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AUTHOR(S)

Pauline Joyce, Zena EH Moore, Janice Christie

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Organisation of health services for preventing and treating pressure ulcers (Review)

Joyce P, Moore ZEH, Christie J

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Organisation of health services for preventing and treating pressure ulcers.

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[Intervention Review]

Organisation of health services for preventing and treating pressure ulcers

Pauline Joyce¹, Zena EH Moore², Janice Christie³

¹School of Medicine, Royal College of Surgeons in Ireland, Dublin, Ireland. ²School of Nursing & Midwifery, Royal College of Surgeons in Ireland, Dublin, Ireland. ³Division of Nursing, Midwifery & Social Work, School of Health Sciences, Faculty of Biology, Medicine & Health, University of Manchester, Manchester Academic Health Science Centre, Manchester, UK

Contact address: Pauline Joyce, School of Medicine, Royal College of Surgeons in Ireland, 121 St. Stephens Green, Dublin, 2, Ireland. pjoyce@rcsi.ie.

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ABSTRACT

Background

Pressure ulcers, which are a localised injury to the skin, or underlying tissue, or both, occur when people are unable to reposition themselves to relieve pressure on bony prominences. Pressure ulcers are often difficult to heal, painful, expensive to manage and have a negative impact on quality of life. While individual patient safety and quality care stem largely from direct healthcare practitioner-patient interactions, each practitioner-patient wound-care contact may be constrained or enhanced by healthcare organisation of services. Research is needed to demonstrate clearly the effect of different provider-orientated approaches to pressure ulcer prevention and treatment.

Objectives

To assess the effects of different provider-orientated interventions targeted at the organisation of health services, on the prevention and treatment of pressure ulcers.

Search methods

In April 2018 we searched the Cochrane Wounds Specialised Register; the Cochrane Central Register of Controlled Trials (CENTRAL); Ovid MEDLINE (including In-Process & Other Non-Indexed Citations); Ovid Embase and EBSCO CINAHL Plus. We also searched three clinical trials registries for ongoing and unpublished studies, and scanned reference lists of relevant included studies as well as reviews, meta-analyses and health technology reports to identify additional studies. There were no restrictions with respect to language, date of publication or study setting.

Selection criteria

Randomised controlled trials (RCTs), cluster-RCTs, non-RCTs, controlled before-and-after studies and interrupted time series, which enrolled people at risk of, or people with existing pressure ulcers, were eligible for inclusion in the review.

Data collection and analysis

Two review authors independently performed study selection, risk of bias assessment, data extraction and GRADE assessment of the certainty of evidence.

Main results

The search yielded a total of 3172 citations and, following screening and application of the inclusion and exclusion criteria, we deemed four studies eligible for inclusion. These studies reported the primary outcome of pressure ulcer incidence or pressure ulcer healing, or both.

One controlled before-and-after study explored the impact of transmural care (a care model that provided activities to support patients and their family/partners and activities to promote continuity of care), among 62 participants with spinal cord injury. It is unclear whether transmural care leads to a difference in pressure ulcer incidence compared with usual care (risk ratio (RR) 0.93, 95% confidence interval (CI) 0.53 to 1.64; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision).

One RCT explored the impact of hospital-in-the-home care, among 100 older adults. It is unclear whether hospital-in-the-home care leads to a difference in pressure ulcer incidence risk compared with hospital admission (RR 0.32, 95% CI 0.03 to 2.98; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision).

A third study (cluster-randomised stepped-wedge trial), explored the impact of being cared for by enhanced multidisciplinary teams (EMDT), among 161 long-term-care residents. The analyses of the primary outcome used measurements of 201 pressure ulcers from 119 residents. It is unclear if EMDT reduces the pressure ulcer incidence rate compared with usual care (hazard ratio (HR) 1.12, 95% CI 0.74 to 1.68; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision). It is unclear whether there is a difference in the number of wounds healed (RR 1.69, 95% CI 1.00 to 2.87; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision). It is unclear whether there is a difference in the reduction in surface area, with and without EMDT, (healing rate 1.006; 95% CI 0.99 to 1.03; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision). It is unclear if EMDT leads to a difference in time to complete healing (HR 1.48, 95% CI 0.79 to 2.78, very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision).

The final study (quasi-experimental cluster trial), explored the impact of multidisciplinary wound care among 176 nursing home residents. It is unclear whether there is a difference in the number of pressure ulcers healed between multidisciplinary care, or usual care (RR 1.18, 95% CI 0.98 to 1.42; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision). It is unclear if this type of care leads to a difference in time to complete healing compared with usual care (HR 1.73, 95% CI 1.20 to 2.50; very low-certainty evidence; downgraded twice for very serious study limitations and twice for very serious imprecision).

In all studies the certainty of the evidence is very low due to high risk of bias and imprecision. We downgraded the evidence due to study limitations, which included selection and attrition bias, and sample size. Secondary outcomes, such as adverse events were not reported in all studies. Where they were reported it was unclear if there was a difference as the certainty of evidence was very low.

Authors' conclusions

Evidence for the impact of organisation of health services for preventing and treating pressure ulcers remains unclear. Overall, GRADE assessments of the evidence resulted in judgements of very low-certainty evidence. The studies were at high risk of bias, and outcome measures were imprecise due to wide confidence intervals and small sample sizes, meaning that additional research is required to confirm these results. The secondary outcomes reported varied across the studies and some were not reported. We judged the evidence from those that were reported (including adverse events), to be of very low certainty.

PLAIN LANGUAGE SUMMARY

Organisation of health services for preventing and treating pressure ulcers

What is the aim of this review?

The aim of this review was to find out whether the way in which health services are organised can affect prevention and treatment of pressure ulcers. Cochrane researchers collected and analysed all relevant studies to answer this question and found four relevant studies.

Key messages

We cannot be certain whether transmural care (a way of providing care that delivers activities to support patients and their family/partners, and activities to promote continuity of care), hospital-in-the-home care, care provided by a team of different disciplines or care that is usually provided, make any difference to whether people develop pressure ulcers, how fast existing ulcers heal, or whether people with ulcers are admitted or readmitted to hospital.

What was studied in the review?

Pressure ulcers, sometimes known as bedsores or pressure sores, are injuries that develop as a result of continued pressure on bony parts of the body such as the hips, heels or lower back. It is thought that the way health services are organised can influence the development of pressure ulcers among people at risk, and may also influence the healing of these wounds.

Care can be delivered to people with pressure ulcers in various ways. We wanted to find out whether different types of care delivery affected the number of people developing pressure ulcers and how fast existing ulcers healed.

What are the main results of the review?

We found four studies dating from 1999 to 2014, that compared alternative types of care delivery to the way care is usually provided. The mean number of participants in the studies was 140, and the ages of participants ranged from 36.5 years to 83 years. In the studies 198 participants were men and 301 were women. All studies were funded by government agencies. Two studies focused on prevention of pressure ulcers, one on prevention and treatment, and one on treatment only.

It is unclear whether any alternative type of care delivery is better than care that is usually provided at reducing risk of pressure ulcers, or improving pressure ulcer healing. It is also unclear whether the way healthcare services are organised improves quality of life, patient and staff satisfaction, reduces hospital admissions, emergency room visits, or death at 28 days. This is because we are very uncertain about the evidence in all studies.

This Plain language summary is up to date as of 18 April 2018.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Transmural care versus usual follow-up care for preventing pressure ulcers						
Patient or population: people with spinal cord injury receiving rehabilitation treatment for the first time Settings: spinal cord injury services Intervention: transmural care versus usual follow-up care						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Usual follow-up care	Transmural care				
Pressure ulcer incidence rate Follow-up 12 months	Study population		RR 0.93 (0.53 to 1.64)	62 (1 study)	⊕○○○ Very low^a	It is unclear whether there is a difference in the risk of developing a pressure ulcer between transmural care or usual care, as the certainty of the evidence is very low
	452 per 1000	419 per 1000 (239 to 741) Difference: 33 fewer per 1000 (213 fewer to 258 more)				
Adverse events: readmission to clinical rehabilitation Follow-up 12 months	Study population		RR 2.00 (0.19 to 20.93)	62 (1 study)	⊕○○○ Very low^b	It is unclear whether there is a difference in the probability of readmission between transmural care or usual care, as the certainty of the evidence is very low
	32 per 1000	65 per 1000 (6 to 675) Difference: 33 fewer per 1000 (26 fewer to 613 more)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the mean risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RR:** risk ratio

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

As per the ROBINS-I tool (details in Appendix 4):

^aDowngraded twice for study limitations, the study was at high risk of selection, and attrition bias and unclear risk of detection bias. Downgraded twice for imprecision, the sample size and event rate were small, and the 95% CI spanned a 47% reduction in risk to a 64% increase in risk.

^bDowngraded twice for study limitations as the study was a non-randomised experimental study, and at high risk of selection, detection and attrition bias. Downgraded twice for imprecision, the sample size and event rate were small, and the 95% CI spanned an 81% reduction in risk to a 193% increase in risk.

