328		285			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.50 (P = 0.13)

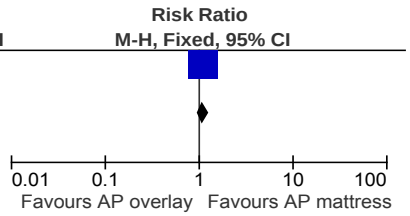


Figure 50 – Proportion of patients with positive comments for mattress motion

Study or Subgroup	AP overlay Events	Total	AP mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Nixon 2006	272	929	263	891	100.0%	0.99 [0.86, 1.14]
Total (95% CI)		**929**		**891**	**100.0%**	**0.99 [0.86, 1.14]**
Total events	272		263			

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

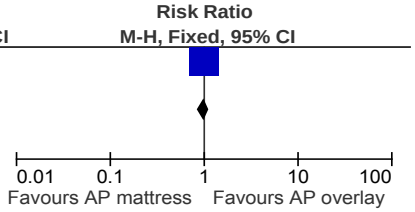


Figure 51 – Proportion of patients commenting negatively on getting into/out of bed

Study or Subgroup	AP overlay Events	Total	AP mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Nixon 2006	124	929	127	891	100.0%	0.94 [0.74, 1.18]
Total (95% CI)		**929**		**891**	**100.0%**	**0.94 [0.74, 1.18]**
Total events	124		127			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.56 (P = 0.58)

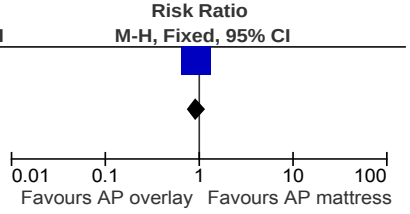


Figure 52 – Proportion of patients commenting negatively on movement in bed

Study or Subgroup	AP overlay Events	Total	AP mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Nixon 2006	290	929	260	891	100.0%	1.07 [0.93, 1.23]
Total (95% CI)		**929**		**891**	**100.0%**	**1.07 [0.93, 1.23]**
Total events	290		260			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.94 (P = 0.34)

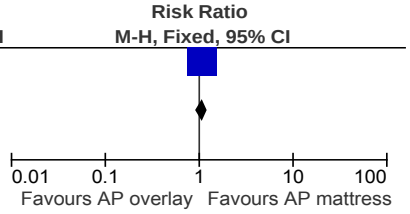


Figure 53 – Proportion of patients commenting positively on movement in bed

Study or Subgroup	AP overlay Events	Total	AP mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Nixon 2006	25	929	27	891	100.0%	0.89 [0.52, 1.52]
Total (95% CI)		**929**		**891**	**100.0%**	**0.89 [0.52, 1.52]**
Total events	25		27			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.43 (P = 0.66)

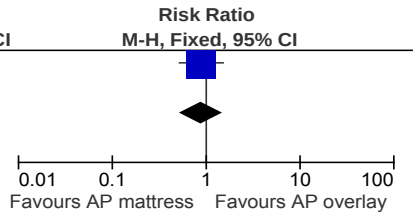


Figure 54 – Proportion of patients commenting on temperature as hot/warm

Study or Subgroup	AP mattress Events	Total	AP overlay Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Nixon 2006	67	929	50	891	100.0%	1.29 [0.90, 1.83]
Total (95% CI)		**929**		**891**	**100.0%**	**1.29 [0.90, 1.83]**
Total events	67		50			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.39 (P = 0.17)

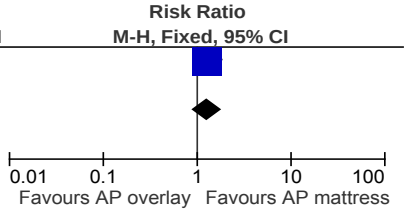


Figure 55 – Proportion of patients commenting on sweaty/sticky temperature

Study or Subgroup	AP overlay Events	Total	AP mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Nixon 2006	32	929	23	891	100.0%	1.33 [0.79, 2.26]
Total (95% CI)		**929**		**891**	**100.0%**	**1.33 [0.79, 2.26]**
Total events	32		23			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.07 (P = 0.28)

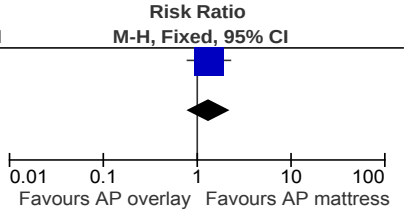


Figure 56 – Proportion of patients commenting on cold/cool temperature

Study or Subgroup	AP overlay Events	Total	AP mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Nixon 2006	11	929	11	891	100.0%	0.96 [0.42, 2.20]
Total (95% CI)		**929**		**891**	**100.0%**	**0.96 [0.42, 2.20]**
Total events	11		11			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.10 (P = 0.92)

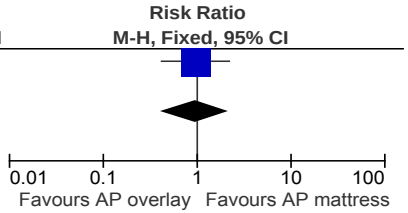


Figure 57 – Proportion of mattresses not working/not working properly

Study or Subgroup	AP overlay Events	Total	AP mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Nixon 2006	16	929	18	891	100.0%	0.85 [0.44, 1.66]
Total (95% CI)		**929**		**891**	**100.0%**	**0.85 [0.44, 1.66]**
Total events	16		18			

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

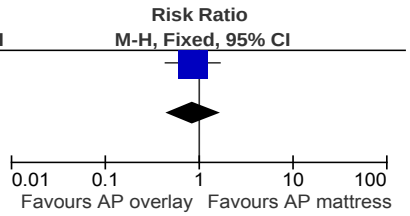


Figure 58 – Hard to tuck sheet under/sheets come off or gather/mattress cover slips

Study or Subgroup	AP overlay Events	Total	AP mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Nixon 2006	19	929	6	891	100.0%	3.04 [1.22, 7.57]
Total (95% CI)		**929**		**891**	**100.0%**	**3.04 [1.22, 7.57]**
Total events	19		6			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.38 (P = 0.02)

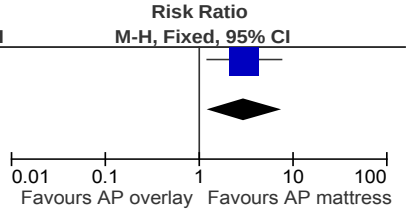


Figure 59 – Mattress/bed too high

Study or Subgroup	AP overlay Events	Total	AP mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Nixon 2006	72	929	48	891	100.0%	1.44 [1.01, 2.05]
Total (95% CI)		**929**		**891**	**100.0%**	**1.44 [1.01, 2.05]**
Total events	72		48			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.02 (P = 0.04)

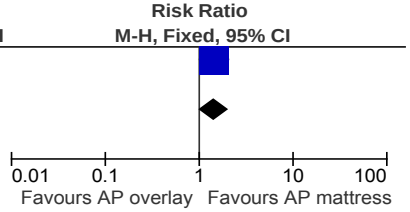


Figure 60 – Mattress slippy

Study or Subgroup	AP overlay Events	Total	AP mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Nixon 2006	9	929	4	891	100.0%	2.16 [0.67, 6.98]
Total (95% CI)		**929**		**891**	**100.0%**	**2.16 [0.67, 6.98]**
Total events	9		4			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.28 (P = 0.20)

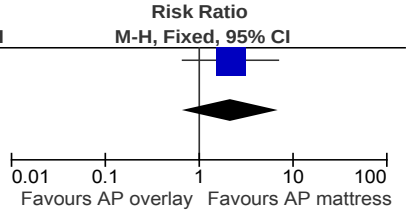


Figure 61 – Mattress too soft/edges soft or slope

Study or Subgroup	AP overlay Events	Total	AP mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Nixon 2006	19	929	29	891	100.0%	0.63 [0.35, 1.11]
Total (95% CI)		**929**		**891**	**100.0%**	**0.63 [0.35, 1.11]**
Total events	19		29			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.59 (P = 0.11)

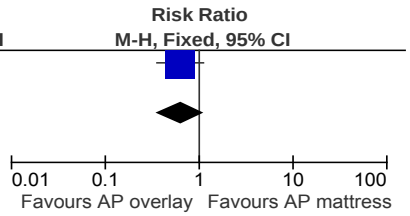


Figure 62 – Not able to use backrest

Study or Subgroup	AP overlay Events	Total	AP mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Nixon 2006	4	929	2	891	100.0%	1.92 [0.35, 10.45]
Total (95% CI)		**929**		**891**	**100.0%**	**1.92 [0.35, 10.45]**
Total events	4		2			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.75 (P = 0.45)

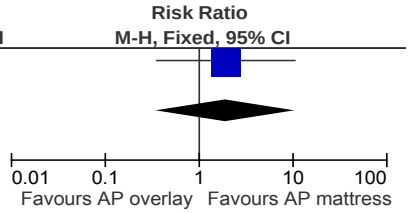


Figure 63 – Mattress-related fall

Study or Subgroup	AP overlay Events	Total	AP mattress Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Nixon 2006	0	828	4	891	100.0%	0.14 [0.02, 1.03]
Total (95% CI)		**828**		**891**	**100.0%**	**0.14 [0.02, 1.03]**
Total events	0		4			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.93 (P = 0.05)

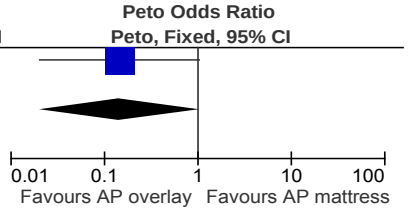


Figure 64 – Mattress-related suspected contact dermatitis

Study or Subgroup	AP overlay Events	Total	AP mattress Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Nixon 2006	0	929	1	891	100.0%	0.13 [0.00, 6.54]
Total (95% CI)		**929**		**891**	**100.0%**	**0.13 [0.00, 6.54]**
Total events	0		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.02 (P = 0.31)

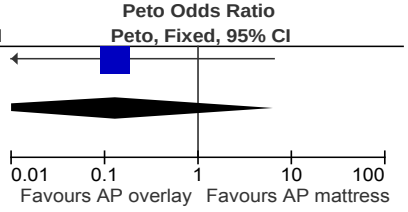


Figure 65 – Mattress-related climbed over/fell through cot sides

Study or Subgroup	AP overlay Events	Total	AP mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Nixon 2006	2	929	1	891	100.0%	1.92 [0.17, 21.12]
Total (95% CI)		**929**		**891**	**100.0%**	**1.92 [0.17, 21.12]**
Total events	2		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.53 (P = 0.59)

