National Clinical Guideline Centre

Draft

Appendix J and K

Pressure ulcer prevention and management

Excluded studies

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Draft for Consultation

Commissioned by the National Institute for Health and Care Excellence

Royal College of Physicians

The Royal College of Surgeons of England

RCGP Royal College of General Practitioners

Royal College of Nursing

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Appendix J: Excluded clinical studies

J.1 Pressure ulcer prevention

J.1.1 Risk assessment (prognostic)

Reference	Reason for exclusion
Anthony 2008	Cross-sectional study
Anthony 2010	No qualitative systematic review
Ayello 2012	Discussion paper
Balzer 2007	Cross-sectional study
Bergstrom 2005	Letter
Bergquist 2001	Retrospective cohort study and community care
Bolton 2007	Abstract; insufficient information
Bolton 2007	No prospective cohort study
Boyle 2001	Patients with pressure ulcer at start included
Brown 2004	No qualitative systematic review
Cowan 2012	Retrospective study
Cox 2012	Review
De Brauwer 2012	Pressure ulcers not reported separately
Defloor 2004	Patients with pressure ulcer at start included
Fernandes 2008	No predictive validity
Franks 2003	No prospective cohort study
Gadd 2012	Narrative review
Gherghina 2011	No predictive validity
Gold 2012	Analysis only conducted for all complications, not pressure ulcer s alone
Gray 2004	Report
Gunningberg 1999	Patients with pressure ulcer at start included
Hagisawa 1999	Patients with pressure ulcer at start included
Halperin 2012	Not pressure ulcer outcome
Harris 2010	Abstract; insufficient information
He 2012	Systematic review of a subgroup; reference list screened
Iranmanesh 2012	No predictive validity
Justo 2011	Retrospective study
Kim 2006	Case-control
Kring 2007	No prospective cohort study
Matuo 2008	Abstract; insufficient information
Mertens 2008	Cross-sectional study
Mertens 2010	Cross-sectional study
Mitchell 2004	No prospective cohort study
Montague 2009	Abstract; insufficient information
Nonnemacher 2009	Patients with pressure ulcer at start included

Reference	Reason for exclusion
Okuwa 2005	No risk assessment tool
Papanikolaou 2003	Cross-sectional study
Poss 2010	Patients with pressure ulcer at start included
Price 2005	No predictive validity
Quesada 2009	No predictive validity
Reynolds 2006	No risk assessment tool
Saleh 2009	Patients with pressure ulcer at start included
Schoonhoven 2005	No prospective cohort study
Serpa 2011	No predictive validity
Sever 2012	Analysis only conducted for all complications, not pressure ulcers alone
Sharp 2006	No prospective cohort study
Stausberg 2011	Comment
Stotts 2007	No prospective cohort study
Suddaby 2006	Not only pressure ulcers
Tannen 2010	Cross-sectional study
Tescher 2012	Retrospective study that focused on subscales
Teslim 2012	Only concerned with subscores
Thompson 2005	No qualitative systematic review
Thorn 2013	Not pressure ulcer s
Walsh 2011	No qualitative systematic review
Webster 2007	Patients with pressure ulcer at start included
Willock 2009	Patients with pressure ulcer at start included

J.1.2 Risk assessment (clinical effectiveness)

No studies were excluded.

J.1.3 Skin assessment (prognostic)

No studies were excluded.

J.1.4 Skin assessment (clinical effectiveness)

No studies were excluded.

J.1.5 Repositioning

Reference	Reason for exclusion
Adelson 1997	Guideline
Anon 2006	Abstract
Balaguer 2013	Not relevant to pressure ulcers
Bergstrom 1996	Not specific to repositioning question
Buss 2002	Literature review
Clark 1998	Literature review
Colin 1996a	Not an RCT; outcomes do not match protocol
Colmenero 2012	Abstract

Reference	Reason for exclusion
Curley 2005	Linked to Fineman
Defloor 1999	Not an RCT; outcomes did not match protocol
Defloor 2000	Not relevant to repositioning question
Defloor 2000a	Not an RCT; outcome do not match protocol
Defloor 2005	Sub-population of included trial (Defloor 2005B)
Gattinoni 2001	Could not separate participants who already had pressure ulcers with those who did not on study entry.
Groah 2011	Not an RCT
Guerin 2004	Not relevant to pressure ulcers
Harada 2002	Not an RCT
Helme 1994	Not an RCT
Jan 2010	Not an RCT, outcomes do not match protocol
Knox 1994	Not an RCT; outcomes do not match protocol
Knox 1999	Outcomes do not match protocol
Krapfl 2008	Systematic review, with little detail for extractions
Mayrovitz 1999	Not an RCT; outcomes do not match protocol
Moore 2009	Abstract
Moore 2010	Abstract
Moore 2012	Systematic review of repositioning for treatment rather than prevention
Moore 2012b	Repositioning for treatment rather than prevention
Moysidis 2011	Devices rather than repositioning
Paratz 2002	Abstract
Peterson 2008	Not an RCT, outcomes do not match protocol
Preston 1998	Not an RCT
Rich 2011	Not an RCT
Seiler 1986	Not an RCT; outcomes do not match protocol
Sideranko 1992	Devices rather than repositioning
Silverthorn 2011	
Sprigle 2010	Not an RCT
Tongyoo 2006	Not an RCT, not pressure ulcer outcomes.