BACKGROUND

Description of the condition

A pressure ulcer is defined as “localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear” (NPUAP 2014). Common pressure ulcer sites are the elbow, heel, hip, shoulder, back, and back of the head. Other terms used to refer to pressure ulcers are decubitus ulcers (bedsores) or pressure sores. Pressure ulcers are often diagnosed by appearance and staged: non-blanchable erythema (persistent redness of the skin) is stage 1; an abrasion, blister, or shallow crater indicating partial loss of skin thickness is stage 2; a deep skin crater, indicating deeper skin loss, is stage 3; and a loss of tissue, skin, and muscle and/or bone is stage 4 (Shea 1975). Under the International NPUAP-EPUAP pressure ulcer classification system (Dealey 2009), two further stages were added to this scheme: unstageable, depth unknown, and suspected deep-tissue injury, depth unknown). Stage 1 or 2 pressure ulcers are the most common (Baumgarten 2006; Whittington 2000).

Pressure ulcers often occur in people who have activity or mobility problems or decreased sensation (neuropathy) and are thereby exposed to prolonged periods of sustained pressure and shear forces (Gefen 2008). Pressure is defined as the amount of force acting on a unit of area and can occur as a result of sitting without a change of position (O’Callaghan 2007). Shear forces occur in soft tissue when these tissues are stretched, for example if someone slides or is moved across a bed as part of nursing care such as cleansing, etc. When this happens, the bony structures move but the skin remains stationary (Sanders 2005). As a result of such pressure and shear forces, the blood supply of oxygen and nutrients to the skin and underlying tissues is impaired (Demidova-Rice 2012). Susceptibility to shear and pressure is exacerbated in people with decreased arterial or venous blood supply and poor nutrition (Demidova-Rice 2012; Pinchcofsky-Devin 1986). Some older people, people with a spinal cord injury, and those who are sedated following trauma or surgery are inclined to have problems with activity and mobility, and therefore commonly display the highest risk for pressure ulcer development (Moore 2014a). Nonetheless, any person of any age can potentially develop a pressure ulcer if they are exposed to the factors that cause sustained unrelieved pressure and shear (McLane 2004).

Pressure ulcers are relatively common wounds that can be complex to manage and heal. Prevalence estimates vary according to the population being assessed, the data collection methods used and decisions about whether or not stage 1 pressure ulcers should be included (since there is no active wound at this stage, but patients are ‘at risk’ and have early tissue damage). A large survey of hospital patients undertaken in several European countries returned a pressure ulcer prevalence (stage 2 and above) of 10.5% (Vanderwee 2007). In 2009, a USA estimate for pressure ulcer prevalence (stage 2 and above), across acute-care, long-term care, and rehabilitation

settings in the USA was 9.0%, with prevalence highest in long-term acute-care settings (29.3%), (VanGilder 2009). In England, pressure ulcer data are collected across community and acute settings (although data collection is not yet universal), as part of the National Health Service (NHS) Safety Thermometer initiative (Power 2012). According to National Safety Thermometer data, an estimated that 5% to 6% of patients across these settings had a pressure ulcer in January 2014 (Durkin 2014). Other indicators of national pressure ulcer data are being considered as part of the NHS Outcomes Framework 2014/15 (DH 2013).

Among surgical patients, pressure ulcer prevalence rates of 8.5% and 33% have been reported (Karadag 2006; Versluisen 1986), and incidence rates of between 14.1% and 54.8% (Aronovitch 2007; Lindgren 2005; Schoonhoven 2002). The majority of these ulcers occur on the heel and the sacrum, and are mainly stage 1 and 2 pressure ulcer damage. Furthermore, it has been suggested that 23% of all nosocomial pressure ulcers develop in the operating department (Aronovitch 2007). According to Bliss 1999, up to a quarter of hospital-acquired pressure sores that develop originate in the operating theatre. A systematic review by Chen 2012, conducted more than 10 years later, suggests that this incidence has increased, and recommends appropriate monitoring and treatment to lower this incidence. Likewise, Jackson 2011 and Tschannen 2012 emphasise the importance of using a valid and reliable risk assessment tool in the prevention of hospital-acquired pressure ulcers.

We note that all the prevalence figures quoted above are for at-risk populations currently receiving medical care. The point prevalence (the proportion of the population that has a condition at a specific point in time), of pressure ulceration in the total adult population was recently estimated using a cross-sectional survey undertaken in Leeds, UK. Of the total adult population of 751,485, the point prevalence of pressure ulceration per 1000 was 0.31 (Hall 2014). UK pressure ulcer prevalence estimates for community settings have reported rates of 0.77 per 1000 adults in an urban area (Stevenson 2013).

Pressure ulcers are a significant healthcare problem, affecting people of all ages, cared for across the variety of healthcare delivery settings (Moore 2013a). Pressure ulcers have an impact on patients and their families, are associated with severe pain in around 43% to 91% of those affected (Briggs 2013; McGinnis 2014; Spilsbury 2007), and increased mortality (Jaul 2015). In addition, people with pressure ulcers report reduced quality of life (Essex 2009), reduced engagement in social activities (Lala 2014), changed body image, and loss of control (Langemo 2000). It has been estimated that pressure ulcer treatment costs account for about 4% of public healthcare expenditure in the UK, with nursing time accounting for 41% of these costs (Bennett 2004). Costs increase with pressure ulcer stage (Bennett 2004; Dealey 2012). It is thought that many pressure ulcers are preventable (Black 2011). Thus, it is important from both patient and service provider perspectives to prevent pressure ulcers where possible, and to treat ulcers effec-

tively when they appear in order to prevent deterioration.

Description of the intervention

This review is based on the premise that patient outcomes are influenced by the ways in which care services are organised and delivered. The organisation of care services is a complex and multidimensional concept that includes culture, leadership, and how human, physical, and financial resources are deployed. Cochrane Effective Practice and Organisation of Care (EPOC), defines four main subtypes of organisational interventions (EPOC 2015):

- provider-orientated interventions (e.g. changes to professional roles, multidisciplinary teams, integration of services, and inter-professional communication);
- patient-orientated interventions (e.g. changes with regards to patient involvement in healthcare governance and mechanisms by which patient feedback is integrated into care delivery);
- structural interventions (e.g. changes in organisational structure, facilities, resources, records, ownership, or nature of services);
- regulatory interventions (e.g. changes to healthcare delivery or costs by legislation or regulation).

This review focuses on the first item in the above list, provider-orientated interventions, which we define here as interventions that change how professionals organise or deliver care to people, or both. As noted by the EPOC taxonomy, such interventions may include various elements related to service delivery such as: changes to professional roles; altered composition of multiprofessional teams; integration of services; and changes to the way that inter-professional communication occurs. Whilst there is no universally agreed way to organise care for pressure ulcer prevention and treatment, there are examples of provider-orientated interventions through introduction of specialist staff roles and multiprofessional care pathways (Asimus 2011; Ramos 1997).

How the intervention might work

There is some evidence that provider-orientated organisational factors such as nursing skill mix (e.g. the number and role of specialist nurses), and inter-professional collaboration can improve patient outcomes (Butler 2011; Zwarenstein 2009). More specifically, it has been suggested that the composition and skill mix of healthcare teams (Armour-Burton 2013; Castle 2011), level of integration of services, and methods of inter-professional communication (Suntken 1996), could positively or negatively affect pressure ulcer outcomes. Given the large number of professional stakeholders often involved in the care of people with, or at risk of pressure ulcers, there are many areas where interventions could be aimed. Dellefeld 2014 reported that nurses felt that pressure ulcer care was influenced by nursing homes' risk assessment and teamwork processes and their organisation's general commitment to patient

care. Social ecological theory suggests that wider social systems influence an individual's actions and decisions (Bronfenbrenner 1979; McLeroy 1988). Thus, while individual patient safety and quality care stem largely from direct healthcare practitioner-patient interactions, each practitioner-patient wound-care contact, for example, may be constrained or enhanced by healthcare organisation (that is delivery, structure, or management), of services (Paine 2006).

Why it is important to do this review

A position document suggested that involving multidisciplinary teams in pressure ulcer prevention and treatment may have a positive impact on wound healing and amputation rates (Moore 2014b). Further research is needed to demonstrate clearly the effect of the team approach to wound healing, particularly in relation to clinical outcomes. This review considered whether different healthcare provider-orientated interventions influence the prevention and treatment of pressure injury. This review question was one of the top 12 uncertainties generated from a James Lind Alliance Priority Setting Partnership on pressure ulcers; a consultation exercise involving patients, carers and clinicians (James Lind Alliance 2012).

There is some systematic review evidence that organisational factors may influence health care (Gilbody 2003; Laver 2014; Miani 2014; Weaver 2013); such evidence is more tentative for large-scale hospital or system-wide organisational changes (Clay-Williams 2014). Cochrane Reviews have evaluated the impact of a variety of organisational interventions on a generic range of patient outcomes. These interventions include: hospital nurse staffing models (Butler 2011), out-of-hospital staffing models (Hodgkinson 2011), clinical pathways (Rotter 2010), nurse-led intermediate care inpatient units (Griffiths 2007), professional collaboration (Zwarenstein 2009), and shared care (Smith 2007).