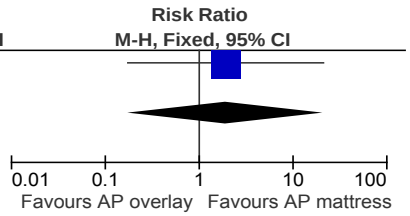
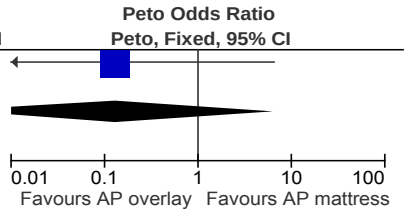


Figure 66 – Mattress deflation during transfer

Study or Subgroup	AP overlay Events	Total	AP mattress Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Nixon 2006	0	929	1	891	100.0%	0.13 [0.00, 6.54]
Total (95% CI)		**929**		**891**	**100.0%**	**0.13 [0.00, 6.54]**
Total events	0		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.02 (P = 0.31)

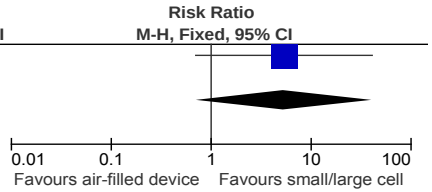


2.3.3.6. Alternating-pressure mattress vs air-filled devices

Figure 67 – Proportion with pressure ulcers completely healed

Study or Subgroup	Small/large cell AP Events	Total	Air-filled device Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Osterbrink 2005	7	34	1	26	100.0%	5.35 [0.70, 40.84]
Total (95% CI)		**34**		**26**	**100.0%**	**5.35 [0.70, 40.84]**
Total events	7		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.62 (P = 0.11)

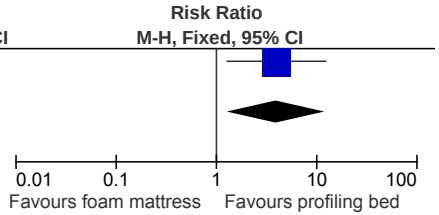


2.3.3.7. Profiling bed vs foam mattress

Figure 68 – Proportion with healed grade 1 pressure ulcers

Study or Subgroup	Profiling bed Events	Total	Foam mattress Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Keogh 2001	4	4	2	10	100.0%	3.96 [1.28, 12.24]
Total (95% CI)		**4**		**10**	**100.0%**	**3.96 [1.28, 12.24]**
Total events	4		2			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.39 (P = 0.02)

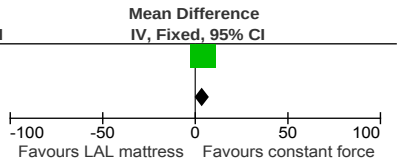


2.3.3.8. Constant force mattress vs LAL mattress

Figure 69 – Mean % rate of closure per week (%/week)

Study or Subgroup	Constant force mattress Mean	SD	Total	LAL mattress Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Branom 2001	9	4.8	10	5	3.7	8	100.0%	4.00 [0.07, 7.93]
Total (95% CI)			**10**			**8**	**100.0%**	**4.00 [0.07, 7.93]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.00 (P = 0.05)



2.3.3.9. Alternating pressure cushion versus alternation pressure cushion

Figure 70 – Proportion with pressure ulcers completely healed

Study or Subgroup	AP mattress 1 Events	Total	AP mattress 2 Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Russell 2000	65	71	65	70	100.0%	0.99 [0.90, 1.09]
Total (95% CI)		**71**		**70**	**100.0%**	**0.99 [0.90, 1.09]**
Total events	65		65			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.29 (P = 0.77)

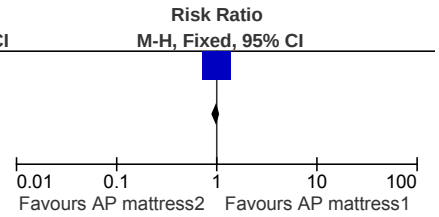
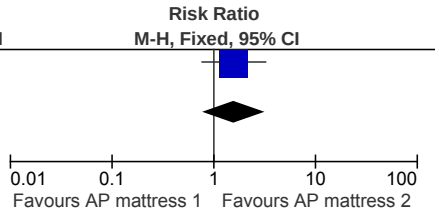


Figure 71 – Mortality

Study or Subgroup	AP mattress 1 Events	Total	AP mattress 2 Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Russell 2000	16	71	10	70	100.0%	1.58 [0.77, 3.23]
Total (95% CI)		**71**		**70**	**100.0%**	**1.58 [0.77, 3.23]**
Total events	16		10			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.24 (P = 0.21)



2.3.3.10.Alternating-pressure cushion vs dry flotation cushion

Figure 72 – Proportion with pressure ulcers completely healed

Study or Subgroup	AP cushion Events	Total	Dry flotation cushion Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Clark 1998	3	14	5	11	100.0%	0.47 [0.14, 1.56]
Total (95% CI)		**14**		**11**	**100.0%**	**0.47 [0.14, 1.56]**
Total events	3		5			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.23 (P = 0.22)

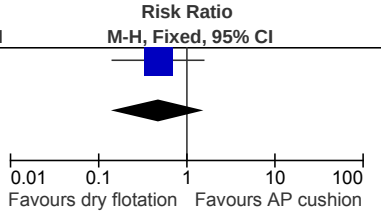


Figure 73 – Rate of healing cm2/day

Study or Subgroup	AP cushion Mean	SD	Total	Dry flotation cushion Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Clark 1998	0.13	0.37	14	0.27	0.56	11	100.0%	-0.14 [-0.52, 0.24]
Total (95% CI)			**14**			**11**	**100.0%**	**-0.14 [-0.52, 0.24]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.72 (P = 0.47)

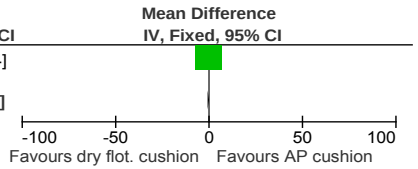


Figure 74 – Rate of healing cm3/day

Study or Subgroup	AP cushion Mean	SD	Total	Dry flotation cushion Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Clark 1998	0.56	0.86	14	0.49	0.86	11	100.0%	0.07 [-0.61, 0.75]
Total (95% CI)			**14**			**11**	**100.0%**	**0.07 [-0.61, 0.75]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.20 (P = 0.84)

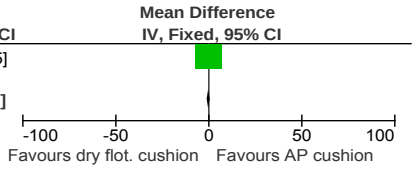


Figure 75 – % change in surface area per day

Study or Subgroup	AP cushion Mean	SD	Total	Dry flotation cushion Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Clark 1998	2.56	7.86	14	5.71	5.57	11	100.0%	-3.15 [-8.42, 2.12]
Total (95% CI)			**14**			**11**	**100.0%**	**-3.15 [-8.42, 2.12]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.17 (P = 0.24)

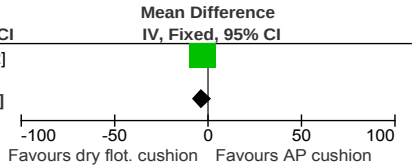
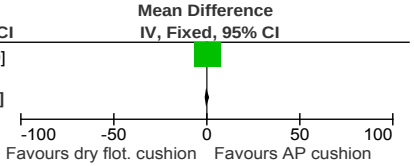


Figure 76 – % change in volume per day

Study or Subgroup	AP cushion Mean	SD	Total	Dry flotation cushion Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Clark 1998	1	1.83	14	0.68	0.86	11	100.0%	0.32 [-0.76, 1.40]
Total (95% CI)			**14**			**11**	**100.0%**	**0.32 [-0.76, 1.40]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.58 (P = 0.56)



2.3.3.11.Wheelchair cushion with individualised cyclic pressure-relief protocol vs standard wheelchair cushion

Figure 77 – Pressure ulcer closure (cm^2)

Study or Subgroup	Pressure-relief cushion Mean	SD	Total	Standard cushion Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Makhous, 2009	12.49	52	22	78.5	74.4	22	100.0%	-66.01 [-103.94, -28.08]
Total (95% CI)			**22**			**22**	**100.0%**	**-66.01 [-103.94, -28.08]**

Heterogeneity: Not applicable
Test for overall effect: Z = 3.41 (P = 0.0006)

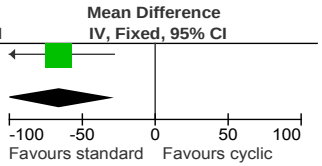


Figure 78 – Pressure ulcer closure rate (cm^2/day)

Study or Subgroup	Pressure-relief cushion Mean	SD	Total	Standard cushion Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Makhous, 2009	0.23	2.04	22	2.17	1.46	22	100.0%	-1.94 [-2.99, -0.89]
Total (95% CI)			**22**			**22**	**100.0%**	**-1.94 [-2.99, -0.89]**

Heterogeneity: Not applicable
Test for overall effect: Z = 3.63 (P = 0.0003)

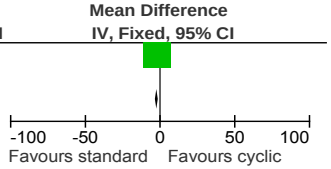


Figure 79 – PUSH score improvement

Study or Subgroup	Pressure-relief cushion Mean	SD	Total	Standard cushion Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Makhous, 2009	2.5	2.3	22	0.7	1.1	22	100.0%	1.80 [0.73, 2.87]
Total (95% CI)			**22**			**22**	**100.0%**	**1.80 [0.73, 2.87]**

Heterogeneity: Not applicable
Test for overall effect: Z = 3.31 (P = 0.0009)

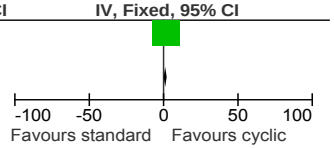


Figure 80 – % surface area reduction

Study or Subgroup	Pressure-relief cushion Mean	SD	Total	Standard cushion Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Makhous, 2009	45	21	22	10.2	34.9	22	100.0%	34.80 [17.78, 51.82]
Total (95% CI)			**22**			**22**	**100.0%**	**34.80 [17.78, 51.82]**

Heterogeneity: Not applicable
Test for overall effect: Z = 4.01 (P < 0.0001)

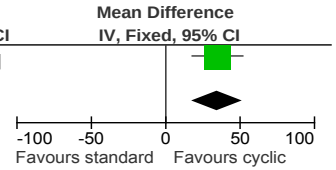
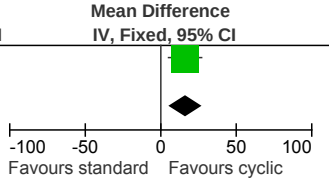