J.1.6 Skin massage

Reference	Reason for exclusion
Arashi 2012	Non-randomised trial

J.1.7 Nutritional supplementation and hydration strategies

Author/title REF ID	Reason for exclusion
Ek 1987	Only outcome given is incidence of pressure sores, but this is given as 9.9% in the experimental and 12% in the control group. There are no details of how many patients were in the experimental and control groups. Is linked to Larsson 1990 but it has a different number withdrawn so don't think figures can be used as the denominator for this outcome.

Author/title REF ID	Reason for exclusion
Gallart 2010	Abstract
Geeganage2012	A Cochrane review found during re-run searches, not only looking at pressure ulcers and does not add anything extra to the review (relevant papers included in this review).
Larsson 1990	None of our outcomes except mortality
Neander2004	Abstract
Okuwa2009	Abstract
Sampson2009	Cochrane review but did not include RCTs.
Stratton2012	Abstract
Vanstijn2013	Not pressure ulcers

J.1.8 Pressure redistributing devices

Reference	Reason for exclusion
Allen 1993	No clinical outcomes, only interface pressure recorded
Andrews 1989	Did not fulfil study design criteria
Ballard 1997	Data recorded were comfort data; no pressure ulcer outcomes
Barhyte 1995	Did not fulfil study design criteria. No data presented
Bliss 1967	Did not fulfil study design criteria. Patients were recruited to the trial on the basis of their risk score
Bliss 1995	Whilst 8 surfaces were evaluated in this prospective trial, not all surfaces were in the trial at the same time, therefore, the surfaces were not truly compared with one another contemporaneously. Furthermore, it was possible for patients to be re-randomised back into the study, which occurred frequently, with a total of 457 mattress trials reported for only 238 patients. The data were not presented by patient only by mattress trial. *Duplicate citation of Bliss 1994 [conference abstract]*
Braniff-matthews 1997	Healing and prevention outcome data were not separated.
Brienza 2001	Study of pressure measurement
Buchner 1995	Did not fulfil study design criteria. Criteria for anti-decubitus management not reported and decided by nurses. Number of pillows provided to third arm of the study was limited and not given to all participants.
Cadue 2008	More relevant to heel ulcer review.
Chaloner 2000	Did not fulfil study design criteria, randomisation corrupted, authors reported that randomisation was compromised on the basis of bed availability
Colin 1996	No clinical outcomes recorded; only measurements taken were for transcutaneous oxygen tension
Conine 1991	Did not fulfil study design criteria
Deboisblanc 1993	Outcome incidence of pneumonia, no pressure ulcer outcomes

Reference	Reason for exclusion
Defloor 1997	Compared turning
Defloor 2000	Did not compare surfaces
Defloor 2004	Compared turning
Dellavalle 2001	Outcome of interface pressure
Economides 1995	Wound breakdown rather than pressure ulcers
Ewing 1964	Outcomes not reported clearly.
Flam 1995	Outcome skin temperature and skin moisture level, no pressure ulcer outcomes
Fleischer 1997	Did not fulfil study design criteria
Geelkerken 1994	Did not fulfil study design criteria. No data presented.
Gentilello 1988	More relevant to repositioning review
Gilagudo 2009	Outcome measure of interface pressure
Gilcreast 2005	More relevant to heel ulcer review.
Gray 2008	Not an RCT, but a clinical audit
Grindley 1996	Patients were crossed between intervention groups at 3 days. Outcome used was the assessment of patient comfort.
Gunningberg 1998	Did not fulfil study design criteria. Study of risk calculation rather than prevention
Haalboom 1994	Did not fulfil study design criteria
Hampton 1998	Did not fulfil study design criteria
Hawkins 1997	Did not fulfil study design criteria
Heyneman 2009	Meta-analysis of 2 previously published RCTs (Vanderwee 2005; Vanderwee 2007). Vanderwee 2005 already included in this review. Vanderwee 2007 excluded as it is a turning trial
Holzgreve 1993	Full paper unavailable. Insufficient information to assess
Huang 2009	Evaluated dressings
Inman 1999	Comparison of a bed rental versus a bed purchase strategy, not a comparison of surfaces
Jacksich 1997	Did not fulfil study design criteria
Jesurum 1996	Did not fulfil study design criteria
Koo 1995	Did not fulfil study design criteria, study of interface pressure in healthy volunteers
Marchand 1993	Did not fulfil study design criteria, was a retrospective chart audit
Mcmichael 2008	Outcome measure of interface pressure
Neander 1996	Paper in german – translator state it was not an RCT. There were no data on how the decision to include patients in the control and intervention groups was made
Ooka 1995	Did not fulfil study design criteria, convenience sample used
Phillips 1999	N of 1 trial design, only one participant in the trial
Regan 1995	This study reported an audit of pressure ulcer