We identified one, non-Cochrane systematic review on organisational-level interventions to prevent pressure sores (Soban 2011). Based on evidence from 39, mostly before-and-after studies published between 1990 and 2009, this review concluded that quality improvement initiatives, often with an educational component, reduced the occurrence of pressure ulcers. Other Cochrane Reviews have investigated patient-practitioner-level interventions that might prevent pressure ulcers through use of risk assessment tools, dressings or topical agents, support services, repositioning, or nutrition (Gillespie 2014; Langer 2014; McInnes 2011; Moore 2013b; Moore 2014a). Cochrane Reviews of patient-practitioner treatments of phototherapy, hydrogel dressings, nutrition, support surfaces, and repositioning for pressure ulcers also exist (Chen 2014; Dumville 2015; Langer 2014; McGinnis 2014; Moore 2015). However, we identified no up-to-date, systematically reviewed evidence about the effect of provider-orientated healthcare organisational interventions, for example, changes to professional roles, multidisciplinary teams, integration of services, and inter-

professional communication, on the prevention and treatment of pressure ulcers.

This Cochrane Review followed the methods outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). We hope that this information is useful for healthcare managers and policymakers in deciding about care structure and systems that prevent patient harm and promote service user well-being.

OBJECTIVES

To assess the effects of different provider-orientated interventions targeted at the organisation of health services, on the prevention and treatment of pressure ulcers.

METHODS

Criteria for considering studies for this review

Types of studies

We followed EPOC 2013 guidance. Due to the nature of the intervention and difficulties associated with randomising individual participants to different service configurations, we planned to include a range of different study designs in this review, all of which have a control group and at least one intervention group: RCTs and appropriately analysed (or re-analysable) cluster-RCTs; non-RCTs; controlled before-and-after studies, with at least two intervention and two control sites; and interrupted time series studies, with at least three data collection points before and after the intervention on the same respondents, were eligible for inclusion in the review.

Types of participants

Studies involving people of any age, in any care setting (hospitals, nursing homes, residential care, rehabilitation centres), who were at risk of developing a pressure ulcer, as identified through either a structured or unstructured risk assessment, or by clinical judgement alone, or who had an existing pressure ulcer (of any stage), were eligible for inclusion.

Types of interventions

The types of interventions that we considered in this review were drawn from EPOC Group taxonomy. They broadly investigate where there is a change in who delivers health care, how care is organised, or where care is delivered (EPOC 2015).

- Revision of professional roles (also known as professional substitution or boundary encroachment): includes the shifting of roles among health professionals, for example, a healthcare assistant without a formal nursing qualification taking an increased role, or the taking on of roles that one would not normally take in their profession.

- Clinical multidisciplinary teams: the creation of a new team of health professionals of different disciplines or adding new members to the team who work together to care for patients.

- Formal integration of services (also known as seamless care): bringing together of services across sectors or teams or the organisation of services to bring all services together at one time.

- Skill mix changes: changes in numbers, types (multidisciplinary), or qualifications of staff.

- Continuity of care: one or many episodes of care for inpatients or outpatients such as the arrangements made for patient follow-up or case management, or both (including co-ordination of assessment, treatment, and arrangement for referrals).

- Communication and case discussion between distant health professionals, for example, telephone links or telemedicine, where there is a television/video link between specialist and remote nurse practitioners.

Types of outcome measures

As this review was concerned with both the prevention and treatment of pressure ulcers, we separated the primary outcome into one outcome for prevention and one outcome for treatment.

We list primary and secondary outcomes below. If a study was apparently eligible (i.e. correct study design, population, and intervention/comparator), but did not report a listed outcome, we contacted the study authors, where possible, to determine whether they measured but did not report an outcome of interest.

We report outcome measures at the latest time point available for a study (assumed to be length of follow-up if not specified), and the time point specified in the methods as being of primary interest (if this was different from latest time point available). We planned to categorise outcomes as follows:

- short-term: under a week to eight weeks;
- medium-term: over eight weeks to 26 weeks;
- long-term: over 26 weeks.

Primary outcomes

Prevention studies

The primary outcome was pressure ulcer incidence, measured in one of the two following ways.

- Incidence rate: number of new cases of pressure ulcers during the specified study period divided by the time each participant was observed, totaled for all participants.

- Incidence proportion or risk: number of participants who developed at least one pressure ulcer during the specified study period divided by the size of population (CDC 2012).

Treatment studies

The primary outcome for treatment studies was complete healing, but study authors may have measured and reported it in several ways, therefore, we planned to include studies that reported any of the following:

- a measure of pressure ulcer healing, such as absolute or percentage change in pressure ulcer area or volume over time;
- proportion of individuals with pressure ulcers healed at the completion of the study period;
- time to complete wound healing (using methods of survival analysis and expressing the intervention effect as a hazard ratio (HR)).

Secondary outcomes

All studies

- Mean or median participant health-related quality of life/health status, measured using a standardised generic questionnaire, such as EQ-5D, SF-36, SF-12 or SF-6. We did not plan to include ad hoc measures of quality of life that were not validated and would not have been common to multiple studies.
- Patient satisfaction
- Staff satisfaction
- Adverse events

Search methods for identification of studies

Electronic searches

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

- Cochrane Wounds Specialised Register (searched 11 April 2018);
- Cochrane Central Register of Controlled Trials (CENTRAL; The Cochrane Library 2018, Issue 3) (searched 11 April 2018);-
- Ovid MEDLINE including In-Process & Other Non-Indexed Citations (1946 to 11 April 2018);
- Ovid Embase (1974 to 11 April 2018);
- EBSCO CINAHL Plus (Cumulative Index to Nursing and Allied Health Literature; 1937 to 11 April 2018).

The search strategies for the Cochrane Wounds Specialised Register, CENTRAL, Ovid MEDLINE, Ovid Embase and EBSCO

CINAHL Plus can be found in Appendix 1. We combined the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version (2008 revision), (Lefebvre 2011). We combined the Embase search with the Ovid Embase RCT filter terms developed by the UK Cochrane Centre (Lefebvre 2011). We combined the CINAHL searches with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN 2017). We also added additional filter terms to the searches, using controlled vocabularies and free-text strings, in order to identify the other study designs that we planned to include in the review (see Types of studies). There were no restrictions with respect to language, date of publication, or study setting.

We also searched the following clinical trials registries for ongoing studies:

- ClinicalTrials.gov (www.clinicaltrials.gov);
- WHO International Clinical Trials Registry (ICTRP; apps.who.int/trialsearch/Default.aspx);
- The EU Clinical Trials Register (www.clinicaltrialsregister.eu).

Searching other resources

We searched reference lists of all included studies and other relevant publications, such as systematic reviews and guidelines. We contacted experts in the field and the authors of relevant publications to identify any completed or ongoing studies. We also performed manual searches of conference proceedings and other grey literature sources to identify authors and papers related primarily to wound care teams for the prevention or treatment, or both, of pressure ulcers.

Data collection and analysis

We carried out data collection and analysis according to methods stated in the published protocol (Joyce 2016), which were based on the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a).

Selection of studies

Two review authors independently assessed the titles and abstracts of the citations retrieved by the searches for relevance. After this initial assessment, we obtained full-text copies of all studies considered to be potentially relevant. Two review authors independently checked the full papers for eligibility; we resolved any disagreements by discussion and, where required, with the input of a third review author. Where the eligibility of a study was unclear, we contacted study authors. We recorded all reasons for exclusion of studies for which we had obtained full-text copies. We completed a PRISMA flowchart to summarise this process (Liberati 2009).

Data extraction and management

Two review authors (PJ and ZM), independently extracted data from eligible studies using a data extraction sheet developed for this purpose. Specifically, we extracted the following information:

- author, title, source;
- date of study, country of origin;
- study design;
- care setting;
- inclusion and exclusion criteria;
- methods of allocation and level of allocation (i.e. participant or organisation level);
- number of participants allocated to each study treatment;
- intervention details (specifically team composition and focus of the intervention), concurrent intervention(s);
- primary and secondary outcomes (with definitions);
- length of follow-up;
- loss to follow-up;
- outcome data for primary and secondary outcomes (by group);
- funding source.

We resolved any differences in opinion by discussion. If data were missing from reports, we contacted study authors in order to obtain the missing information. In order to extract the maximal amount of information, we included multiple reports of the same study, ensuring that data were not duplicated. One review author (PJ), entered data into Review Manager 5 software (Review Manager 2014), with a second review author (ZM) verifying accuracy.

Assessment of risk of bias in included studies

Two review authors independently assessed the randomised studies using the Cochrane tool for assessing risk of bias, which addresses six specific domains: sequence generation, allocation concealment, blinding, incomplete data, selective outcome reporting, and other issues (Appendix 2; Higgins 2017). For studies using cluster randomisation, we assessed the risk of bias using the following domains: recruitment bias, baseline imbalance, loss of clusters, incorrect analysis, and comparability with individually randomised studies (Appendix 3; Higgins 2011b). The third review author checked the 'Risk of bias' assessment.

We have presented the 'Risk of bias' assessment using two 'Risk of bias' summary figures: one providing a summary of bias for each item across all studies, and the second providing a cross-tabulation of each study for all 'Risk of bias' items.