Figure 81 – % PUSH score improvement

Study or Subgroup	Pressure-relief cushion Mean	SD	Total	Standard cushion Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Makhous, 2009	21.9	24.6	22	5.8	9.2	22	100.0%	16.10 [5.13, 27.07]
Total (95% CI)			**22**			**22**	**100.0%**	**16.10 [5.13, 27.07]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.88 (P = 0.004)



2.3.4. Clinical evidence tables

Table 51 – ALLMAN1987

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Allman 1987 Title: Air-fluidized beds or conventional therapy for pressure sores. A randomised trial Journal: Annals of Internal Medicine 1987; 107 (5); 641-8 Type of study: RCT Sequence generation: random number table (low risk) Allocation concealment: sealed envelopes numbered sequentially – no mention if they were opaque (unclear risk) Blinding: masked assessment included review of serial photographs of all pressure sores (low risk) Addressing incomplete outcome data: yes, 7 withdrew and details of	Patient group: surgical patients with pressure ulcers All patients Randomised N: 72 were randomised but do not know which groups. Completed N: 65 Drop-outs: 90% follow-up; Group 1 Randomised N: 35 Completed N: 31 Dropouts: 4 patients withdrew because of difficulty transferring in and out of the air-fluidised bed Group 2 Randomised N: 37 Completed N: 34 Dropouts: 3 were withdrawn because	Group 1: Air-fluidised therapy (CLINITRON) repositioned every 4 hours Group 2: Conventional treatment (including 2-hourly turns, heel and elbow protectors, alternating-pressure mattresses)	Outcome 1: Change in total surface area of ulcers – median (range) (cm2)	Group 1: -1.2 (-38.0 to +15.5) Group 2: +0.5 (-55.1 to +94.7) Difference: -1.7cm2 (95%CI: -9.2cm2 to -0.6cm2) P=0.01 Insufficient data available to calculate the difference in effects between the two interventions using Revman	Funding: Grant in part from Support Systems International Inc. Limitations: unclear allocation concealment; baseline difference and size of ulcer at baseline not reported. Study underpowered. Additional outcomes: N/A
			Outcome 2: Proportion with improvement in condition of pressure ulcer (judged from photographs by blinded assessors)	Group 1: 22/31 Group 2: 16/34 Difference: 24% (95% CI 1% to 47%) P=0.05	
			Outcome 3: Proportion with 50% reduction in total surface area	Group 1: 9/31 Group 2: 8/34 Difference: 5% (95% CI -16% to 26%) P=0.64	
			Median length of stay in hospital after	Group 1: 16 days Group 2: 15 days	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
when and where. Patients were not included in the analysis. Selective reporting: all of the study's pre-specified outcomes were reported (low risk) Analysis: ITT analysis specified in study report (low risk) Statistical analysis: two-tailed chi-square or Fisher exact tests for categorical variables. Wilcoxon rank sum test used for continuous and ordinal data; stepwise logistic regression analysis to determine factors associated with a masked assessment of improvement after adjustment. Nonparametric methods used for CIs for median change in total surface area and normal approximation used for CIs for differences in % of	pressure sore getting worse; one withdrew because of noise of the bedside pump used to inflate the air mattress. Inclusion criteria: aged 18 or over, with pressure ulcers of all stages; patients expected to be limited to bed/chair and in hospital for a minimum of 1 week. Exclusion criteria: if been in trial previously; skin graft or flap was planned for the pressure sore within one week.		randomisation		
			Mortality	Group 1: 8/31 Group 2: 7/34	
			Outcome 4: Change in pain intensity from baseline: from asking patients to score 0 to 5 on words to describe pain (none, mild, discomforting, distressing, horrible or excruciating) Decreased		
				Group 1: 8/13 Group 2: 4/14	
			No change		
				Group 1: 5/13 Group 2: 7/14	
			Increased		
				Group 1: 0/13 Group 2: 3/14 P=0.01	
			Outcome 5: Change in comfort		

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
patients showing improvement or 50% reduction in surface area. Baseline differences: patients on air-fluidised beds had a more limited activity level. Size of baseline ulcers not measured. (high risk) Study power/sample size: a priori sample size calculation. Study was underpowered. Setting: hospital, USA Length of study: mean 13 days follow-up (range 4-77 days) Assessment of PUs: surface area was obtained by tracing borders of pressure sores on clear, plastic transparencies then using a computerised digitiser and summing all areas from various areas. Photographs taken. Classification of PUs: Shea classification			from baseline: Increased No change Decreased	 Group 1: 8/13 Group 2: 3/14 Group 1: 4/13 Group 2: 4/14 Group 1: 1/13 Group 2: 6/14 P=0.04	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Multiple ulcers: NR Timing of outcome assessment similarity: data collected weekly (low risk)					

Table 52 – BRANOM2001

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Branom 2001 Title: 'Constant force therapy' versus low-air-loss therapy in the treatment of pressure ulcers. Journal: Ostomy Wound Management 2001; 46 (9); 38-46 Type of study: RCT Sequence generation: patients who met the inclusion criteria were randomly assigned to one of the two groups, the study mattress or the LAL, in an alternating pattern as they were admitted	Patient group: inpatients from long-term and subacute care centre specialising in ventilator-dependent patients and those with extensive wound care needs. All patients Randomised N: 20 Completed N: not reported Drop-outs: not reported Group 1 Randomised N: 10 Completed N: not reported	Group 1: PressureGuard CTF (Constant Force Therapy) (non-powered mattress) Group 2: LAL mattress	Outcome 1: Mean % of closure per week (at week 8)	Group 1: 9% (s.d 4.8) Group 2: 5% (s.d 3.7)	Funding: not reported Limitations: randomisation inadequate; unclear allocation concealment and blinding; no details of incomplete outcome data, type of analysis, ulcer sizes at baseline and classification of pressure ulcers. Very small sample size. Two of the ten patients in the LAL group at

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
(high risk) Allocation concealment: inadequate information given (unclear risk) Blinding: unstated (unclear risk) Addressing incomplete outcome data: unstated (unclear risk) Analysis: not specified in report (high risk) Statistical analysis: not reported Baseline differences: baseline comparability for initial ulcer size not reported (low risk) Study power/sample size: very small Setting: Long term and subacute care centre specialising in ventilator-dependent patients and those with extensive wound care needs Length of study: 8-week follow-up Assessment of PUs: not specified	Dropouts: not reported Group 2 Randomised N: 10 Completed N: not reported Dropouts: not reported Inclusion criteria: bedridden patients had a pressure ulcer at grade 3 or 4 on trunk or pelvis. Exclusion criteria: not stated 2 groups were matched in age, nutritional deficiency and use of g-tubes.				randomisation were switched from the LAL to the study mattress. Additional outcomes: N/A Notes: each facility used the LAL mattress brand most familiar to them

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Classification of PUs: not specified. Multiple ulcers: not reported Timing of outcome assessment similarity: wound measurements taken at 3 weeks (low risk)					

Table 53 – CALEY1994

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Caley 1994 Title: Randomised prospective trial of two types of low air loss therapy. Journal: Personal communication 1994 Type of study: RCT Sequence generation: method of randomisation not stated. Authors state	Patient group: Acute care patients with existing pressure ulcers, for whom an Enterostomal Therapy Nurse had recommended low-air-loss therapy. All patients Randomised N: 93 Completed N: 55 Drop-outs: 38 (those	Group 1: LAL bed (Mondarch, Mediscus) Group 2: LAL overlay (SPR Plus, Gaymar) Skincare protocol applied to both groups.	Outcome 1: Median change in ulcer area (measured by multiplying ulcer length by ulcer width) Outcome 3: mean changes in pressure ulcer surface area	Group 1: 3.9cm2 Group 2: 1.9cm2 Very little data provided P=0.060 Perimeter 0.171 Group 1: 10.2cm2 Group 2: 3.8cm2 Insufficient data to calculate the mean difference between the two interventions.	Funding: not reported Limitations: very little data provided (median change in area and range); unclear (and unlikely) that the outcome assessment was blind to treatment group. No description of co-

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
subjects were randomised to either the low-air-loss bed or the low-air-loss overlay (unclear risk) Allocation concealment: allocation concealment not stated (high risk) Blinding: No blinding (high risk) - unclear (and unlikely) that outcome assessment was blind to treatment group. Addressing incomplete outcome data: insufficient reporting of attrition/exclusions (unclear risk) Selective reporting: all of the study's pre-specified outcomes were reported (low risk) Analysis: unclear Statistical analysis: not reported Baseline differences: not reported Study power/sample size: small sample size	discharged before 3rd week of study were not included in analysis ie those who improved quickest). Gender (f/m): 60%/40% Age, mean (range): 76 (42-98 years) Group 1 Randomised N: unclear Completed N: 23 Dropouts: not reported Group 2 Randomised N: unclear Completed N: 32 Dropouts: not reported Inclusion criteria: acute care patients with existing pressure ulcers and for whom an enterostomal therapy nurse had recommended low air loss therapy Exclusion criteria: not reported				interventions except skincare protocol applied to both groups; insufficient reporting of incomplete outcome data; high drop-out; Additional outcomes: healing progress over time

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Setting: acute care ward Length of study: average 24-day follow-up Assessment of PUs: not reported Multiple ulcers: not reported Timing of outcome assessment similarity: pressure ulcers measured every week for 1 month or until discharge (low risk)					