Reference	Reason for exclusion
	incidence after implementation of a comprehensive pressure ulcer policy; it is not a prospective RCT
Reynolds 1994	This study Did not fulfil study design criteria
Rosenthal 1996	Did not fulfil study design criteria. Outcome measure of interface pressure
Scott 1995	Insufficient information available to make a decision
Scott 1999	No clinical outcomes, healthy volunteer study of interface pressures
Scott 2000	Not an RCT of beds and mattresses
Stoneberg 1986	Historical control group
Suarez 1995	Controlled clinical trial which recorded only pressure measurements
Summer 1989	More relevant to repositioning review
Takala 1994	Not an RCT, outcome measure of interface pressure
Thomas 1994	Did not fulfil study design criteria
Timmons 2008	Did not fulfil study design criteria. Review of a product not a trial
Torraibou 2002	Evaluated dressings
Turnage-carrier 2008	Outcome measure of interface pressure
Tymec 1997	More relevant to heel ulcer review.
Vanderwee 2007	Compared turning
Vanderwee 2008	Literature review of previously conducted studies
Wells 1984	Only recorded interface pressure measurements
Wild 1991	Interface pressure measurements
Zernike 1997	Incidence of pressure ulcers not reported
Zernike 1994	Unable to assess due to information in research paper. Email address provided was no longer valid and we were unable to find other contact details.

J.1.9 Pressure redistributing devices for the prevention of heel ulcers

Reference	Reason for exclusion
Aronovitch 1998	Ordered for devices for prevention review
Bain 2011	Abstract
Bales 2012	Literature review
Berthe 2007	Ordered for devices for prevention review
Brienza 2010	Ordered for devices for prevention review
Brown 2000	Ordered for devices for prevention review
Chaloner 2000	Ordered for devices for prevention review
Cheneworth 1994	Literature review
Conine 1990a	Heel pressure ulcers data given but not by patient.
Defloor 2000b	Not our outcomes
Dekeyser 1994	Not our outcomes
Eksteen 2006	Not an RCT
Erratum 1993	Study which erratum was included was not in this review

Reference	Reason for exclusion
Evans 2009	Not an RCT/abstract not freely available
Ewing 1964	Cochrane excluded as it was considered too small and suffering from risk of bias to the extent that its results could not be regarded as valid. Does not mention pressure ulcers but 'reddening of skin of heels and ankles'.
Fawcett 2005	Paper not available
Ferrell 1995	Economic study
Finnegan 2008	Not our outcomes
Gil-agudo 2009	Not our outcomes
Gonzalez della valle 2001	Not our outcomes
Goossens 2008	Not our outcomes
Grindley 1996	Not our outcomes
Grisell 2008	Ordered for devices for prevention review
Gunningberg 2000	Heel pressure ulcers data given but not by patient.
Haisma 2007	Not relevant to review
Hampton 2012	Not our outcomes
Heyneman 2009	Pooled 2 RCTs (which were included in review)
Huang 2011	Not our outcomes
Huber 2008	Not our outcomes
Ismail 2001	Ordered for devices for prevention review. But the paper states that 'those who developed pressure sore were not turned at night' unclear if just these patients or all patients.
Jan 2011	Not RCT
Jolley 2010	Ordered for devices for prevention review
Junkin 2009	Systematic review
Lockyer-stevens	Not a relevant intervention
Macfarlane 2006	Ordered for the devices for prevention review
Makhsous 2009	Ordered for devices for prevention review
Mayrovitz 2003	Not an RCT
Mayrovitz 2004	Not an RCT
Mcinnes 2012	Ordered for devices for prevention review
Milne 2011	Abstract not freely available
Mistiaein 2010	Ordered for devices for prevention review
Mistiaen 2008	Cost-effectiveness study protocol
Mistiaen 2010	Ordered for devices for prevention review
Pinzuri 1991	Not an RCT
Rafter 2011	Not relevant to review
Russell 2000	Ordered for devices for prevention review
Russell 2003	Ordered for devices for prevention review
Scott 1999	Ordered for devices for prevention review
Scott 1999	Ordered for devices for prevention review
Silverthorn 2011	Not pressure ulcers
Simms 2011	Abstract

Reference	Reason for exclusion
Sterzi 2003	Ordered for devices for prevention review
Stone 2011	Abstract
Taccone 2009	Not relevant to review
Van leen 2011	Ordered for devices for prevention review
Vermeiden 2009	Not relevant to review
Vuolo 2010	Not a relevant comparison
Vyhlidal 1997	Heel pressure ulcers data given but not by patient.
Williams 1995	Zernike 1994 study which did not include our outcomes
Zernike 1994	Not our outcomes
Zernike 1997	Not our outcomes