To assess bias with regard to non-randomised results, we used the ROBINS-I tool (Appendix 4; Sterne 2016). This tool assesses seven domains for non-randomised studies: bias due to confounding; bias in the selection of participants into the study; bias in the classification of interventions; bias due to deviations from intended interventions; bias due to missing data; bias in measurement of outcomes; and bias in selection of the reported results. Each domain can be considered at low risk of bias; moderate risk

of bias; serious risk of bias; critical risk of bias; or recorded as there being no information on which to make a decision.

Measures of treatment effect

For dichotomous outcomes (e.g. proportion of participants with a pressure ulcer), we calculated the risk ratio (RR) with 95% confidence intervals (CI). The risk ratio is the ratio of the risk of an event in the two groups. An RR of 1 means there is no difference in risk between the two groups; an RR of less than 1 means the event is less likely to occur in the experimental group than in the control group; and an RR of greater than 1 means the event is more likely to occur in the experimental group than in the control group (Deeks 2017).

For continuously distributed outcome data (e.g. pain), if all studies used the same assessment scale, we planned to use the mean difference (MD) with 95% CIs. If studies used different assessment scales, we planned to use the standardised mean difference (SMD) with 95% CI. The MD is a standard statistic that measures the absolute difference between the mean value in two groups in a clinical study. It estimates the amount by which the experimental intervention changes the outcome on average compared with the control. Interpretation of the results is the same as with RR except the point of no effect is 0 rather than 1 (Deeks 2017). The SMD expresses the size of the intervention effect in each study relative to the variability observed in that study. An SMD of 0 means that in a clinical study the intervention and the control have equivalent effects (Deeks 2017). As we did not find any continuously distributed outcome data that lent themselves to this type of analysis, we were unable to use this approach.

We reported time-to-event data (e.g. time to complete wound healing), as hazard ratios (HR), where possible, in accordance with the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2017). The HR is the chance of an event occurring in the treatment arm divided by the chance of the event occurring in the control arm, or vice versa, of a study (Deeks 2017). We planned to present incidence rate data meta-analysis as a rate ratio, which compares the rate of events in the two groups by dividing one by the other (Deeks 2017), and would have analysed the data using the generic inverse-variance method in Review Manager 5 (Review Manager 2014).

If we suspected skewness, and if scale data had finite upper and lower limits, we planned to use the easy 'rule of thumb' calculation to test for skewness, that is, if the standard deviation, when doubled, was greater than the mean, it is unlikely that the mean is the centre of the distribution (Altman 1996), and we planned not to enter the data into any meta-analysis. If we found relevant data that were skewed, we planned to present the data in 'Other data' tables. As we did not find these types of data, we were unable to use this approach to the analysis.

Unit of analysis issues

We anticipated unit of analysis issues occurring in cluster studies when allocation occurred at the level of the organisation or the team and data were collected from individual participants. Where a cluster study had been conducted and correctly analysed, we planned to use the generic inverse-variance method in Review Manager 5 to meta-analyse effect estimates and their standard errors (Deeks 2017; Review Manager 2014).

We planned to record where a cluster-randomised study had been conducted but incorrectly analysed as part of the 'Risk of bias' assessment. If possible, we planned to approximate the correct analyses based on *Cochrane Handbook for Systematic Reviews of Interventions* guidance (Higgins 2011b), using information on:

- the number of clusters (or groups), randomised to each intervention group or the average (mean), size of each cluster;
- the outcome data, ignoring the cluster design, for the total number of participants (e.g. number or proportion of participants with events, or means and standard deviations); and
- an estimate of the intracluster (or intraclass) correlation coefficient.

Where we could not analyse the study data, we extracted and presented, but did not further analyse and did not include, outcome data in any otherwise relevant meta-analysis.

Dealing with missing data

It is often the case that data are missing from studies. Excluding participants after allocation from the analysis, or ignoring those participants who are lost to follow-up, compromises findings from all study designs, potentially introducing bias. Where data that we thought should be included in the analyses were missing, we contacted the relevant study authors to enquire whether these data were available.

Where data for 'proportion of pressure ulcers healed' remained missing, we planned to assume that if participants were not included in an analysis, their pressure ulcer did not heal (that is they would be considered in the denominator but not the numerator). As we did not find missing data, we did not need to adopt this approach to the analysis.

In a time-to-healing analysis using survival analysis methods, dropouts should be accounted for as censored data, so we planned to take no action regarding missing data. As we did not find these types of data, we did not need to adopt this approach to the analysis.

For continuous variables and all secondary outcomes, we planned to present the data available from the study reports/study authors and not impute missing data. Where possible, we planned to calculate missing measures of variance if not reported using the total number at the start of the study. Where these measures of variation were not available, we planned to exclude the study from any relevant meta-analyses we might conduct. As we did not find these types of data, we did not need to adopt this approach to the analysis.

Assessment of heterogeneity

Assessment of heterogeneity can be a complex, multifaceted process. Firstly, we planned to consider clinical and methodological heterogeneity, that is the degree to which the included studies varied in terms of participants, interventions, outcomes, and characteristics such as length of follow-up. We planned to supplement this assessment of clinical and methodological heterogeneity with information regarding statistical heterogeneity assessed using the Chi² test (we planned to consider a significance level of P less than 0.10 to indicate statistically significant heterogeneity), in conjunction with the I² statistic (Higgins 2003). The I² statistic examines the percentage of total variation across RCTs that is due to heterogeneity rather than chance (Higgins 2003). Very broadly, we planned to consider that I² statistic values of 25% or less may mean a low level of heterogeneity (Higgins 2003), and values of 75% or more may indicate very high heterogeneity (Deeks 2017). Where there was evidence of high heterogeneity, we planned to explore this further; see [Data synthesis](#) section. As we did not undertake meta-analysis, we did not use this approach to the analysis.

Assessment of reporting biases

We assessed reporting bias using guidelines in the *Cochrane Handbook for Systematic Reviews of Interventions* (Sterne 2017). If enough studies had been available for a meaningful assessment of publication bias, we planned to construct a funnel plot of primary outcomes to test for asymmetry. We also planned to consider selective reporting, that is, reporting some outcomes and not others, in our assessment of reporting bias.

Data synthesis

We planned to combine details of included studies in a narrative review according to the comparison between intervention and comparator, the population, and the time point of the outcome measurement. We also planned to consider clinical and methodological heterogeneity and would have undertaken pooling only when studies appeared appropriately similar in terms of intervention type, study design, duration of treatment, and outcome assessment, and when we could have clearly interpreted data. We planned to present RCTs and non-randomised studies separately. As we did not combine data, we did not use this approach to the analysis.

We were unable to pre-specify the amount of clinical, methodological and statistical heterogeneity in included studies but it might have been extensive. Thus, we anticipated using a random-effects approach for meta-analysis. Conducting meta-analysis with a fixed-effect model in the presence of even minor heterogeneity may provide overly narrow confidence intervals. We would only have used a fixed-effect approach when we assessed clinical and methodological heterogeneity to be minimal, and the assumption that a single underlying treatment effect was being estimated held.

We would have used the Chi² test and I² statistic to quantify heterogeneity but would not have used these results to guide our choice of model for meta-analysis. We would have exercised caution when meta-analysed data were at risk of small-study effects, because a random-effects model may be unsuitable. In this case, or where there were other reasons to question the selection of a fixed-effect or random-effects model, we would have assessed the impact of the approach using sensitivity analyses to compare results from alternate models. (Thompson 1999).

We would have presented data using forest plots where possible. For dichotomous outcomes, we have presented the summary estimate as a RR with 95% CI. Where continuous outcomes had been measured in the same way across studies, we planned to present a pooled MD with 95% CI; we planned to pool SMD estimates where studies measured the same outcome using different methods. For time-to-event data, we planned to plot (and, if appropriate, pool), estimates of HRs and 95% CIs as presented in the study reports using the generic inverse variance method in Review Manager 5 (Review Manager 2014). Where studies analysed time to healing as a continuous measure, but it was not clear if all wounds had healed, we planned to document use of the outcome in the study but not to summarise or use the data in any meta-analysis. As we did not undertake meta-analysis, we did not use this approach to the analysis.

Subgroup analysis and investigation of heterogeneity

If substantial heterogeneity existed between studies for the primary outcomes, we planned to explore reasons for heterogeneity. We envisaged that the number of studies meeting our inclusion criteria would have been low. Consequently, in order to avoid type 1 errors we planned to conduct a minimal number of subgroup analyses, including the following:

- the setting in which service delivery took place: hospital, community nursing home, or the participant's home.

Sensitivity analysis

We planned to perform a sensitivity analysis by including only those studies assessed as having a low risk of selection bias (i.e. both low risk for sequence generation and allocation concealment). We also planned to explore the effect of unpublished studies and cluster studies, where the analysis was not at the same level as the allocation (i.e. allocation by cluster and analysis by participant).