Table 54 – CLARK1998

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Clark 1998 Title: A randomised controlled trial comparing the healing of pressure sores upon two pressure-redistributing seat	Patient group: Elderly patients in 2 acute care hospitals and 2 nursing homes. All patients Randomised N: 33	Group 1: ProActive 2 cushion (Pegasus). Cushion for day chairs and wheelchairs. Seating automatically adjusts to patient's weight. Cycle time 12 minutes. Group 2: ROHO cushion. Dry flotation system. All patients	Outcome 1: Number of ulcers healed completely	Group 1: 3/14 Group 2: 5/11 RR 0.47 (0.14 to 1.56)	Funding: Pegasus Airwave Ltd. Limitations: unclear details of randomisation; unblinded observer; grading
			Outcome 2: rate of healing (cm2/day)	Group 1: 0.13 (SEM 0.10) Group 2: 0.27 (SEM 0.17)	
			Outcome 3: rate	Group 1: 0.56 (SEM 0.23)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
cushions. Journal: Proceedings of the 7th European Conference on Advances in Wound Management; 1997, 18-20 November; Harrogate, UK. 1998: 122-5. Type of study: RCT Sequence generation: all eligible subjects were allocated to a cushion according to a pre-determined randomisation protocol (unclear risk) Allocation concealment: allocation using sequential, sealed, opaque envelopes (low risk) Blinding: a single unblinded observer collected all data (low risk) All data were analysed blinded. Addressing incomplete outcome data: no missing outcome data (low risk)	Completed N: 25 Drop-outs: 8 Group 1 Randomised N: 17 Completed N: 14 Dropouts: 2 withdrawn due to enzymatic debridement of sores; 1 withdrawn due to deteriorating medical condition prompting confinement to bed Group 2 Randomised N: 16 Completed N: 11 Dropouts: 1 died within 7 days of recruitment; 2 were withdrawn due to enzymatic debridement of sores, 2 withdrawn due to deteriorating medical condition prompting confinement to bed Inclusion criteria: predicted to remain in the trial for at least 7 days; with established	had a Pegasus Airwave system in bed.	of healing (cm3/day)	Group 2: 0.49 (SEM 0.26)	system of ulcers not specified; high drop-out Additional outcomes: N/A Author used data from subjects with more than one assessment completed.
			Outcome 4: % change in area per day	Group 1: 2.56 (SEM 2.10) Group 2: 5.71 (SEM 1.68)	
			Outcome 5: % change in volume per day	Group 1: 1.00 (SEM 0.49) Group 2: 0.68 (SEM 0.26)	
			Mortality	Group 1: 3/14 Group 2: 1/11 RR 2.36 (95% CI 0.28 to 19.66)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Selective reporting: all of the study's pre-specified outcomes were reported in original study report Analysis: data analysis was based on the remaining 25 subjects (high risk) Statistical analysis: SPSS no mention of statistical tests. Baseline differences: groups well matched at baseline for important variables such as Waterlow score, mobility, nutritional status, continence. Baseline comparability for initial area of ulcer also reported (low risk). Study power/sample size: although a priori sample size calculation was done, projected sample size not achieved. Setting: 2 acute care hospitals and 2 nursing homes. Length of study:	pressure ulcers grade 2 or above; Exclusion criteria: patients with pressure sores with a surface are of greater than 15cm2.				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
average 58.6 days (Proactive) and 43.73 days (ROHO) Categorisation of PUs: not reported Assessment of PUs: wound area calculated using the formula length x width x 0.785 while wound volume was calculated by the formula (length x width x 0.785) x depth. Classification of PUs: grading system not specified Multiple ulcers: not reported Timing of outcome assessment similarity: subjects assessed at weekly intervals.					

Table 55 – DAY1993

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Day 1993 Title: Seeking quality care for patients with pressure ulcers. Journal: Decubitus 1993; 6(1); 32-43 Type of study: RCT Sequence generation: patients were randomised to either the air-suspension bed or the foam mattress overlay (unclear risk) Allocation concealment: allocated by sealed envelopes. No other details (unclear risk) Blinding: not state (unclear risk) Addressing incomplete outcome data: insufficient reporting of attrition/exclusions (unclear risk) Selective reporting: not all of the study's pre-specified outcomes were reported (high	Patient group: hospitalised, adult patients with existing grade 2-4 pressure ulcers (NPUAP) All patients Randomised N: 83 Completed N: 48 Drop-outs: 35 Group 1 Randomised N: 44 Completed N: 25 Dropouts: 19 Age, mean (s.d, range): 75.09 (15.37, 32 to 102 years) Males/females: 17/27 Mean weight: 130.35lbs. Karnofsky performance status (0% dead to 100% nor mal activity level): 36.25% (severely disabled and required special care and assistance). Most common diagnoses: dehydration	Group 1: Air suspension bed (Therapulse, Kinetic concepts) Group 2: Foam mattress overlay (Geomatt, SpanAmerica) Wound care standardised for 2 groups.	Outcome 1: Mean ulcer size divided into grade 2 and grade 3/4 ulcers.	Stage II Group 1: 7.3 (s.d 2.4) Group 2: 5.3 (2.1) Stage III and IV Group 1: 37.1 (8.1) Group 2: 12.4 (3.5) All pressure ulcers: Ancova: F [1,78} = 0.35, p>0.05	Funding: in part by Kinetic Concepts Inc. Limitations: unclear randomisation, allocation concealment and blinding, insufficient reporting of incomplete outcome data, not all of the pre-specified outcomes were analysed. Did not report initial ulcer sizes. Additional outcomes: N/A Notes: no p values given, but all analyses reported as not statistically significantly different. Comfort
			Outcome 2: Mean comfort scores	Group 1: 4.1 (sd 1.3) n=20 Group 2: 3.7 (s.d 1.3) n=19 T[37] 0.91, p>0.05	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
risk) Analysis: not specified in study report (high risk) Statistical analysis: ancova; logarithmic transformation was used due to highly skewed ulcer size. Baseline differences: baseline comparability for initial ulcer size : no significant differences(low risk) Study power/sample size: power calculation given, underpowered. Setting: hospital Length of study: 7 day follow Assessment of PUs: not reported Classification of PUs: NPUAP grading system Multiple ulcers: 22 patients in the air-suspension group and 17 in the foam overlay group had multiple pressure ulcers, the most severe ulcer was	(n=10), fever of unknown origin (n=10), pneumonia (n=7), dementia (n=7), respiratory failure (n=7) Modified Norton Scale scores: 8.84 (s.d 2.84) (n=44) Group 2 Randomised N: 39 Completed N: 23 Dropouts: 16 Age, mean (s.d, range): 77.13 (10.76, 54 to 93 years) Males/females: 18/21 Mean weight: 125.83lbs. Karnofsky performance status (0% dead to 100% normal activity level): 36.66% (severely disabled and required special care and assistance). Most common diagnoses: dehydration (n=10), fever of unknown origin (n=7), urinary tract infection (n=6), pneumonia (n=5)				score results only completed by half the subjects (Group 1, n=20; Group 2, n=21) Distribution of the ulcer size within each stage was highly skewed for both study groups so logarithmic transformation was applied to ulcer size in an attempt to meet the assumption of normality.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
selected for analysis Timing of the outcome assessment similarity: patient assessment flow sheet completed daily by nursing staff. Nutrition and comfort assessed weekly by staff. Ulcer measurements taken weekly.	Modified Norton Scale Scores: 9.03 (s.d 3.19) (n=39) Inclusion criteria: hospitalised patients older than 18 years of age with a stage II, III or IV pressure ulcer(s); life expectancy of at least one week; activity limited to chair or bed during hospitalisation; informed consent signed by the patient, or patient's family or guardian; and permission of the attending physician Exclusion criteria: patient previously enrolled in the study; patient hospitalised for less than 7 days; patient having undergone skin grafting or flap within 7 days of enrolment in the study.				

Table 56 – DEVINE1995

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Devine 1995 Title: Alternating pressure air mattresses in the management of established pressure sores. Journal: Journal of Tissue Viability, 1995; 5; 94-8 Type of study: RCT Sequence generation: allocation to each group was achieved using a computer-generated list of random numbers kept separately from the trial co-ordinator (low risk) Allocation concealment: see above (low risk) Blinding: no blinding (high risk) Addressing incomplete outcome data: detailed (low risk) Analysis: not specified in study report (high	Patient group: Elderly patients in hospital admitted with ulcers of grade 2 or above (grading system not reported) All patients Randomised N: 41 Completed N: 30 Drop-outs: withdrawal rates by group and reasons for withdrawal stated. 11 patients (24%) died (9) or moved to other hospitals (2). Age, mean (range): 82.5 years (69-98 years) Group 1 Randomised N: 22 Completed N: 16 Dropouts: 5 (died) Group 2 Randomised N: 19 Completed N: 14 Dropouts: 4 (died), 2	Group 1: Alternating-pressure mattress (Nimbus 1). Modular, with rows of figure-of-eight shaped cells. Two sets of cells are inflated and deflated over 10 min cycle. Group 2: Alternating-pressure mattress (Pegasus Airwave). Double layer mattress with a 3-cell alternating cycle lasting 7.5min. All patients were subject to the standard hospital protocol for wound dressings; details of this were not provided.	Outcome 1: Complete healing at 4 weeks	Group 1: 10/16 ACA Group 2: 5/14 ACA RR 0.57 (95% CI 0.26 to 1.27)	Funding: HNE Healthcare provided a grant for employment of a part time research nurse Limitations: no blinding; baseline differences and baseline ulcer size not reported. Additional outcomes: N/A
			Outcome 2: Decrease in pressure ulcer size	Group 1: 4/16 ACA Group 2: 6/14 ACA RR 0.58 (95% CI 0.21 to 1.65)	
			Outcome 3: Increase in pressure ulcer size	Group 1: 2/16 ACA Group 2: 3/14 ACA RR 0.88 (95% CI 0.21 to 3.66)	
			Outcome 2: Comfort	Group 1: median 8/10 Group 2: median 8/10 Should be interpreted with caution due to very small response rate.	
			Outcome 3: Median rate of reduction in area (cm/day)	Group 1: 0.089cm2/day Group 2: 0.107cm2/day Difference: 0.018 cm2 (95% CI 0.179 to 0.143, p=0.92) this difference was calculated using the median of all possible pairwise differences between the groups, not the difference in the 2 medians	
			Mortality	Group 1: 6/21	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
risk) Statistical analysis: not reported Baseline differences: More people incontinent of urine in Nimbus group; more people catheterised in Airwave group. Baseline comparability for initial ulcer size not reported Study power/sample size: no power calculation, small sample size Setting: geriatric unit Length of study: 4-week follow-up Assessment of PUs: length and breadth to calculate surface area Classification of PUs: grading system not stated. Multiple ulcers: not reported Timing of outcome assessment similarity: timing of outcome assessment only	(moved to other hospital) Inclusion criteria: ulcers of grade 2 or above; Exclusion criteria: not reported.			Group 2: 5/19 RR 1.43 (95% CI 0.38 to 2.86)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
stated for grading of pressure sore 'at 3 day intervals.					