J.1.10 Barrier creams

Reference	Reason for exclusion
Anthony 1985	No relevant outcomes and does not match review question.
Baatenburg 2004	No relevant outcomes and does not match review question (treatment of pressure ulcers not prevention)
Bale 2004	Incorrect study design (pre and post intervention study)
Barton 1976	Intervention does not match protocol (Intramuscular injection)
Bauer 2007	Abstract
Beeckman 2009	Literature review
Beeckman 2011	No relevant outcomes and does not match review question
Bliss 2007	Incorrect study design (non-randomised trial)
Brett 2007	Incorrect study design (laboratory testing of product, not RCT)
Byers 1995	No relevant outcomes and does not match review question
Chiari 2012	Foreign language study
Colin 2007	Unable to locate paper
Corcoran 2013	Literature review
Dealy 1995	Incorrect study design (non-randomised trial)
Declair 1997	Incorrect study design (non-randomised trial)
Draelos 2000	No relevant outcomes and does not match review question
Duimel 2003	Abstract only (abstract of a planned trial, not including results)
Duimel 2003a	Management of pressure ulcers rather than prevention
Duimel 2008	Incorrect study design (non-randomised trial)
Duimel-peters 2007	Intervention does not match review question.
Fankhanel 2009	Abstract

Reference	Reason for exclusion
Flynn 2011	Incorrect study design (non-randomised trial)
Gallart 2010	Abstract only (no English language paper available for full results)
Garciagonzales 2002	Abstract
Goldemeier 1997	Foreign language
Gozen 2011	Abstract
Guest 2011	Systematic review – question does not match the protocol
Health quality Ontario	Guideline
Hodgkinson 2005	Systematic review – question does not match the protocol
Hofman 1994	Management of pressure ulcers rather than prevention
Hoggarth 2005	Incorrect study design (non-randomised trial)
Hollingworth 2008	Incorrect study design (non-systematic review)
Houwing 2008	Comparison does not match review question
Hughes 1962	Incorrect study design (non-randomised trial)
Hunter 2003	Incorrect study design (non-randomised trial)
Jones 2012	Incorrect study design (non-systematic review)
Kennedy 1996	No relevant outcomes and does not match review question.
Koerner 2011	Abstract
Kuisma 1987	No relevant outcomes and does not match review question.
Lambert 2012	Systematic review – question does not match the protocol
Lewis 2002	Intervention does not match protocol (comparison of skin care protocols which includes a number of different elements and so effect of barrier cream unable to be isolated)
Lopez 2004	Same study as Bou2005
Milward	Abstract
Nakagami 2007	Intervention does not match protocol (dressing rather than barrier cream)
Nazarko 2007	Incorrect study design (non-systematic review)
Niazi 2010	Abstract
Sugama 2012	No relevant outcomes and does not match review question (treatment of incontinence associated dermatitis not prevention)
Torrance 1981	Incorrect study design (non-systematic review)
Visscher 2009	Intervention does not match protocol (Wipe with minimal topical barrier protection)
Watkin 1987	Abstract; management of pressure ulcers rather than prevention
Whittingham 1998	Incorrect study design (non-randomised trial)
Wiren 2009	No relevant outcomes and does not match review question.

Reference	Reason for exclusion
Wolfman 2010	Unable to locate paper.
Wright 1998	Incorrect study design (non-randomised trial)
Zehrer 2004	Incorrect study design (non-randomised trial)
Zehrer 2005	No relevant outcomes and does not match review question.
Zeron 2007	Management of pressure ulcers rather than prevention
Zimmaro 2006	Incorrect study design (non-randomised trial)

J.1.11 Information for patients and carers

Reference	Reason for exclusion
Alamgir 2009	Not pressure ulcers
Benbow 1996a	Not a qualitative study
Dorsett 2008.	Not patient/carer education
Eisenberger 2004	Informants are healthcare professionals not patients/carers
Fagan 1996b.	Not a qualitative study
Fox 2002.	Not pressure ulcers
Gelis 2012.	Not a qualitative study
Gelis 2012a.	Not a qualitative study
Gelis 2011.	Not a qualitative study
Gibson 2002.	Not what information patients/carers required to prevent ulcers
Houlihan 2011	Not a qualitative study
Kapp 2010.	Not what information patients/carers required to prevent ulcers
Mudzi 2001.	Not a qualitative study
Oliveira 2011.	Not a qualitative study
Petrella 2005.	Not a qualitative study
Sebern 1996.	Not what information patients/carers required to prevent ulcers
Thiyagarajan 1984.	Not what information patients/carers required to prevent ulcers
Vanloo 2010.	Not a qualitative study
Wall 2005.	Not a qualitative study
Winkler 2002.	Not a qualitative study
Yasenchak 1993	Not a qualitative study
Yumang 2009.	Not pressure ulcers

J.1.12 Training and education for healthcare professionals

Reference	Reason for exclusion
Adejumo 2010	Not education/training
Anon 2012	Not a qualitative study
Barth 2012	Not a qualitative study
Baxter 2008	Not education/training