'Summary of findings' tables and assessment of the certainty of the evidence using the GRADE approach

We have presented the main results of the review in 'Summary of findings' tables, using GRADEpro GDT 2015. These tables present key information concerning the certainty of the evidence, the magnitude of the effects of the interventions examined, and the sum of available data for the main outcomes (Schünemann

2011a). The 'Summary of findings' tables also include an overall grading of the evidence related to each of the main outcomes using the GRADE approach, which defines the certainty of a body of evidence as the extent to which one can be confident that an estimate of effect or association is close to the true quantity of specific interest. The certainty of a body of evidence involves consideration of 5 factors: within-study risk of bias (methodological quality), directness of evidence, heterogeneity, precision of effect estimates, and risk of publication bias (Schünemann 2011b).

When undertaking a GRADE assessment, we downgraded only when studies were classed as high risk of bias for one or more domains and there was unclear risk of bias. In assessing the precision of effect estimates, we also followed GRADE guidance (GRADE 2013); we assessed the size of confidence intervals, downgrading twice for imprecision where there were few events, wide CIs or if clustering effects were not considered during analysis.

Where relevant, we have presented 2 sets of outcomes in the 'Summary of findings' tables, firstly prevention outcomes and secondly treatment outcomes.

For prevention studies we have presented the following outcomes:

- pressure ulcer incidence;
- adverse events.

For treatment studies we have presented the following outcomes:

- pressure ulcer healing;
- adverse events.

We did not pool data, so we conducted the GRADE assessment for each comparison and have presented this narratively within the results section with associated 'Summary of findings' tables.

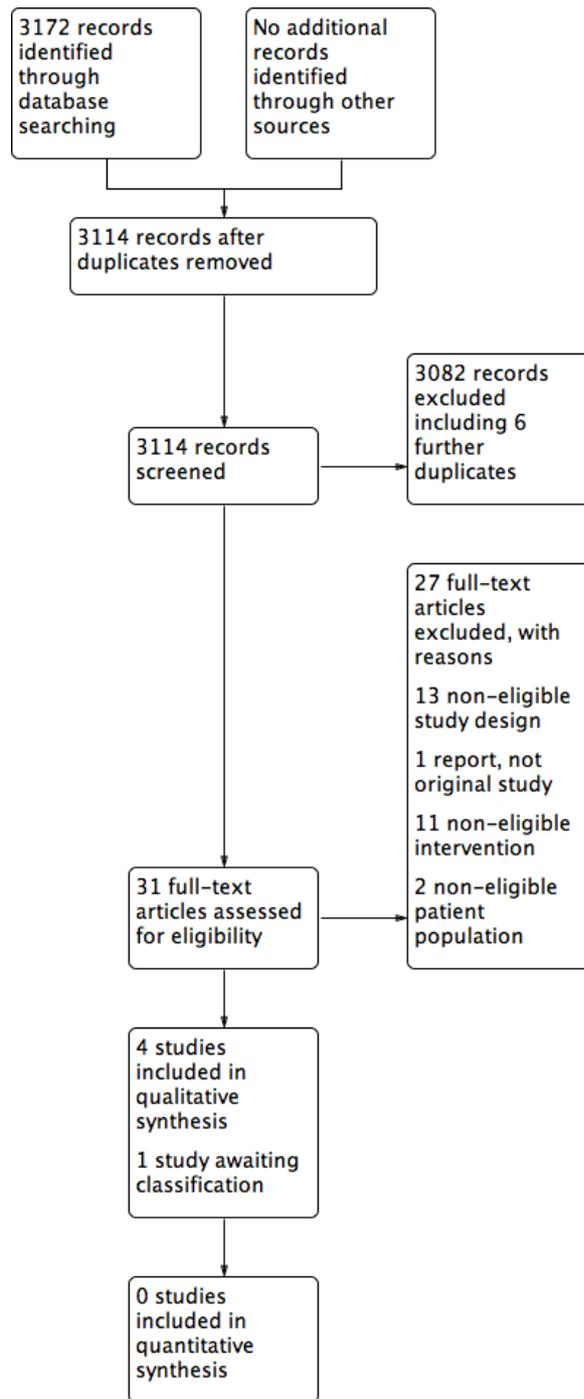
RESULTS

Description of studies

Results of the search

The search yielded a total of 3172 citations. Two review authors examined the abstracts of all papers independently to assess for potential relevance. After excluding duplicates, we screened 3114 records. We excluded 3082 records which included six further duplicates. We obtained the full texts of 31 articles and were unable to get the full text of one article, which is still awaiting classification. We excluded a further 27 studies; reasons for their exclusion are shown in Figure 1 and are detailed in the Characteristics of excluded studies table. PJ contacted 15 study authors and experts in the field, and no further studies were found. We did not identify any additional studies through the searches of the clinical trials registries.

Figure 1. Study flow diagram



Included studies

We included four studies, with a total of 499 participants, in the review: one controlled before-and-after study (Bloemen-Vrencken 2007), one randomised, parallel RCT (Caplan 1999), one cluster-randomised stepped wedge study (Stern 2014) and one quasi-experimental cluster study (Vu 2007). See the [Characteristics of included studies](#) table. Two studies (Bloemen-Vrencken 2007; Caplan 1999), related to the prevention of pressure ulcers, one related to prevention and treatment (Stern 2014), and one related to treatment only (Vu 2007).

Participants

The studies included the following participants: people with spinal cord injuries, attending rehabilitation centres (Bloemen-Vrencken 2007), people with a variety of acute medical conditions, attending a tertiary referral hospital affiliated with a university (Caplan 1999) and people in long-term care (Stern 2014; Vu 2007).

Bloemen-Vrencken 2007 was conducted in the Netherlands (n=62); Caplan 1999 (n=100), and Vu 2007 (n=176), were conducted in Australia; and Stern 2014 (n=161), was conducted in Canada. The mean age of participants in Bloemen-Vrencken 2007 was 36.5 years, whereas, in Caplan 1999, the mean age of participants was 76 years. The mean age of the participants in Stern 2014 and Vu 2007 was 82 years and 83 years respectively.

Interventions and comparisons

In Bloemen-Vrencken 2007, the intervention was transmural care. The core component of the transmural care consisted of a transmural nurse, who liaised between former patients living in the community, primary care professionals and the rehabilitation team. The transmural care model provided activities to support patients and their family/partners and activities to promote continuity of care. The comparator was usual follow-up in the rehabilitation centre.

In Caplan 1999, the intervention was a hospital-in-the-home service. This involved the delivery of treatment in the home by a hospital community outreach team, to the individual, based on their presenting diagnosis in the hospital. The comparison was to admission to hospital.

The intervention in Stern 2014 was an enhanced multidisciplinary team (EMDT). They consisted of advanced practice nurses (APNs), who provided outreach to long-term-care facilities, and were linked to a hospital-based expert wound care team. The intervention was implemented in two phases at each long-term-care facility. Phase 1 was three months in length and focused on training

of long-term-care staff. Phase 2 was 1 to 11 months in length, and involved primarily remote support of the facilities' wound care, led by the APNs via email and telephone. The comparison was to wound care within long-term-care facilities, typically provided by the usual care staff, who may or may not have had expertise in wound care.

In Vu 2007 the intervention was a multidisciplinary team of pharmacists and nurses. Training was provided to the team in the intervention arm in both how to use the study protocol and documentation procedures for data collection purposes. The comparator was usual care from nurses.

Outcomes

Three studies reported the primary outcome of pressure ulcer incidence (Bloemen-Vrencken 2007; Caplan 1999; Stern 2014), and two studies reported the primary outcome pressure ulcer healing (Stern 2014; Vu 2007). One study reported the secondary outcome, quality of life (Stern 2014). Two studies reported staff/participant satisfaction (Bloemen-Vrencken 2007; Caplan 1999). Three studies reported adverse events (Bloemen-Vrencken 2007; Caplan 1999; Stern 2014).

Excluded studies

We excluded 13 studies because they had a non-eligible study design (Abadi 2017; Alvarez 1993; Anderson 2009; Brosolo 1989; Charrier 2008; Elliott 2008; Ellis 2006; Futtrup 2013; Kapoor 2008; Liu 2016; Hart 2011; O'Leary 2011; Rodney 2015), and one because it was a description of a programme rather than a study (Bensmail 2012). We evaluated 11 studies as having non-eligible interventions (Al Awamleh 2012; Anonymous 1994; Arora 2017; Berlowitz 2007; Chaboyer 2016; Houser 2012; Jones 1993; Rantz 2012; Van Gaal 2011; Warshawsky 2013; Yap 2013), and two included a non-eligible patient population (Biji 2014; Zarchi 2015).

One study is awaiting classification Onyebueke 2017. We have contacted the study author for more information on the study. See the [Characteristics of excluded studies](#) table and [Figure 1](#).

Risk of bias in included studies

We assessed Caplan 1999, Stern 2014 and Vu 2007 using the Cochrane 'Risk of bias' tool and we used the Cochrane ROBINS-I tool (Reeves 2011), to assess Bloemen-Vrencken 2007, as it was non-randomised. All included studies were at high risk of bias. See [Figure 2](#) for the summary of the risk of bias and [Figure 3](#) for the graph of the risk of bias of the included studies.