Table 57 – EVANS2000

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Evans 2000 Title: A clinical evaluation of the nimbus 3 alternating pressure mattress replacement system Journal: Journal of wound care, April 2000, 9 (4). Type of study: RCT Sequence generation: method of randomisation not stated (unclear risk) Allocation concealment: treatments were randomly allocated to sequentially-labelled sealed envelopes – no mention if opaque (unclear risk)	Patient group: hospital and nursing patients, over 65 years All patients Randomised N: 32 Completed N: unclear Drop-outs: Large proportion of patients did not complete follow-up (11/20 in nursing home group, 75% in hospital group) Group 1 Randomised N: 17 Completed N: 6 Dropouts: 11 Group 2	Group 1: Alternating-pressure mattress replacement system (APMRS) (Nimbus 3) Group 2: Alternating-pressure mattress replacement system (APMRS) for hospital patients (P.Biwave, P.Airwave, P.Cairwave or AlphaXCell) or alternating-pressure mattress overlay (AlphaXCell or Quattro) for nursing home patients.	Outcome 1: Absolute and relative reduction in wound surface area (calculated twice weekly by planimetry) in hospital patients	Median absolute reduction in wound surface area per day: Group 1: 0.12cm2 (range 0 to 0.21cm2) Group 2: 0.08cm2 (range 0.04 to 0.33cm2) P=0.570 (mann-whitney u-test) Median relative reduction in wounds surface area (and range): Group 1: 2.44% (range 0-7.14%) Group 2: 1.34% (range 1.11-2.88%) P=0.570 (mann-whitney u-test) There were insufficient data available in the study report to calculate the mean difference	Funding: not reported Limitations: method of randomisation not reported. Unclear allocation concealment. Large proportion of patients did not complete follow-up (11/20 in nursing home group and 75% of hospital group); very small sample size. Additional outcomes: N/A

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Blinding: 2 research team members, blind to the surface used, carried out the WSA measurements (low risk) Addressing incomplete outcome data: no missing outcome data (low risk) Selective reporting: all of the study's pre-specified outcomes were reported (low risk) Analysis: unclear risk Statistical analysis: Mann-Whitney U-test. Normality tests on continuous data showed that some ordinal data sets did not come from normal distributions, so descriptive statistics used to summarise continuous data sets were medians and ranges. Baseline differences: baseline comparability for initial area of ulcer	Randomised N: 15 Completed N: 6 Dropouts: 9 Inclusion criteria: over 65 years; either grade 2 or 3 ulcer or grade 2 and one or more of the following: difficult to reposition in bed, unable to tolerate 30 degree tilt, unable to move in bed, in bed for >20 hours/24 hours, >108kg and bed-bound, undergone spinal anaesthetic. Exclusion criteria: spinal metastases; exudating wounds that may lead to hygiene or infection control problems; weight >250kg (39 stone).			between the two interventions	
			Outcome 2: Absolute and relative reduction in wound surface area (calculated twice weekly by planimetry) in nursing home patients	Median absolute reduction in wound surface area per day: Group 1: 0.11cm2 (range 0.04 to 0.41cm2) Group 2: 0.05cm2 (range 0 to 0-0.48cm2) P=0.570 (mann-whitney u-test) Median relative reduction in wounds surface area (and range): Group 1: 1.57% (range 0.45-5%) Group 2: 0.99% (range 0-2.54%) P=0.570 (mann-whitney u-test) There were insufficient data available in the study report to calculate the mean difference between the two interventions	
			Outcome 3: Comfort	Median comfort score hospital patients Group 1: 5 (very comfortable) Group 2: 4 (comfortable) P=0.006	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
also reported (low risk) Study power/sample size: no sample size calculation, small sample. Setting: hospital and nursing home. Length of study: 2-week follow-up. Assessment of PUs: Planimetry. Classification of PUs: grading system not specified. Multiple ulcers: one ulcer per subject,, if more than one the largest with the highest grade used. Timing of outcome assessment similarity: primary outcome (ulcer size, size and grade) measured twice weekly, secondary outcome measure (patient comfort) measured weekly.				Median comfort score nursing home patients: Group 1: 5 (very comfortable) Group 2: 4 (comfortable) P=0.002	
			Outcome 3: mortality	Hospital patients Group 1: 0/7 Group 2: 2/5 Nursing home patients Group 1: 7/10 Group 2: 1/10	
			Outcome 2: Comfort	Group 1: 14/18 Group 2: not reported	
			Outcome 3: Relief of redness	Group 1: 14/18 Group 2: 0/18 RR 29 (95% CI 1.86 to 425.00)	

Table 58 – FERRELL1993

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Ferrell 1993 A randomised trial of low air loss beds for treatment of pressure ulcers. Journal: JAMA 1993; 269; 494-7 Type of study: RCT Sequence generation: method of unclear - randomisation in blocks of 10; 5 to each treatment (unclear risk) Allocation concealment: assignments were sealed in individual envelopes and opened sequentially on establishment of study criteria (low risk) Blinding: unclear (unclear risk) Addressing incomplete outcome data: insufficient reporting of attrition/exclusions (unclear risk) Selective reporting: all of the study's pre-	Patient group: Elderly nursing home residents with multiple medical problems and with trunk or trochanter pressure ulcers (Shea grade 2 or greater) All patients Randomised N: 84 Completed N: 45 Drop-outs: 18 died, 8 transferred to another facility Group 1 Randomised N: 43 Completed N: 26 Dropouts: 11 died, 4 transferred to another facility, 2 discontinued at subject's request Group 2 Randomised N: 41 Completed N: 19 Dropouts: 7 died, 4 transferred to another facility, 2 discontinued at	Group 1: LAL bed (KINAIR) Group 2: 10cm convoluted foam overlay on top of standard foam mattress. Both groups had similar co-interventions as per standard care i.e. mobilisation as much as possible; 2-hourly turning during walking hours; avoidance of head-of-bed elevation; avoidance of dragging patients on sheets; nutritional support; infection control.	Outcome 1: Rate of healing mm2/day -median (25^{th}, 75^{th} percentiles)	Group 1: 9.0 (4.0, 19.8) Group 2: 2.5 (0.5, 6.5) P=0.0002 P=0.004	Funding: supported in part by the Jewish Home for the Aging of Greater Los Angeles; the Sepulveda Veterans Affairs Geriatric Research Education and Clinical Center; the West Los Angeles Veterans Affairs Geriatric Research Education and Clinical Center and a gift by Kinetic Concepts International. Limitations: study terminated at interim analysis as difference much larger than expected. Method of sequence Unclear blinding; insufficient reporting of
			Outcome 2: Ulcers completely healed (covered with epithelium)	Group 1: 26/43 (60%) Group 2: 19/41 (46%) RR 1.30 (95% CI 0.87 to 1.96) P=0.19	
			Outcome 3: mortality	Group 1: 11/43 (26%) Group 2: 7/41 (17%) P=0.34	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
specified outcomes were reported (low risk). Analysis: ITT analysis specified in study report (low risk) Statistical analysis: Student's tests for normally distributed continuous data and X2 or Wilcoxon rank-sum tests used to compare categorical variables or variables with non-normal distributions. Healing rates adjusted for follow-up using Kaplan-Meier and further covariate adjustment by Cox regression models. Baseline differences: groups appeared to be well matched at baseline, including ulcer area, except that patients in LAL bed group had significantly lower serum albumin. Study power/sample size: a priori sample size calculation;	subject's request, 9 protocol deviators Inclusion criteria: Trunk or trochanter pressure ulcers (grade 2 or greater); Exclusion criteria: expected to survive < 1 month; had already participated in the study; surgery to the ulcer was planned.				incomplete outcome data. Additional outcomes: superficial and deep ulcers given for rate of healing. Notes: study terminated early after finding a much larger difference between the two groups than initially anticipated.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Setting: Nursing home. Length of study: median follow-up of 33 days (LAL group) and 40 days (foam mattress group) Assessment of PUs: Wound surface area was traced twice/week on plastic film, and area measured using planimetry. Classification of PUs: Shea grading system. Multiple ulcers: where patient had multiple ulcers, largest ulcer chosen as index ulcer. Timing of outcome assessment similarity: healing assessed twice weekly (low risk)					

Table 59 – GROEN1999

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Groen 1999 Title: Comparative study of a foam	Patient group: Nursing home patients >59 years old with pressure ulcer on trunk of grade 3 or 4	Group 1: Foam replacement mattress: 3 layers of polyurethane foam designated as comfort, load-	Outcome 1: Proportion with healed ulcers at 4 weeks	Group 1: 27/60 (45%) Group 2: 29/60 (48%) RR 0.93 (0.63 to 1.37)	Funding: not reported

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
mattress and a water mattress. Journal: Journal of Wound Care 1999; 8(7): 333-5. Type of study: RCT Sequence generation: method of randomisation not stated (unclear risk) Allocation concealment: subjects were randomly divided into two groups of 60 by selection of sealed envelopes - no mention of envelopes being opaque (unclear risk) Blinding: no blinding (high risk) Addressing incomplete outcome data: insufficient reporting of attrition/exclusions (unclear risk) Selective reporting: not all of the study's pre-specified outcomes were reported (high risk) Analysis: not specified	All patients Randomised N: 120 Completed N: 101 Drop-outs: withdrawals: 11 from Group 1, 8 from Group 2, but not stated at which time points withdrawals occurred. Reasons for withdrawals included severe illness and discharge. Group 1 Randomised N: 60 Completed N: 49 Dropouts: 11 Average age: 81.9 years Pressure ulcer severity: 4.8 Group 2 Randomised N: 60 Completed N: 52 Dropouts: 8 Average age: 83.5 years Pressure ulcer severity: 5.5	distributing and support layers Group 2: Secutex water mattress: placed on top of standard hospital mattress, 3 PVC sections holding 26L water each, with heating element. Standard turning protocol (every 2-3 hours) for both groups.	Outcome 3: % with pain (final values)	Group 1: 4.1% Group 2: 3.8%	Limitations: no details of randomisation method; unclear allocation concealment; no blinding; insufficient reporting of incomplete outcome data; no details of type of analysis; selective reporting. More patients reported slight pain (40%) than in group B (20%) at baseline. Additional outcomes: N/A

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
in study report (high risk) Statistical analysis: categorical variables analysed using the chi-square test and Mann Whitney test was used for analysis of numerical values. Baseline differences: more patients in group reported slight pain than in group B. Baseline comparability for initial area of ulcer also reported (low risk) Study power/sample size: a priori sample size of 60 in each group Setting: 3 nursing homes Length of study: 4-week follow-up Assessment of PUs: ulcer severity assessed weekly using a validated quantitative scoring system, no details of how measured the wound. Classification of PUs:	Inclusion criteria: 60 years or over, pressure ulcer on trunk of grade 3 (superficial cutaneous or subcutaneous necrotic) or grade 4 (deep subcutaneous necrotic). Exclusion criteria: severe or terminal illness.				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
no grading system specified. Multiple ulcers: not reported Timing of outcome assessment similarities: pressure ulcer severity measured once a week (low risk).					