Reference	Reason for exclusion
Bergquistberinger 2011	Not education/training
Black 2010	Not a qualitative study
Cowman 2012.	Not a qualitative study
Davies 1998a.	Not a qualitative study
Dellefield 2008.	Not prevention of pressure ulcers
Farren 2011a	Not a qualitative study
Funkesson 2007.	Not education/training
Goldsworthy 2008	Not education/training
Harris 2010.	Not qualitative study of education/training
Judge 2011	Abstract
Kwong 2011.	Not qualitative study of education/training
Law 2003.	Not qualitative study of education/training
Maylor 2001a.	Not a qualitative study
Maylor 2012.	Not a qualitative study
Rosengren 2012.	Not education/training for prevention of pressure ulcers
Scott 2011.	Not a qualitative study
Spilsbury 2008.	Not education/training for prevention of pressure ulcers
Stephens 2012.	Not education/training for prevention of pressure ulcers
Stevenson 2004a.	Not a qualitative study
Taylor 2001.	Not a qualitative study of education/training for prevention of pressure ulcers
Thornton 2007.	Not a qualitative study

J.2 Pressure ulcer management

J.2.1 Ulcer measurement

Reference	Reason for exclusion
Sarhan 2010	Not measuring pressure ulcers
Ferrell 1997	Review article, not an evaluation.
Rennert 2008	Not our outcomes
Treuillet 2009	Wounds not pressure ulcers
Russell 2006	Not measuring pressure ulcers
Mayrovitz 2009	Wounds not pressure ulcers
Rennert 2009	Not measuring pressure ulcers
Firooznia 1982	Did not include any of our critical outcomes
Clark 1989	Did not include any of our critical outcomes
Aoi 2009	Did not include any of our critical outcomes
Kosaka 2004	Correspondence with description of measurement instrument; not an evaluation.
Bohannon 1983	Did not include any of our critical outcomes
Hendrix 1981	Did not include any of our critical outcomes

Reference	Reason for exclusion
Berman 2009	Abstract
Louis 1992	Did not include any of our critical outcomes
Lowie 2008	Abstract
Schwartz 1991	Aim not measuring pressure ulcers
Firooznia 1983	Did not include any of our critical outcomes
Peters 2000	Commentary
Andersen 2008	Did not include any of our critical outcomes
Russell 2002	Did not include any of our critical outcomes
Deprez 2007	Did not include any of our critical outcomes
Romenelli 2007	Brief descriptive review
Wendelken 2003	Brief descriptive review
Musser 2009	Abstract
Nishimura 2011	Abstract
Halstead 2003	Did not include any of our critical outcomes
Iizaka 2011	Not measuring pressure ulcers
Ueta 2011	Did not include any of our critical outcomes
Harris 2010	Wound assessment tool that did not focus on measurement. Did not include any of our critical outcomes
Houghton 2000	Recruited various wound types (leg ulcers, foot ulcers and pressure ulcers). Majority were leg and foot ulcers and no separate data for pressure ulcers.
Plassman 1998	Wounds not pressure ulcers.

J.2.2 Categorisation

Reference	Reason for exclusion
Allcock 1994	Grading tool not on protocol
Allman 1995	No relevant outcomes
Allman 1997	Review
Alves 2006	Poster
Andersen 2008	No assessment of relevant outcomes
Arnold 1998	No useable outcomes
Ayello 2010	Information document
Baath 2008	Categorisation tools not on protocol
Barbenel 1997	Unclear outcomes and non-protocol tools used
Baumgarten 2009	Not about categorisation – instead concerned with whether an ulcer is present or not present.
Bergquist 1999	No relevant outcomes
Bergquist 2001	Concerned with prediction of pressure ulcers, not categorisation
Bergquist-Beringer 2009	Qualitative study
Bergquist-Beringer 2011	Tool not on protocol
Bergstrom 1996	Non protocol tools (Braden)
Bergstrom 1998	Non protocol tools (Braden)
Black 2007	No categorisation analysis

Reference	Reason for exclusion
Black 2007	No categorisation analysis
Black 2007	No categorisation analysis
Black 2007	No categorisation analysis
Bours 2002	Non protocol tools (Braden)
Bours 1999	Non protocol tools (Braden and another un-named tool)
Braden 1994	Non protocol tools (Braden)
Briggs 2006	Outcomes not in a useable format
Briggs 2011	Opinion piece
Bruce 2012	Review
Carlson 1999	No analysis of categorisation
Estocado 2011	No categorisation analysis
Evans 2009	Abstract
Evans 2007	Information piece
Ferrell 1995	Non protocol tools (Sessing)
Feuchtinger 2007	Non protocol tools (Norton, Braden)
Gajewski 2007	Bayesian modelling study – no useable outcomes
Gawron 1994	Non protocol tools (Braden)
George-Saintilus 2009	Focussed on clinical observation
Groeneveld 2004	No categorisation analysis
Gunes 2009	No protocol outcomes
Gunningberg 2009	No categorisation analysis
Gunningberg 2006	No categorisation analysis
Gupta 2009	No assessment of relevant outcomes
Guy 2007	Review document
Halfens 2001	No categorisation analysis
Hill 2009	No outcomes relevant to protocol
James 2010	Prevalence data only
Konishi 2008	Predictive outcomes only
Kottner 2009	Review document
Kottner 2009	No categorisation analysis
Kottner 2009	Systematic review – all papers ordered and perused
Kwong 2005	Non protocol tools (Norton, Braden)
Lardenoye 2009	Opinion piece
Levine 2011	Information article
Levine 2010	Information article
Localio 2006	Binary grading (pressure ulcer / no pressure ulcer) only
Lyder 1999	Non protocol tools (Braden)
Lynn 2007	No categorisation information
Mahoney 2011	Not about categorisation of pressure ulcers – instead about differentiating pressure ulcers from other types of ulcer.
Moore 2011	No categorisation analysis