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies, except for [Bloemen-Vrencken 2007](#), which was a non-randomised controlled trial, and not assessed using these criteria.

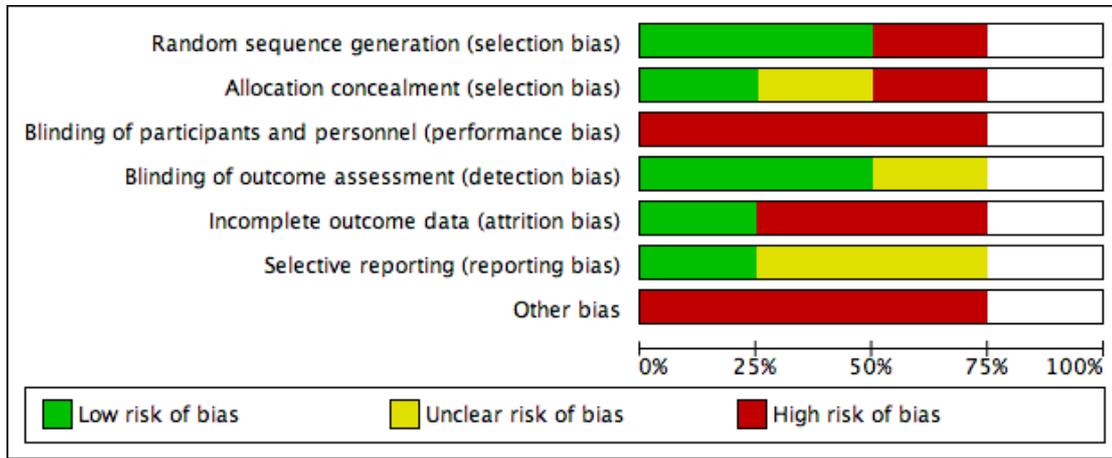


Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study, except for **Bloemen-Vrencken 2007**, which was a non-randomised controlled trial, and not assessed using these criteria.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bloemen-Vrencken 2007							
Caplan 1999	+	?	-	+	+	?	-
Stern 2014	+	+	-	+	-	+	-
Vu 2007	-	-	-	?	-	?	-

Allocation

Random sequence generation

[Vu 2007](#) was at high risk for this domain. Within each geographic domain of the sample, investigators approached nursing homes by telephone to participate. They assigned the first nursing home to accept the invitation to take part in the study to the intervention arm and the second, with similar resident numbers, from the same region, to the control arm. We classed [Caplan 1999](#) and [Stern 2014](#) as being at low risk of bias, with the allocation sequence achieved using computer-generated random numbers.

Allocation concealment

[Vu 2007](#) did not describe a method for achieving allocation concealment and we classed this study at high risk of bias based on the assessment that it was a quasi-randomised study. [Stern 2014](#) used a researcher external to the study team to generate random allocation and we classed it at low risk of bias. [Caplan 1999](#) used sealed envelopes, but it was not clear whether these had sequential numerical coding or were opaque. We judged this study to be at unclear risk of bias for allocation concealment.

Blinding

We judged [Vu 2007](#) as being at high risk of performance bias, as blinding of staff and participants would not have been possible. We classed [Caplan 1999](#) and [Stern 2014](#) as high risk of performance bias as the staff and participants knew which group they were allocated to.

We judged two studies at low risk of detection bias. [Caplan 1999](#) used independent reviewers to assess the study outcomes and [Stern 2014](#) used an assessor blinded to facility allocation. Blinding was not mentioned in [Vu 2007](#), and therefore we judged it as at unclear risk of detection bias.

Incomplete outcome data

It is not known how many people were excluded from the [Bloemen-Vrencken 2007](#) study on the basis of incomplete outcome data and if this differed between the groups. [Caplan 1999](#) reported no losses to follow-up. We judged the study to be at low risk of bias for this domain. We judged outcome data reporting to be incomplete for [Stern 2014](#) and [Vu 2007](#). In the [Stern 2014](#) study the loss to follow-up was N = 11 (control) and N = 23 (intervention period). Outcomes reported in the [Vu 2007](#) study were per wound, and some wounds were lost to follow-up. We judged these studies to be at high risk of bias for this domain.

Selective reporting

[Stern 2014](#) had a registered protocol and reported outcomes as per the protocol, and we judged it to be at low risk of selective reporting bias. We judged [Caplan 1999](#) and [Vu 2007](#) to be at unclear risk of selective reporting bias as their study protocols were not registered and thus we could not verify if they had reported all their planned outcomes.

Other potential sources of bias

We judged [Caplan 1999](#), [Stern 2014](#) and [Vu 2007](#) to be at high risk of other bias. In [Caplan 1999](#), there was a difference in the length of time spent in the emergency department, and in hospital length of stay between the study groups. The follow-up differed for each facility in [Stern 2014](#) and the baseline characteristics were not similar across the groups. In [Vu 2007](#), there were differences in baseline characteristics for nutrition and history of pressure ulcers. There were also differences in wound characteristics at baseline.

Risk of bias (ROBINS-I Tool)

As [Bloemen-Vrencken 2007](#) was a non-randomised study we assessed it for risk of bias using the ROBINS-I tool. See [Table 1](#)

Bias due to confounding

While the groups were comparable at baseline, we judged [Bloemen-Vrencken 2007](#) as being at serious risk of bias because it had not controlled for at least one important domain.

Bias in selection of participants into the study

Participants were not randomised. Matching between the experimental and control groups was not done until the 12-month point so as to include those for whom follow-up data was available. For this reason we judged the [Bloemen-Vrencken 2007](#) study to be at unclear risk of bias for this domain.

Bias in classification of interventions

As [Bloemen-Vrencken 2007](#) determined some aspects of assignment retrospectively, we judged the study as at moderate risk of bias for this domain.

Bias due to deviations from intended interventions

We judged [Bloemen-Vrencken 2007](#) as being at moderate risk of bias for this domain, as deviation from the protocol was apparent but it was unclear if this deviation was sufficient to have an effect.

Bias due to missing data

We judged [Bloemen-Vrencken 2007](#) as being at moderate risk of bias for this domain because it was not clear how many people were excluded from the study on the basis of incomplete outcome data and if this differed between the groups.

Bias in measurement of outcomes

In this domain, we judged [Bloemen-Vrencken 2007](#) as low risk of bias because the prevalence of pressure ulcers was unlikely to be influenced by knowledge of the intervention.

Bias in selection of the reported result

As there was no subgroup analysis (other than a retrospective analysis of participants for whom data were available), we judged [Bloemen-Vrencken 2007](#) as low risk of bias for this domain.

Overall bias

We judged [Bloemen-Vrencken 2007](#) as being at a critical risk of bias overall due to a critical risk of bias in one domain.

Effects of interventions

See: [Summary of findings for the main comparison](#) Transmural care versus usual follow-up care for preventing pressure ulcers; [Summary of findings 2](#) Hospital-in-the-home versus hospital admission for preventing pressure ulcers; [Summary of findings 3](#) Enhanced multidisciplinary team (EMDT) versus usual care for preventing and treating pressure ulcers; [Summary of findings 4](#) Multidisciplinary wound care versus usual care for treating pressure ulcers

One study assessed the effect of transmural care versus the usual follow-up care, a second study assessed the effect of hospital-in-the-home versus hospital admission, a third study assessed EMDTs versus usual care, and a fourth study assessed multidisciplinary wound care versus usual care. For all outcomes, the level of evidence is of very low certainty due to downgrading for serious study limitations and imprecision.

Comparison 1: transmural care versus usual follow-up care (1 study; 62 participants)

One study ([Bloemen-Vrencken 2007](#)), assessed the effect of transmural care versus usual follow-up care on the development of a new pressure ulcer.

Primary outcome

Incidence proportion or risk: number of new cases of pressure ulcers during specified study period divided by the size of population

It is unclear whether there is a difference in the risk of developing a pressure ulcer between transmural care or usual care (RR 0.93, 95% CI 0.53 to 1.64; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision), see Analysis 1.1 and [Summary of findings for the main comparison](#).

Secondary outcomes

Health-related quality of life

Not measured

Participant satisfaction

It was not clear in the included study how many people reported the outcomes, as the study authors reported these as a range of numbers. In the transmural care group, between 27 and 29 participants gave their opinion on the quality of follow-up care; in the usual follow-up-care group, between 20 and 23 participants gave their opinion. The study authors reported results individually for each of the 15 items on the questionnaire, however, they did not provide an overall result, but rather reported narratively that there was no difference between the study groups in the perceived quality of follow-up care experienced (very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision).

Staff satisfaction

Not measured

Adverse events

Adverse incident: hospital readmission

It is unclear whether there is a difference in the probability of hospital readmission between transmural care or usual care (RR 2.00, 95% CI 0.19 to 20.93; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision), see Analysis 1.2 and [Summary of findings for the main comparison](#).

Comparison 2: hospital-in-the-home versus hospital admission (1 study; 100 participants)

One study (Caplan 1999), assessed the effect of hospital-in-the-home care versus hospital admission on the development of a new pressure ulcer. Follow-up was for 28 days.