Table 60 – KEOGH2001

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Keogh 2001 Title: Profiling beds versus standard hospital beds: effects on pressure ulcer incidence outcomes. Journal: Journal of wound care 2001; 10(2):15-9. Type of study: RCT Sequence generation: the block design randomisation code was computer generated by an	Patient group: surgical and medical ward patients, >18 years with tissue damage no greater than grade 1 (EPUAP) All patients Randomised N: 100 but only 14 had existing pressure ulcers at start of study Completed N: unclear Drop-outs: data incomplete 30 patients. The extent of follow-up	Group 1: Profiling bed with a pressure reducing foam mattress/cushion Group 2: Flat-based bed with a pressure relieving/redistributing mattress/cushion	Outcome 1: Proportion with healed grade 1 ulcers	Group 1: 4/4 Group 2: 2/10 RR 3.96 (95% CI 1.28 to 12.24)	Funding: Huntleigh Healthcare Ltd Limitations: unclear blinding; not all of the study's pre-specified outcomes were reported; not all patients had pressure ulcers (only 14 had existing pressure ulcers), so small sample size and

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
independent statistician using blocks of 8 (low risk) Allocation concealment: the allocation for each patient was placed in sealed, opaque envelopes that were numbered sequentially (low risk) Blinding: unstated (unclear risk) Addressing incomplete outcome data: insufficient reporting of attrition/exclusions Selective reporting: not all of the study's pre-specified outcomes were reported (high risks) Analysis: all 100 patients were included in an intent-to-treat analysis in respect of pressure ulcer incidence Statistical analysis: Fisher's exact test Baseline differences: baseline comparability	was difficult to ascertain. Group 1 Randomised N: 50, but only 4 had pressure ulcers Completed N: unclear Dropouts: unclear Group 2 Randomised N: 50, but only 10 had pressure ulcers Completed N: unclear Dropouts: unclear Inclusion criteria: > 18 years old; Waterlow score of 15-25; tissue damage no greater than grade 1 (EPUAP) Exclusion criteria: see above				uneven distribution, with only 4 in the experimental group). Grade 1 ulcers analysed only. Insufficient reporting of attrition/exclusions. High drop out from study and do not know how many of those who dropped-out had existing pressure ulcers at start of the trial. Additional outcomes: * All 100 patients were included in an ITT analysis irrespective of pressure ulcer incidence. Except for secondary outcome n=70. Only 14 had existing grade 1 pressure ulcers, and had results.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
for initial ulcer size not reported (low risk) Study power/sample size: a priori sample size calculation done; but only 14 patients had existing pressure ulcers and this was unevenly distributed. Setting: 2 surgical and 2 medical wards Length of study: 5-10 days' follow-up Assessment of PUs: not reported. Classification of PUs: EPUAP grading system Multiple ulcers: not reported Timing of outcome assessment similarity: unclear risk.					

Table 61 – MULDER1994

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Mulder 1994	Patient group: Nursing home patients with	Group 1: Air suspension bed (Therapulse, Kinetic	Outcome 1: Wound closure.	Group 1: 5/31 Group 2: 3/18	Funding: grant from Kinetic

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Title: A study of pressure ulcer response to low air loss beds vs. conventional treatment. Journal: Journal of Geriatric Dermatology 1994;2(3): 87-91 Type of study: RCT Sequence generation: method of randomisation not stated. Authors state 'this was a single center study conducted as a randomised controlled trial' (unclear risk) Allocation concealment: unclear (unclear risk) Blinding: unclear (unclear risk) Addressing incomplete outcome data: no details of which groups drop-outs came from (unclear risk) Selective reporting: not all of the study's pre-specified outcomes were reported (high	grade 3-4 pressure ulcers All patients Randomised N: 49 Completed N: 39 Drop-outs: 10: 8 died, 1 lost to follow-up, 1 protocol violation. No information about groups from which withdrawals came. No explanation of why the stated 1:1 randomisation ratio resulted in such disproportionate groups Group 1 Randomised N: 31 Completed N: unclear Dropouts: unclear Group 2 Randomised N: 18 Completed N: unclear Dropouts: unclear Inclusion criteria: stage III or IV pressure ulcers	concepts): a pulsating air suspension therapy (cushions alternatively inflate and deflate but classed as LAL rather than AP) Group 2: Convoluted foam mattress overlay (Geomatt, SpanAmerica) Wound care and repositioning standardised for both groups.		RR 0.97 (95% CI 0.26 to 3.58)	Concepts Inc. Limitations: no details of randomisation method; unclear allocation concealment and blinding; no details of which groups drop-outs came from; not all of the pre-specified outcomes were reported; ulcer size not reported at baseline. Additional outcomes: N/A
			Outcome 2: Pressure ulcer improvement (pressure ulcer reduced by one grade or more, including healed completely)	Group 1: 10/31 Group 2: 5/18 RR 0.29 (95% CI 0.12 to 0.72)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
risk) Analysis: ITT analysis specified in study report (low risk) Statistical analysis: ANCOVA on log-transformed decrease in ulcer area and volume. Baseline differences: baseline comparability for initial ulcer size not reported (unclear risk) Study power/sample size: no sample size calculation. Small sample Setting: nursing home Length of study: maximum 12 weeks follow-up, or until ulcers healed, whichever occurred first. Assessment of PUs: wound surface area assessed by photoplanimetry. Ulcer volume = ulcer length x width x depth (of deepest ulcer point). Classification of PUs:	within a range of 1.5cm x 1.5cm to 10.0 cm x 20.0 cm Exclusion criteria: carcinomatosis; osteomyelitis affecting the target ulcer; uncontrolled target ulcer infection; immune deficiency disorders; inadequate nutritional status.				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
International Association of Enterostomal Therapists staging system). Multiple ulcers: not reported Timing of outcome assessment similarity: wounds assessed weekly (low risk)					

Table 62 – MUNRO1989

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Munro 1989 Title: Pressure ulcers: one bed or another? Journal: Geriatric Nursing 1989; 10:190-2. Type of study: RCT Sequence generation: method of randomisation not stated. Authors state 'eligible, consenting patients... were	Patient group: Male patients with grade 2 or 3 pressure ulcers. All patients Randomised N: 40 Completed N: unclear Drop-outs: unclear Group 1 Randomised N: 20 Completed N: unclear	Group 1: Air-fluidised bed (Clinitron) Group 2: Standard care The bed/mattress in the standard care group was not described. Sheepskins or gel pads were placed beneath ulcer areas. Standard care involved positioning and massage.	Outcome 1: Change in mean ulcer area (mm2) measured on day 15 but provided only mean values and no data regarding the spread of results. Final area presented as % of initial nursing time in minutes/8h shift.	Group 1: 1158mm2 Group 2: 2051mm2 Standard deviations not reported. P=0.05 There were insufficient variance data available from the study to calculate the mean difference between the two interventions.	Funding: grant from Support Systems International Limitations: Unclear allocation concealment; no information regarding sample size calculations, randomisation method, blinding, baseline characteristics or
			Outcome 2:	Group 1: not reported (n=13)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
randomly assigned to the Clinitron bed (experimental group) or to a standard hospital bed (control group) Allocation concealment: unclear (unclear risk) Blinding: No blinding (high risk) Addressing incomplete outcome data: insufficient reporting of attrition/exclusions (unclear risk) Analysis: unclear (unclear risk) Statistical analysis: repeated-measures analysis of variance used to compare mean ulcer size; patient satisfaction on an 8-item scale. Pain measured by an adaptation of the Levitt and Derogatis scale. Baseline differences: groups described as comparable for age, diagnosis, size of ulcer, pain and Gosnell score	Dropouts: unclear Group 2 Randomised N: 20 Completed N: unclear Dropouts: unclear Inclusion criteria: patients with grade 2 or 3 pressure ulcers, expected to remain in hospital for at least 15 days. Exclusion criteria: patients with grade 4 ulcers; patients weighing >250lbs; patients at less than 70% of ideal body weight; patients with serum albumin <2.1g/100ml.		Patients' perception of pain (11 point scale from no pain to worst pain imaginable on that day)	Group 2: not reported (n=13) F=0.87, p=0.359	extent of follow-up. No raw data presented in the paper; insufficient reporting of incomplete outcome data.
			Outcome 3: Patient satisfaction (higher score more satisfaction)	Group 1: 57.5 (s.d 6.1)(n=8) Group 2: 48.6 (s.d 12.3)(n=10) T=1.99, p=0.067	Additional outcomes: Change in mean ulcer area (mm2) measured on 1st, 3rd, 8th, 15th days; nursing time

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
at baseline, but data not presented by group. Baseline comparability for initial ulcer size not reported (unclear risk) Study power/sample size: no information regarding sample size calculations. Setting: hospital Length of study: 15-day follow-up Assessment of PUs: tracing perimeters on Saran-wrap sheet then digitizer tablet and Zeiss MOP videoplan used. Classification of PUs: Staging systems used to classify PUs not specified. Multiple ulcers: not reported Timing of outcome assessment similarity: ulcer size/patient pain/administration of modified Gosnell scale measured on days 1,3,8, and 15. Nursing					

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
time measured on day 8. Not mentioned when patient satisfaction measured.					