Reference	Reason for exclusion
Nixon 2007	No relevant outcomes
Noonan 2006	Non protocol tools (Braden)
Rafter 2008	Tool not in protocol
Santangelo 2009	No categorisation analysis
Schoonhoven 2007	No categorisation analysis
Schoonhoven 2002	No analysis relevant to categorisation
Schoonhoven 2002	No categorisation analysis
Schoonhoven 2002	Unclear which tool is assessed
Shojaei 2008	No categorisation analysis
Stausberg 2007	Tool not on protocol
Sterner 2011	Tools not on protocol
Stewart 2009	Review
Sun 2011	Statistical information article
Talley 2010	Not relevant to review question
Thurs 2009	Information article
van Lis 2010	Review
Vanderwee 2007	Non protocol tools (Braden)
Vanderwee 2006	Only analysed a single grade
Vanderwee 2005	Non protocol tools (Braden)
Verdu 2003	Grading system unclear
Vogel 2012	abstract
Vowden 2009	No categorisation analysis
Warner 1986	Non protocol tools (Norton)
Young 2011	Tool not on protocol
Young 2012	Health economics model based on estimates from other studies
Young 1996	Review article
Zulkowski 2009	Information article

J.2.3 Nutritional supplementation and hydration strategies

Reference	Reason for exclusion
Stratton 2005	Review.
Brewer 2004	Not an RCT.
Myers 1990	Not included in Cochrane or old guideline. Nutritional supplementation was not clearly described.
Starke 2011	Not pressure ulcers
Thibaut 2011	Systematic review which did not look at pressure ulcers.
Rypkema 2004	Cost-effectiveness study.
Gray 2003a	Review
Yamamoto 2009	Not an RCT – retrospective study.
Heyman 2008	Not an RCT

J.2.4 Pressure redistributing devices

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

Reference	Reason for exclusion
Mistiaen 2010c	Prevention not treatment
Tang 2010	Abstract
Jan 2011	Not an RCT
Mastrangelo 2010	Abstract
Soares 2012A	Not an RCT

J.2.5 Adjunctive therapies

Hyperbaric oxygen therapy

Reference	Reason for exclusion
Black 2000	Not relevant to this review
Chiu 2006	Not relevant to this review
Courville 1998	Not a relevant study design
Depenbusch 1972	Not a relevant study design
Edsberg 2002	Not a relevant study design; combination of HBOT and electrical stimulation
Eltorai 1981	Not a relevant study design
Fischer 1966	Abstract
Fischer 1969	Not a relevant study design
Fischer 1970	Not a relevant study design
Gray 2006	Systematic review of wounds
Kranke 2012	Wounds not pressure ulcers
Niinikoski 2004	Literature review
Roeckl-wiedmann 2005	Systematic review on wounds
Rosenthal 1971	Inadequate randomisation 'three patients who were selected randomly served as controls'.
Sahni 2003	Literature review
Thackham 2008	Systematic review of wounds
Torelli 1973	Not a relevant study design
Villanueva	Abstract

Electrotherapy

Reference	Reason for exclusion
Sheffet 2000	Not a systematic review
Karba 1997	Wounds not pressure ulcers
Gupta 2009	Electromagnetic not electrotherapy
Schubert 2001	Phototherapy not electrotherapy
Gentzkow 1993	Not an RCT
Gardner 1999	Meta-analysis which included RCTs and non-RCTs and other wound types
Ullah 2007	Errors in publication
Feedar 1991	Mixed ulcer types
Carley 1985	Mixed ulcer types
Gault 1976	Mixed ulcer types

Negative pressure wound therapy

Reference	Reason for exclusion
Alfadhli 2009	Not an RCT
Apelqvist 2008	Diabetic foot wounds, not pressure ulcers
Ashby 2010	Abstract of pilot RCT.
Ashby 2011	Abstract
Baharetstani 2008	Not an RCT
Cadth 2012	Systematic review, which did not add any more details to review
Debruin 2008	Not relevant to review.
Delaat 2011	Wounds, not just pressure ulcers
Greer 1999	Abstract of an RCT in progress.
Gregor 2008	Systematic review, which did not add any more details to review
Joseph 2000	Wounds, not just pressure ulcers
Mody 2008	Wounds, not just pressure ulcers
Niezgoda 2004	Abstract
Pham 2003	Systematic review, which did not add any more details to review
Suissa 2011	Meta-analysis of NPWT for wounds, not just pressure ulcers
Vikatmaa 2008	Systematic review, which did not add any more details to review
Webster 2012	Not pressure ulcers
Wild 2008	2 different methods of vacuum sealing
Xie 2010	Systematic review, which did not add any more details to review
Zhang 2012a	Foreign language