Primary outcome

Incidence proportion or risk: number of new cases of pressure ulcers during specified study period divided by the size of population

It is unclear whether there is a difference in the probability of pressure ulcer development between hospital-in-the-home, or hospital admission (RR 0.32, 95% CI 0.03 to 2.98; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision) see Analysis 2.1 and [Summary of findings 2](#). In the hospital-in-the-home group, 2% (1 of 51), participants developed a pressure ulcer, whereas, 6% (3 of 49), in the hospital-admission group developed a pressure ulcer.

Secondary outcomes

Health-related quality of life

Not measured

Satisfaction

After discharge, the study investigators sent a satisfaction survey to participants, carers and general practitioners (GPs). They asked participants, "How would you rate your treatment overall?", with answers on a four-point scale: excellent (1), good (2), fair (3) and poor (4). Lower scores indicated higher satisfaction. They asked the participants' GPs how satisfied they were with the participants' care, and scored responses in a similar way to the participants' responses, with lower scores indicating higher satisfaction.

Patient satisfaction

It is unclear whether there is a difference in participant satisfaction scores between the study groups (very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision). Mean satisfaction scores for the participants were: 1.1 (95% CI 1.0 to 1.2; hospital-in-the-home group), and 2.0 (95% CI 1.7 to 2.6; hospital-admission group). We have not re-analysed these data, the results presented are from the study authors' analysis.

Staff satisfaction

It is unclear whether there is a difference in staff satisfaction scores between the study groups (very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision). Mean satisfaction scores for the participants' GPs (number not specified) were: 1.7 (95% CI 1.4 to 2.0; hospital-in-the-home group), and 1.8 (95% CI 1.4 to 2.2; hospital-admission group). We have not re-analysed these data, the results presented are from the study authors' analysis.

Adverse events

Death at 28 days

It is unclear whether there is a difference in the risk of death at 28 days between hospital-in-the-home, or hospital admission, because the evidence is of very low certainty (evidence downgraded twice for very serious study limitations and twice for very serious imprecision), see [Summary of findings 2](#). In the hospital-in-the-home group, 6% (3 of 51), died, whereas, 8% (4 of 49), died in the hospital-admission group (RR 0.72, 95% CI 0.17 to 3.06; Analysis 2.2).

Readmission to hospital

It is unclear whether there is a difference in the risk of hospital readmission between hospital-in-the-home, or hospital admission, (very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision), see [Summary of findings 2](#). In the hospital-in-the-home group, 6% (3 of 51), were readmitted, whereas, 10% (5 of 49), in the hospital-admission group were readmitted (RR 0.58, 95% CI 0.15 to 2.28; Analysis 2.3).

Comparison 3: enhanced multidisciplinary teams (EMDTs) versus usual care (1 study; 161 participants)

The study by [Stern 2014](#) investigated the effect of an EMDT via telemedicine, who provided outreach to long-term-care facilities, versus usual care in these facilities. The study focused on prevention and treatment of pressure ulcers.

Primary outcome

Pressure ulcer incidence rate

The pressure ulcer incidence rate in the EMDT follow-up period was HR 1.12 (95% CI 0.74 to 1.68), times larger than the incident rate of the usual-care follow-up period (very low-certainty

evidence, downgraded twice for very serious study limitations and twice for very serious imprecision). We have not re-analysed these data, the results presented are from the study authors' analysis

Number of pressure ulcers healed

It is unclear whether there is a difference in the number of pressure ulcers healed between EMDT care, or usual care (very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision), see [Summary of findings 3](#). In the EMDT period 42% (30 of 71), participants had healed pressure ulcers, whereas, in the control period, 25% (14 of 56) participants had healed pressure ulcers (RR 1.69, 95% CI 1.00 to 2.87; Analysis 3.1).

Reduction in pressure ulcer surface area

The analyses of the primary outcome used measurements of 201 pressure ulcers from 119 long-term-care facility residents. It is unclear whether there is a difference in the incidence of reduction in pressure ulcer surface areas, with and without EMDT, (healing rate 1.006; 95% CI 0.99 to 1.03; very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision).

Time to complete healing

It is uncertain whether there is a difference in time to healing between EMDT compared with usual care (very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision), see [Summary of findings 3](#). Hazard ratios (HR) for time to healing were 1.48 (95% CI 0.79 to 2.78). We have not re-analysed these data, the results presented are from the study authors' analysis.

Secondary outcomes

Health-related quality of life

[Stern 2014](#) measured quality of life using the EQ5D. The mean utilities were 0.03 (95% CI -0.03 to 0.09), units lower during the intervention period than during the control period. We have not re-analysed these data, the results presented are from the study authors' analysis. It is unclear whether there is a difference in quality of life between EMDT care, or usual care (very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision).

Patient or staff satisfaction

Not measured

Adverse events

Hospitalisation

The study authors estimated the mean hospitalisation rate to be 1.2 (95% CI 0.62 to 2.36), times larger during the EMDT follow-up period than during the usual-care follow-up period (very low-certainty evidence, downgraded twice for very serious study limitations and twice for very serious imprecision), see [Summary of findings 3](#). We have not re-analysed these data, the results presented are from the study authors' analysis.

Emergency department visits

The study authors estimated the mean emergency department visit rate to be 1.3 (95% CI 0.58 to 2.90), times larger during the EMDT follow-up period than during the usual-care follow-up period. We have not re-analysed these data, the results presented are from the study authors' analysis. The evidence is of very low certainty (downgraded twice for very serious study limitations and twice for very serious imprecision), see [Summary of findings 3](#).

Comparison 4: multidisciplinary wound care versus usual care (1 study; 176 participants)

[Vu 2007](#) evaluated the impact of multidisciplinary wound care in nursing homes versus usual care on treatment of pressure ulcers.

Primary outcome

Number of pressure ulcers healed

While the study authors' planned outcome measure for treatment studies was 'proportion of individuals with pressure ulcers healed at the completion of the study period', this study reports on the percentage of pressure ulcers healed (i.e. a unit of analysis error, in addition to not accounting for clustering). It is unclear whether there is a difference in the number of pressure ulcers healed between multidisciplinary care or usual care (RR 1.18, 95% CI 0.98 to 1.42; very low-certainty evidence; downgraded twice for very serious study limitations and twice for very serious imprecision), see Analysis 4.1 and [Summary of findings 4](#).

Time to complete healing

This study randomised individuals but analysed data at the ulcer level not the patient level, thus results for this outcome are also impacted by unit of analysis issues. It is unclear whether there is a difference in time to complete healing between multidisciplinary care or usual care, as the certainty of the evidence is very low

(HR 1.73, 95% CI 1.20 to 2.50; very low-certainty evidence; downgraded twice for very serious study limitations and twice for very serious imprecision), see [Summary of findings 4](#).

Secondary outcomes

None reported

ADDITIONAL SUMMARY OF FINDINGS *[Explanation]*

Hospital-in-the-home versus hospital admission for preventing pressure ulcers						
Patient or population: people requiring admission to hospital Settings: tertiary hospital Intervention: hospital-in-the-home versus hospital admission						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Hospital admission	Hospital-in-the-home				
Pressure ulcer incidence rate Follow-up: 28 days	Study population		RR 0.32 (0.03 to 2.98)	100 (1 study)	⊕○○○ Very low^a	It is unclear whether there is a difference in the probability of pressure ulcer development between hospital-in-the-home, or hospital admission, as the certainty of the evidence is very low
	61 per 1000	20 per 1000 (2 to 182) Difference: 40 fewer per 1000 (59 fewer to 121 more)				
Adverse events: death Follow-up: 28 days	Study population		RR 0.72 (0.17 to 3.06)	100 (1 study)	⊕○○○ Very low^b	It is unclear whether there is a difference in the risk of death at 28 days between hospital-in-the-home, or hospital admission, as the certainty of the evidence is very low

	82 per 1000	59 per 1000 (14 to 250) Difference: 23 fewer per 1000 (68 fewer to 168 more)				
Adverse events: hospital readmission; follow-up 28 days Follow-up: 28 days	Study population		RR 0.58 (0.15 to 2.28)	100 (1 study)	⊕○○○ Very low^c	It is unclear whether there is a difference in the risk of hospital readmission between hospital-in-the-home, or hospital admission, as the certainty of the evidence is very low
	102 per 1000	59 per 1000 (15 to 233) Difference: 43 fewer per 1000 (87 fewer to 131 more)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the mean risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; RR: risk ratio

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

^aDowngraded twice for study limitations due to high risk of performance bias and twice for imprecision, the sample size and event rate were small, and the 95% CI spanned a 97% reduction in risk to a 198% increase in risk.

^bDowngraded twice for study limitations due to high risk of performance bias and twice for imprecision, the sample size and event rate were small, and the 95% CI spanned an 83% reduction in risk to a 206% increase in risk.

^cDowngraded twice for study limitations due to high risk of performance bias and twice for imprecision, the sample size and event rate were small, and the 95% CI spanned an 85% reduction in risk to a 128% increase in risk.