Table 63 – NIXON2006

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Nixon 2006 Title: Randomised, controlled trial of alternating pressure mattresses compared with alternating pressure overlays for the prevention of pressure ulcers: PRESSURE (pressure relieving support surfaces) trial. Journal: BMJ 2006; 332 (7555):1416 Title of 2nd publication: Pressure relieving support surfaces: a randomised evaluation Health Technology Assessment, 10, 22	Patient group: patients in vascular, orthopaedic, medical or care of elderly wards with grade 2 pressure ulcers All patients Randomised N: 1971; only n=113 had pressure ulcers Completed N: unclear Drop-outs: unclear Group 1 Randomised N: 59 (with existing pressure ulcers of the 989 randomised to this group) Completed N: unclear Dropouts: unclear	Group 1: Alternating-pressure overlay within 24 hours of admission Group 2: Alternating-pressure mattress within 24 hours of admission	Outcome 1: Healing of existing pressure ulcers	Group 1: 20/59 (34%) ITT Group 2: 19/54 (35%) ITT RR 0.96 (95% CI 0.58 to 1.60)	Funding: UK department of health through HTA programme. Limitations: no blinding. Additional outcomes: proportion of patients developing a new pressure ulcer of grade 2 or worse; time to development of new pressure ulcers; proportion of participants developing a new pressure ulcer
			Outcome 2: time to healing (median time)	Group 1: 20 days Group 2: 20 days P=0.86, log rank test	
			Outcome 3: Patient acceptability (proportion of people requesting one or more changes for comfort and other device related reasons)	Group 1: 230/989 (23.3%) ITT Group 2: 186/982 (18.9%) ITT 4.4% (95% CI 0.7% to 7.9%), p=0.02, x2 test) This is all patients in the study, although only 113 patients had pressure ulcers.	
			Outcome 4: absolute change in surface area (cm2) – change	Group 1: 1 (s.d 2.3) Group 2: 2 (s.d 6.1)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Type of study: RCT Sequence generation: randomisation was through an independent, secure, 24 hour randomisation automated telephone system (low risk) Allocation concealment: randomisation was through an independent, secure, 24 hour randomisation automated telephone system, ensuring allocation concealment (low risk) Blinding: no blinding (high risk) Addressing incomplete outcome data: no missing outcome data (low risk) Selective reporting: all of the study's pre-specified outcomes were reported (low risk) Analysis: ITT analysis specified in study report (low risk)	Group 2 Randomised N: 54 (with existing pressure ulcers of the 982 randomised to this group) Completed N: unclear Dropouts: unclear Inclusion criteria: patients at least 55 years old; from vascular, orthopaedic, medical or care of the elderly wards; expected length of stay at least 7 days; Braden Score of 1 or 2; existing grade 2 pressure ulcer Exclusion criteria: pressure ulcer on admission of grade 3 or worse; had a planned admission to an intensive care unit after surgery; were admitted to hospital more than 4 days before surgery; slept at night in a chair; or weighted more than 140kg or less than 45k g (as per mattress		values		within 30 days Notes: study funded by HTA ITT analysis used in study. Although all withdrawal reasons given only 113 patients had pressure ulcers and do not know how many of these had missing data.
			Outcome 5: % change in surface area (change values)	Group 1: -35 (s.d 605.5) Group 2: 34.4 (s.d 108.6)	
			Outcome 6: negative comments for mattress motion	Group 1: 328/929 (35.3%) Group 2: 285/891 (32%)	
			Outcome 7: positive comments for mattress motion	Group 1: 272/929 (29.3%) Group 2: 263/891 (29.5%)	
			Outcome 8: patients commenting negatively on getting into/out of bed	Group 1: 124/929 (13.3%) Group 2: 127/891 (14.3%)	
			Outcome 9: commenting negatively on movement in bed	Group 1: 290/929 (31.2%) Group 2: 260/891 (29.2%)	
			Outcome 10: commenting positively on movement in bed:	Group 1: 25/929 (2.75) Group 2: 27/891 (3%)	
			Outcome 11: commenting on temperature as	Group 1: 67/929 (7.2%) Group 2: 50/891 (5.6%)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Statistical analysis: X2 test for primary endpoint; logistic regression analysis to adjust for minimisation factors and pre-specified baseline covariates. As data on area of new ulceration were skewed they compared the maximum total area between the groups using a Mann-whitney U test. Using a X2 test to compare the proportions of participants between groups requesting a change owing to dissatisfaction with the trial surface. Log rank test used to compare time to complete healing of existing ulcers between groups. Cochran Armitage test used. Baseline differences: baseline comparability for initial area of ulcer also reported Study power/sample	specifications)		hot/warm		
			Outcome 12: commenting on temperature as sweaty/sticky	Group 1: 32/929 (3.4%) Group 2: 23/891 (2.6%)	
			Outcome 13: commenting on cold/cool temperature	Group 1: 11/929 (1.2%) Group 2: 11/891 (1.2%)	
			Outcome 14: mattress not working properly	Group 1: 16/929 (1.7%) Group 2: 18/891 (2%)	
			Outcome 15: hard to tuck sheet/undersheets come off or gather/mattress cover slips	Group 1: 19/929 (2%) Group 2: 6/891 (0.7%)	
			Outcome 16: mattress/bed too high	Group 1: 72/929 (7.8%) Group 2: 48/891 (5.4%)	
			Outcome 17: mattress slippy	Group 1: 9/929 (1%) Group 2: 4/891 (0.4%)	
			Outcome 18: mattress too soft/edges soft or slope	Group 1:19/929 (2%) Group 2: 29/891 (3.3%)	
			Outcome 19: not able to use	Group 1: 4/929 (0.4%)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
size: a priori sample size of 2000 for 80% power to detect a 50% reduction in the proportion of people developing a pressure ulcer of grade 2 or worse. 1972 were randomised. Setting: 11 hospitals in six NHS trusts Length of study: 30-day follow-up Assessment of PUs: skin assessment Classification of PUs: grading system not specified Multiple ulcers: not reported Timing of outcome assessment similarity: skin status assessed twice weekly for 30 days and then once weekly for 60 days			backrest	Group 2:2/891 (0.2%)	
			Outcome 20: Mattress-related fall	Group 1: 0/828 (0%) Group 2: 4/891 (0.4%)	
			Outcome 21: Mattress-related suspected contact dermatitis	Group 1: 0/929 (0%) Group 2: 1/891 (0.1%)	
			Outcome 22: Mattress-related climbed over/fell through cot sides	Group 1:2/929 (0.2%) Group 2: 1/891 (0.1%)	
			Outcome 23: mattress deflation during transfer	Group 1:0/929 (0%) Group 2: 1/891 (0.1%)	
			Outcome 24: time in hospital (mean)	Group 1: 22.17 days Group 2: 20.05 days P=0.23	
			Outcome 4: mortality	Group 1: 20/59 (33.9%) Group 2: 12/54 (22.2%)	

Table 64 – OSTERBRINK2005

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Osterbrink 2005 Title: Clinical evaluation of the effectiveness of a multimodal static pressure relieving device. Journal: Journal of Wound Healing European Wound Conference 'From the Laboratory to the Patient: Future organisation and the care of problem wounds' September 15-17 2005. Type of study: RCT Sequence generation: unclear (unclear risk) Allocation concealment: unclear (unclear risk) Blinding: unstated (unclear risk) Addressing incomplete outcome data: insufficient reporting of attrition/exclusions (unclear risk)	Patient group: Patients from aged care facility, acute care hospitals and home care settings with at least 1 grade 2 pressure ulcer at any bony prominence All patients Randomised N: 60 Completed N: 50 Drop-outs: 10 Group 1 Randomised N: unclear Completed N: 28 Dropouts: unclear Group 2 Randomised N: unclear Completed N: 12 Dropouts: unclear Group 3: Randomised N: unclear Completed N: 10 Dropouts: unclear	Group 1: Repose air-filled device Group 2: Small cell AP Group 3: Large cell AP Group 3: There was no standardisation of pressure ulcer care across the participating centres.	Outcome 1: Wound healing success (completely healed pressure ulcers)	Group 1: Air-filled device: 7/34 Group 2:(Small/large cell AP: 1/26 RR 5.35 (95% CI 0.70 to 40.84)	Funding: not reported but think it is Industry funded Limitations: unclear randomisation method, allocation concealment, blinding; insufficient reporting of incomplete outcome data; baseline ulcer size not reported. Very small study. Additional outcomes: Weekly changes in wounds (ulcer size, grade, wound bed, edge appearance and local wound treatment) Could not acquire full conference

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Selective reporting: all of the study's pre-specified outcomes were reported (low risk) Analysis: ITT analysis specified in study report (low risk) Statistical analysis: do not know as abstract only Baseline differences: baseline comparability for initial ulcer size not reported (low risk) Study power/sample size: very small Setting: recruited from aged care facility, acute care hospitals and home care setting. Length of study: for as long as clinical circumstances allowed (42 days maximum) Assessment of PUs: do not know as abstract only Classification of PUs: EPUAP classification system Multiple ulcers: not	Inclusion criteria: >18 years old; at least 1 grade 2 pressure ulcer at any bony prominence. If recruited from hospital, must have been nursed on care of the elderly, neurological or surgical units. Exclusion criteria: not reported				proceedings so used results from Cochrane Review on support surfaces for treatment alone.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
reported Timing of outcome assessment similarity: weekly assessment of patient vulnerability to developing a new pressure ulcer and changes in pressure ulcers assessed weekly (low risk)					

Table 65 – RUSSELL2000

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Russell 2000 Title: Randomised controlled trial of two pressure-relieving systems. Journal: Journal of Wound Care 2000; 9(2):52-5. Type of study: RCT Sequence generation: "on admission to the study, subjects were randomly allocated to trial equipment". Method of	Patient group: patients from elderly units with pressure ulcer of grade 2 or above All patients Randomised N: 141 Completed N: 112 Drop-outs: 29 Age: average 83.9 and 84.6 years Group 1 Randomised N: 70	2 types of alternating cell mattress systems with pressure-relieving cushions: Group 1: Huntleigh Numbus 3 with Aura cushion and 4-hourly turning Group 2: Pegasus Cairwave Therapy System with Proactive 2 seating cushion and 8-hourly turning.	Outcome 1: Ulcer healing: all types	Group 1: 65/71 ulcers Group 2: 65/70 ulcers RR 0.99 (95% CI 0.90 to 1.09)	Funding: not reported Limitations: no details of randomisation method; unclear allocation concealment. Additional outcomes: Ulcer healing: all types, and divided into heel and sacral ulcers at 12 and
			Outcome 2: mortality	Group 1: 16/71 Group 2: 10/70	
			Outcome 3: average length of stay (for patients who completed the trial)	Group 1: 21.6 days Group 2: 21.7 days	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
randomisation not described (unclear risk) Allocation concealment: unclear (unclear risk) Blinding: "images [of the pressure ulcers] were stored on compact discs, using codes that ensured image analysis could be carried out 'blind' to treatment group" Addressing incomplete outcome data: no missing outcome data Selective reporting: all of the study's pre-specified outcomes were reported. Analysis: not specified in study report (high risk) Statistical analysis: Wilcoxon-Mann-Whitney rank sum test Baseline differences: baseline comparability for initial area of ulcer also reported (low risk) Study power/sample size: a priori sample	Completed N: 57 Dropouts: 13 Age (mean): 83.9 years Group 2 Randomised N: 71 Completed N: 55 Dropouts: 16 Age (mean): 84.6 years Inclusion criteria: patients from care of the elderly units; pressure ulcer of > grade 2; Exclusion criteria: patients excluded if randomised equipment unavailable (not stated how often this occurred)				18 months

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
size calculation of 80% power was 100 patients per group, the study was underpowered. Setting: care of elderly unit, hospital Length of study: Length of intervention period unclear. 18 month follow-up Assessment of PUs: insufficient information on outcome measurements. Ulcer healing was recorded by weekly camera and nurse gradings – called 'improvement factor'. Classification of Pus: Torrance classification system Multiple ulcers: if patient had two ulcers areas this counted as two separate ulcers. Timing of outcome assessment similarity: ulcers photographed weekly and patients surveyed at 7 days after trial entry. Not					

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
stated when comfort was assessed (low risk)					