J.2.6 Debridement

Reference	Reason of exclusion
Agren 1985	Intervention: no debridement, but autolytic debridement enhancement
Alvarez 2002	Same study as in Alvarez 2000 but less complete outcome reporting (no critical outcome)
Alvarez 2003	Inadequate study design
Bale 1998	Intervention: no debridement, but autolytic debridement enhancement
Bass 2007	Inadequate study design
Bello 2000	Inadequate study design
Colin 1996	Intervention: no debridement, but autolytic debridement enhancement
Cullen 2009	Inadequate study design
Martin 1996	Intervention: no debridement, but autolytic debridement enhancement
Milne 2011	Other (only abstract, no full text)
Settel 1969	Essential information to assess quality is missing (no

Reference	Reason of exclusion
	information about control and experimental group, no information about placebo, no information about protocol); author developed the experimental product; language is very coloured.
Van Leen 1994	Inadequate study design
Varma 1973	Outcome

Larval therapy

Reference	Reason of exclusion
Bolton 2006	Inadequate study design
Fiorini 2012	Inadequate study design
Gilead 2012	Inadequate study design
Greene 2008	Inadequate study design
Lee 2011	Inadequate study design
Lee 2011a	Inadequate study design
Mumcuoglu 1999	Inadequate study design
Tanyuksel 2009	Inadequate study design

J.2.7 Systemic antibiotics

RCTs

Reference	Reason of exclusion
Baker 1981	Design (not an RCT)
Culter 1994	Design (not an RCT, no comparison)
O'Meara 2000	Design (systematic review)
O'Meara 2001	Design (systematic review)
Parish 1984	Outcome: data for patients with pressure ulcers could not be extracted
Parish 1984	Outcome: absence of outcome measures as defined in the protocol

Cohort studies

Reference	Reason of exclusion
Does metronidazole help leg ulcers and pressure sores? 1982	Design (opinion letter)
Bacteria & pressure ulcers: the role of silver versus traditional antimicrobials... 2002	Paper could not be retrieved
Baker 1981	Inadequate design – crossover study.
Burkhardt 2006	Design (no comparison)
Cutler 1994	Design (no comparison)
D'Silva 1983	Outcome (impossible to extract data for pressure ulcers)
Mookhoek 1994	Inadequate study design
Parish 1984	Outcome: absence of outcome measures as defined in the protocol
Parish 1984a	Outcome (impossible to extract data for pressure

Reference	Reason of exclusion
	ulcers)
Parish 1989	Inadequate study design
Romanelli 2003	Inadequate study design

J.2.8 Topical antimicrobials and antibiotics

Reference	Reason for exclusion
No author - Does metronidazole help leg ulcers and pressure sores?	Not an original study
Baker 1981	Not an RCT
Burke 1998	Hydrotherapy
Cutler 1994	No original study
Dealey 1995	Not treatment
Flock 2003	Study on analgesic
Gerber 1979	No outcome of interest
Griffiths 2001	Pressure ulcers not reported separately
Gray 2004	Incontinence associated dermatitis
Ho 2012	Hydrotherapy
Janssens 1989	Pressure ulcers not reported separately
Konya 2005	Not an RCT
Le Vasseur 1991	Not an RCT
Maas-Irslinger 2003	No original data
Naviau 1964	Not an RCT
Prentice 2004	No pressure ulcers
Romanelli 2008	Pressure ulcers not reported separately
Saji 1995	Not an RCT
Tytgat 1988	Pressure ulcers not reported separately
Zeppetella 2003	Study on analgesic

J.2.9 Dressings

Reference	Reason of exclusion
Abbott 1968	Case report
Baker 1981	Not an RCT
Banks 1997	Pressure ulcers not reported separately
Barr 1993	Not an RCT
Barr 1995	Not an RCT
Barrois 2007	Not an RCT
Beele 2010	Pressure ulcers not reported separately
Bolton	Not a primary study
Brem 2000	Not an RCT
Carr 1990	Not an RCT
Cheneworth 1994	Not an RCT

Reference	Reason of exclusion
Diehm 2005	Not an RCT
Engdahl 1980	Not retrievable
Fowler 1991	Not an RCT
Fowler 1981	Not an RCT
Fu 2002	Pressure ulcers not reported separately
Gerding 1992	Topical agent
Gorse 1987	Not an RCT
Hurd 2009	Not an RCT
Jones 1997	Case reports
Kallianinen 2000 Kalowes 2013 Keogh2013	Not an RCT Abstract Cochrane protocol not full review
Kucan 1981	Topical agent
Leonard 2009	Not an RCT
Lingner 1984 Lisco 2013	Not an RCT Abstract
Lobe 1980	Not an RCT
Cheung 1996	Abstract proceeding, no full text
McMullen 1991	Not an RCT
Meaume 1996	French publication of Sayag
Mian 1992	Not an RCT
Moberg 1983	Topical agent
Motta 1991	Not an RCT
Motta 2004	Pressure ulcers not reported separately
Pierce 1994	See Mustoe
Philbin2013 Price 2000	Not an RCT No dressing
Shamimi 2008	Topical agent
Sibbald 2011	No pressure ulcers
Smietanka 1981	Not an RCT
Subbanna 2007	Topical agent
Takahash 2006	Not an RCT
Tytgat 1988	Pressure ulcers not reported separately
Van Leen 1994	Not an RCT
Walker 2008 Wild 2012	Pressure ulcers not reported separately Not relevant outcomes
Wollina 1997	Not an RCT
Yura 1984	Japanese
Zur Nieden	Oral treatment