Table 66 – RUSSELL2003

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Russell 2003 Title: Randomised comparison trial of the RIK and the Nimbus 3 mattresses. Journal: British Journal of Nursing 2003; 12(4):254-9. Type of study: RCT Sequence generation: "allocations were made using a random number generator in Excel 97" (low risk) Allocation concealment: "allocation was by selection of a sealed envelope in which a trial number and bed allocation was enclosed" but opaque	Patient group: patients in hospital with grade 1 or 2 pressure ulcers All patients Randomised N: 199 were included but 41 were discharged before could be assessed more than one and were included from analysis Completed N: 158 Drop-outs: 41 Age (mean): 80 years Group 1 Randomised N: 100 Completed N: 83 Dropouts: 17 Baseline Waterlow scores: 21.8	Group 1: Alternating-pressure, multicell mattress with 10 minute cycle time (Nimbus 3) Group 2: Fluid overlay mattress (RIK static) All patients had standard 4-hourly re-positioning, but could have additional turning at the patient's request – the effect of this co-intervention on treatment effect is unclear.	Outcome 1: improved ulcer response	Group 1: 60/83 Group 2: 56/75 RR 0.97 (95% CI 0.80 to 1.17)	Funding: from makers of Nimbus 3 mattress. Limitations: unclear allocation concealment; no blinding of patients or caregivers; insufficient reporting of incomplete outcome data. Additional outcomes: N/A No information on reliability, specificity or sensitivity for
			Outcome 2: worsening of pressure ulcers	Group 1: 22/83 Group 2: 16/75 RR 1.24 (95% CI 0.71 to 2.18)	
			Outcome 3: length of hospital stay (mean):	Group 1: 22.17 days Group 2: 20.05 days P=0.23	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
envelope not mentioned(unclear risk) Blinding: No blinding of treatment allocation to patients or clinicians described. Blinded photographic assessment of ulcer grading. (low risk) Addressing incomplete outcome data: insufficient reporting of attrition/exclusions (unclear risk) Selective reporting: all of the study's pre-specified outcomes were reported (low risk) Analysis: not specified in study report (high risk) Statistical analysis: Mann-Whitney test Baseline differences: patients well matched at baseline. Baseline comparability for initial area of ulcer also reported (low risk) Study power/sample	Baseline Burton scores: 14.6 Group 2 Randomised N: 99 Completed N: 75 Dropouts: 24 Baseline Waterlow scores: 21.3 Baseline Burton scores: 14.2 Inclusion criteria: patients in hospital with grade 1 or 2 pressure ulcers; Exclusion criteria: patients previously enrolled in the trial; obese patients (>25 stone); those with >grade 3 ulcers.				identification and/or classification of ulcers.

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
size: power calculations stated. Setting: hospital Length of study: length of follow-up unclear, but presumably until discharge from enrolment hospital Assessment of PUs: all ulcers were photographed using a high-resolution digital camera at weekly intervals by a medical photographer. Classification of PUs: EPUAP classification system Multiple ulcers: either evaluated as the overall pressure ulcer burden as if aggregating all individual ulcers into one large ulcer, or by examining the changes in the worst pressure ulcer present on admission to the trial. Timing outcome assessment similarity: patients assessed daily					

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
and full assessment performed weekly (low risk)					

Table 67 – STRAUSS1991

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Strauss 1991 Title: The cost of home air-fluidized therapy for pressure sores. A randomised controlled trial. Type of study: RCT Journal: Journal of Family Practice 1991; 33(1):52-9. Sequence generation: randomisation took place "using forms created by a computerised random-number-generating system" (low risk) Allocation concealment: unclear (unclear risk) Blinding: "the study assessed clinical	Patient group: people with at least 1 grade 3 or 4 pressure ulcer All patients Randomised N: 112 Completed N: 97 Drop-outs: 15 Group 1 Randomised N: 58 Completed N: 29 (n=47 who did not completely drop out) Dropouts: 14 died during study; 4 partially dropped from study, 11 completely dropped from study. 7 patients had missing or uninterpretable pressure ulcer	Group 1: Home air-fluidised therapy (CLINITRON) when grade 3 or 4 ulcers present, plus the consultative and technical services of a visiting nurse specialist Group 2: Conventional or standard therapy, patient specific and as prescribed, but included alternating – pressure pads, air-filled mattresses, water-filled mattresses, high density foam pads.	Outcome 1: Pressure ulcers classified by blinded observers as improved	Group 1: 19/2 Group 2: 9/13 RR 1.25 (95% CI 0.84 to 1.86)	Funding: Support Systems International Limitations: unclear allocation concealment; insufficient reporting of attrition/exclusions ; ulcer size at baseline not reported; high drop-out rate. Retrospective assessment. Additional outcomes: Pressure ulcer-related hospitalisations and costs/patients
			Outcome 2: time in hospital (mean)	Group 1: 11.5 (s.d 8.8) days Group 2: 21.5 (s.d 23.8) days P<0.05	
			Outcome 3: mortality	Group 1: 14/58 (24.1%) Group 2: 19/54 (35.2%)	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
outcomes through reviews by two independent nurses who were experts in the care of pressure sores and who were blinded to treatment category" (low risk) Addressing incomplete outcome data: insufficient reporting of attrition/exclusions (unclear risk) Selective reporting (reporting bias): all pre-specified outcomes reported (unclear risk) Analysis: ITT analysis specified in study report (low risk) Statistical analysis: t tests or chi-square. Baseline differences: baseline comparability for initial ulcer size not reported (low risk) Study power/sample size: no a priori sample size calculation Setting: patient's homes Length of study: 36-	photographs/nurses notes and could not be reviewed for improvement by the blinded nurse assessors Group 2 Randomised N: 54 Completed N: 30 (but n=50 did not completely drop out) Dropouts: 19 died during study; 1 partially dropped from study; 4 completely dropped from study. 17 patients had missing or uninterpretable pressure ulcer photographs/nurses notes and could not be reviewed for improvement by the blinded nurse assessors Inclusion criteria: at least 1 grade 3 or 4 pressure ulcer; who would probably require future hospitalisation for the pressure ulcer; with severely limited mobility;				

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
week follow-up Assessment of PUs: measured and photographed. Classification of PUs: Shea classification Multiple ulcers: not reported Timing of outcome assessment similarities: unclear (unclear risk)	for who home air-fluidised therapy was a practical option; likely to comply; live at least 1 year; aged 16 years or over. Exclusion criteria: febrile or septic or otherwise required immediate hospitalisation; pressure sores on radiated skin.				

Table 68 – MAKHSOUS2009

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: Makhsous 2009 Title: Promote pressure ulcer healing in individuals with spinal cord injury using an individualised cyclic pressure-relief protocol Type of study: RCT Journal: Advances in skin and wound care, 22 (11), 514-521 Sequence generation:	Patient group: inpatients or outpatients with spinal cord injury ulcers with stage II or stage III pressure All patients Randomised N: 44 Completed N: 44 Drop-outs: 0 Age: 18-79 years	Group 1: wheelchairs with an individually adjusted automated seat that gave cyclic pressure relief (manual and powered). The cyclic pressure-relief system consisted of a split seat and a backrest with an enhanced lumbar support. The wheelchairs were configured with the backrest reclined 5 degrees from perpendicular and a split seat cushion oriented parallel to the floor.	Outcome 1: median time to healing (days)	Group 1: 25.0 (2.9) Group 2: >30 P=0.007	Funding: supported in part by grant from National Institutes of Health Award. Limitations: no details of sequence generation, allocation concealment and blinding. Small
			Outcome 2: % reduction in wound area	Group 1: 45.0 (22.0) Group 2: 10.2 (34.9) P<0.001	
			Outcome 3: % improvement in PUSH score	Group 1: 21.9 (24.6) Group 2: 5.8 (9.2) P=0.003	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
no details Allocation concealment: no details Blinding: no blinding. Addressing incomplete outcome data: none Selective reporting (reporting bias): no Statistical analysis: Kaplan Meier for median time and 30% reduction of the wound area; and log rank (Mantel-Cox) chi-square for group difference; % reduction in wound and % improvement in PUSH score t-test used. Baseline differences: no significant differences Study power/sample size: no power calculation and small sample size. Setting: Rehabilitation Institute of Chicago. Length of study: 30 days.	Group 1 Randomised N: 22 Completed N: 22 Dropouts: 0 Age (year):42.4 (16.6) BMI (kg/m2): 25.2 (6.7) Years on SCI: 6.1 (6.6) Sex (f/m): 1/21 Disability: paraplegia: 10; tetraplegia: 12 ASIA*: A: 11 B: 10 C: 1 Group 2 Randomised N: 22 Completed N: 22 Dropouts: 0 Age (year): 44.5 (15.1) BMI (kg/m2): 25.2 (7.1) Years on SCI: 3.9 (2.9) Sex (f/m): 2/20 Disability: paraplegia: 9; tetraplegia: 13 ASIA*: A: 12	The split seat cushion had a movable portion located at the posterior and tilted downward away from the individual, reducing the contact between the user's buttocks and the seat. The backrest had an inflatable air pouch as an adjustable lumbar support that inflated when the posterior portion of the split seat dropped. The participants were told of the pressure-relief of the chair and could either continue doing manual pressure relief or rely on the experimental seating device. Group 2: standard wheelchair (manual or powered ranging from 16- to 20- inch width and 16- to 20- inch depth fit according to the patient's body size). The participants were instructed to perform arm push-ups every 20 to 30 minutes for pressure relief. All patients had treatment by physician or a trained nurse and was patient-specific for each wound. A variety of	Outcome 4: wound area closure (mm2)	Group 1: 785.0 (744.0) Group 2: 124.9 (520) P=<0.001	sample size. Additional outcomes: Pressure ulcer-related hospitalisations and costs/patients
			Outcome 5: wound area closure rate (mm2/day)	Group 1: 21.7 (14.6) Group 2: 2.3 (20.4) P=<0.001	
			Outcome 6: Wound PUSH score improvement	Group 1: 2.5 (2.3) Group 2: 0.7 (1.1) P=0.001	
			Outcome 7: proportion with 30% wound closure	Group 1: 16/22 Group 2: 8/22	

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Assessment of PUs: wound dimensions recorded with digital photographs twice a week. Classification of PUs: not reported. Multiple ulcers: not reported	B: 10 C: 0 Inclusion criteria: stage II or III pressure ulcers in the sacral or ischial areas; able to independently use either a manual or a power wheelchair; sitting tolerance for at least 4 hours per day. Exclusion criteria: patients with degenerative disorders of the spine and with histories of injury or surgery of the pelvis, hip joint, and the thigh, or with hip contractures; those with severe pain, spasm, and psychological concerns preventing proper cooperation.	wound care modalities were used, including topical wound dressings eg gel, hydrocolloid, alginate, foam and moisture barrier. More advanced modalities included silver antimicrobial dressing and NWPT. Patients were required to sit for a minimum of 4 hours in the assigned wheelchairs daily.			

**ASIA: American Spinal Injury Association.*

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