J.2.10 Management of heel pressure ulcers

Reference	Reason for exclusion
Taylor 1979	Intervention does not match protocol – cleansing sponge

Reference	Reason for exclusion
Houwing 2008	Prevention not management of heel ulcers
Cheneworth 1994	Not an RCT
Collier 2000	Review
Dekeyser 1994	Outcomes do not match protocol
Frain 2008	Not an RCT
Hampton 2010	Not an RCT
Zernike 1997	Outcomes do not match protocol
Hampton 2012	Prevention not management of heel ulcers
Hsu 2013	Prevention not management of heel ulcers, not an RCT
Kotz 2013	Abstract

Appendix K: Excluded economic studies

K.1 Pressure ulcer prevention

K.1.1 Risk assessment

No studies were excluded.

K.1.2 Skin assessment

No studies were excluded.

K.1.3 Repositioning

No studies were excluded.

K.1.4 Skin massage

No studies were excluded.

K.1.5 Nutritional supplementation and hydration strategies

Reference	Reason for exclusion
Banks 2013	No incremental analysis provided - this study calculates the total annual cost savings of a nutritional intervention for health care providers in Queensland, Australia.
Bayoumi 2008	Pham 2011 is an updated version of this paper.

K.1.6 Pressure redistributing devices

Reference	Comparators	Reason for exclusion
Bayoumi 2008	Current practice vs pressure redistributing mattress	This is the same study as PHAM2011A

Reference	Comparators	Reason for exclusion
Iglesias 2006	Alternating pressure replacement mattresses Vs alternating pressure overlays	This is the same study as NIXON2006
Inman 1999	Rented products Vs purchased products	Comparison of rented verses purchased products. Both groups included various types of mattresses and overlays.
Trueman and Whitehead 2010	Constant low pressure or alternating pressure Vs standard foam	No incremental analysis presented

K.1.7 Pressure redistributing devices for the prevention of heel ulcers

Reference	Reason for exclusion
Conine 1990	This was a cost-comparison of devices for the prevention of pressure ulcers (not specific to heels).
Nixon 2006	This was a cost-comparison of devices for the prevention of pressure ulcers (not specific to heels).

K.1.8 Barrier creams

Reference	Reason for exclusion
Bayoumi 2008	Pham 2011 is an updated version of this study.
Bliss 2007	No incremental analysis provided.
Narayanan 2005	Only includes nursing labour costs.
Warshaw 2002	No incremental analysis provided.
Whittingham & May 1998	Outcomes are Waterlow score and patient acceptability – these are of limited use in determining cost-effectiveness.
Zehrer 2004	Clinical outcomes are not reported for all interventions, and one group of patients switched interventions after 6 weeks of follow up; this may not affect the calculation of costs but the clinical effectiveness results could be misleading.

K.1.9 Information for patients and carers

No studies were excluded.

K.1.10 Training and education for healthcare professionals

No studies were excluded.

K.2 Pressure ulcer management

K.2.1 Ulcer measurement

No studies were excluded.

K.2.2 Categorisation

No studies were excluded.

K.2.3 Nutritional supplementation and hydration strategies

No studies were excluded.

K.2.4 Pressure redistributing devices

Reference	Reason for exclusion
Trueman & Whitehead 2010	No incremental analysis presented

K.2.5 Adjunctive therapies

Reference	Reason for exclusion
Philbeck 1999	This study was based in the US in 1999, and does not consider quality of life. It is therefore less applicable than the included evidence. This analysis was also subject to several limitations; for example it is unclear how resource use and costs have been calculated, and results of effectiveness from the intervention and comparator groups are taken from two different studies, thus there is no guarantee that the groups are comparable.

K.2.6 Debridement

Reference	Comparators	Reason for exclusion
Thomas 2006	Maggots vs conventional debridement techniques	This study uses clinical effectiveness estimates (based on assumption) which show a substantially greater relative effectiveness of maggots than has been found through the systematic review above. In addition the cost of maggots quoted in the paper is well below current cost of maggot therapy; this study is therefore not considered useful on which to base decisions of cost-effectiveness.

K.2.7 Systemic antibiotics

No studies were excluded.

K.2.8 Topical antimicrobials and antibiotics

Reference	Comparators	Reason for exclusion
Robson 2000	Growth factors vs. placebo	This study only includes the cost of surgically closing the wound; cost of the interventions themselves are not considered.

K.2.9 Dressings

Reference	Comparators	Reason for exclusion
Harding 2000	Hydrocolloid dressing verses gauze	Only average cost-effectiveness ratios are presented
Kerstein 2004	Saline soaked gauze verses	Adapted from Kerstein 2001

Reference	Comparators	Reason for exclusion
	hydrocolloid	

K.2.10 Management of heel pressure ulcers

No studies were excluded.