Enhanced multidisciplinary team (EMDT) versus usual care for preventing and treating pressure ulcers						
Patient or population: people with pressure ulcers residing in long-term-care facilities Settings: long-term-care facilities Intervention: EMDT versus usual care						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Usual Care	EMDT				
Pressure ulcer incidence rate	Not estimated		HR 1.12 (0.74 to 1.68)	161 (1 study)	⊕○○○ Very low ^a	It is unclear whether there is a difference in incident rate between EMDT and usual care, as the certainty of the evidence is very low
Number of pressure ulcers healed Follow-up 14 months	Study population 250 per 1000	422 per 1000 (250 to 717) Difference 170 more healed per 1000 (0 more healed to 467 less healed)	RR 1.69 (1.00 to 2.87)	161 (1 study)	⊕○○○ Very low ^b	It is unclear whether there is a difference number of wounds healed between EMDT and usual care, as the certainty of the evidence is very low
Reduction in pressure ulcer surface area	Not estimated		healing rate 1.006 (0.99-1.03)	161 (1 study)	⊕○○○ Very low ^c	It is unclear whether there is a difference in the average healing rate between EMDT and usual care, as the certainty of the evidence is very low

Time to complete healing Follow-up 12 months	Not estimated	HR 1.48 (0.79 to 2.78)	161 (1 study)	⊕○○○ Very low^d	It is unclear whether there is a difference in time to healing between EMDT and usual care, as the certainty of the evidence is very low
Adverse events: hospital admission	Not estimated	Mean hospitalisation rate estimated to be 1.2 (0.62 to 2.36) times larger during the EMDT follow-up period than during the usual-care follow-up period	161 (1 study)	⊕○○○ Very low^e	It is unclear whether there is a difference in hospital admission rate between EMDT and usual care, as the certainty of the evidence is very low
Adverse events: ED visits	Not estimated	The mean ED visit rate estimated to be 1.3 (0.58 to 2.90) times larger during the EMDT follow-up period than during the usual-care follow-up period	161 (1 study)	⊕○○○ Very low^f	It is unclear whether there is a difference in ED visits between EMDT and usual care, as the certainty of the evidence is very low

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the mean risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **ED:** emergency department; **EMDT:** enhanced multidisciplinary team; **HR:** hazard ratio; **RR:** risk ratio

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

^aDowngraded twice for study limitations due to high risk of attrition bias and performance bias. Downgraded twice for imprecision, the sample size and event rate were small, the 95% CI was wide and the study authors did not undertake any analysis for the potential effects of clustering.

^bDowngraded twice for study limitations due to high risk of attrition bias and performance bias. Downgraded twice for imprecision, the sample size and event rate were small, the 95% CI spanned a 0% reduction in risk to a 187% increase in risk and the study authors did not undertake any analysis for the potential effects of clustering.

^cDowngraded twice for study limitations due to high risk of attrition bias and performance bias. Downgraded twice for imprecision, the sample size and event rate were small, the 95% CI was wide and the study authors did not undertake any analysis for the potential effects of clustering.

^dDowngraded twice for study limitations due to high risk of attrition bias and performance bias. Downgraded twice for imprecision, the sample size and event rate were small, the 95% CI spanned a 21% reduction in risk to a 178% increase in risk and the study authors did not undertake any analysis for the potential effects of clustering.

^eDowngraded twice for study limitations due to high risk of attrition bias and performance bias. Downgraded twice for imprecision, the sample size and event rate were small, the 95% CI was wide and the study authors did not undertake any analysis for the potential effects of clustering.

^fDowngraded twice for study limitations due to high risk of attrition bias and performance bias. Downgraded twice for imprecision, the sample size was small, the 95% CI was wide and the study authors did not undertake any analysis for the potential effects of clustering.

Multidisciplinary wound care versus usual care for treating pressure ulcers						
Patient or population: people who were resident in nursing homes Settings: high-care nursing homes Intervention: multidisciplinary wound care versus usual care						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Usual care	Multidisciplinary wound care				
Number of pressure ulcers healed; follow-up 20 weeks Follow-up: 20 weeks	Study population		RR 1.18 (0.98 to 1.42)	176 (1 study)	⊕○○○ Very low^a	It is unclear whether there is a difference in the number of pressure ulcers healed between multidisciplinary care, or usual care, as the certainty of the evidence is very low
	525 per 1000	617 per 1000 (512 to 712) Difference: 92 more healed per 1000 (13 more healed to 187 fewer)				
Time to complete healing	Not estimated		HR 1.73 (1.20 to 2.50)	176 (1 study)	⊕○○○ Very low^b	It is unclear whether there is a difference in time to complete healing between multidisciplinary care or usual care, as the certainty of the evidence is very low
Adverse events	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the mean risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; HR: hazard ratio; RR: risk ratio

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

^aDowngraded twice due to study limitations: study was at high risk of selection bias, and attrition bias, unclear risk of performance and detection bias there is a unit of analysis error and the study authors did not seem to correctly account for clustering in its analysis. Downgraded twice for imprecision due to the 95% CI spanning a reduction in risk of 2% to an increased risk of 42%. Additionally the 95% CI may have been narrower due to clustering of data not having been accounted for.

^bDowngraded twice due to study limitations: study was at high risk of selection bias, and attrition bias, unclear risk of performance and detection bias. Downgraded twice for imprecision due a wide 95% CI, additionally the 95% CI may have been narrower due to clustering of data not having been accounted for.

DISCUSSION

Summary of main results

The search yielded a total of 3172 citations and, following screening and application of the inclusion and exclusion criteria, four studies were eligible for inclusion. The studies reported the primary outcome of pressure ulcer incidence or pressure ulcer healing, or both. The studies included four different interventions, namely, transmural care, hospital-in-the-home, EMDT care and multidisciplinary wound care. The studies compared these interventions with usual care, which, in the case of the hospital-in-the-home study, involved hospital admission. Participants included people with spinal cord injuries, people with a variety of acute medical conditions, and people in long-term care.

- It is unclear whether transmural care leads to a difference in pressure ulcer incidence rate, participant satisfaction and adverse events compared with usual care because the certainty of the evidence is very low.
- It is unclear whether hospital-in-the-home leads to a difference in pressure ulcer incidence rate, participant satisfaction, staff satisfaction and adverse events compared with hospital admission because the certainty of the evidence is very low.
- It is unclear whether EMDTs lead to a difference in time to complete healing, reduction in pressure ulcer surface area, number of wounds healed, pressure ulcer incidence rate, quality of life and adverse events compared with usual care because the certainty of the evidence is very low.
- It is unclear whether multidisciplinary wound care leads to a difference in time to complete healing and number of wounds healed compared with usual care because the certainty of the evidence is very low.

While reviewing the organisation of health services it is important to consider national differences in healthcare systems. One could suggest that what works in one country around organisation of health services may work in another country. However, the healthcare services are very much bounded by the societal, policy and economic factors of the country in which the study takes place. Even though, for example, studies can show that transmural care in the Netherlands prevents pressure ulcers, it may not be possible to apply this model to another country, due to variations in organising health care from country to country. This is a huge challenge for the future as we try to find a good model of care or recommendation for organisation of service for prevention and effective treatment of pressure ulcers. Overall, the uncertainty in the evidence arises because GRADE assessments of the evidence resulted predominantly in judgements of very low certainty. The studies were at high risk of bias, and outcome measures were imprecise due to wide confidence intervals and small sample sizes. Thus, more research is warranted, as it is likely that further studies

that address some of the problems identified with the certainty of evidence will alter the effect estimate.

Overall completeness and applicability of evidence

Given the importance of pressure ulcer management for health service budgets, there remains a gap in the evidence base. Four studies evaluated different types of organisation of health services for treating and preventing pressure ulcers; one RCT, one pragmatic cluster-randomised trial, one controlled before-and-after study, and one quasi-randomised pragmatic-cluster trial. The participants included in these studies, older people and people with spinal cord injuries, are representative of those most at risk of pressure ulcer development, however, there are other at-risk groups who were not included, for example, those with mobility problems from other causes, such as neurological problems, stroke or multiple sclerosis. The studies did not report data for all outcomes. Furthermore, the studies generally had small sample sizes, so were underpowered to detect a difference between the study groups, should such a difference have existed. Thus, the evidence to date is incomplete pertaining to the organisation of health services for the prevention and treatment of pressure ulcers.

Quality of the evidence

Limitations in study design and implementation

We assessed risk of bias according to six domains for three studies: sequence generation; allocation concealment; blinding; incomplete follow-up, selective outcome reporting, and other potential biases (Caplan 1999; Stern 2014; Vu 2007). We used the ROBINS-I tool to assess Bloemen-Vrencken 2007. This tool assesses seven domains for non-randomised studies: bias due to confounding; bias in the selection of participants into the study; bias in the classification of interventions; bias due to deviations from intended interventions; bias due to missing data; bias in measurement of outcomes; and bias in selection of the reported results. Each domain can be considered at low risk of bias; moderate risk of bias; serious risk of bias; critical risk of bias; or recorded as there being no information on which to make a decision. The methodological quality of the four studies was poor, with limitations in a number of these domains (Figure 3).

Indirectness of evidence

We did not downgrade the evidence for indirectness.

Imprecision of results

For the individual analysis of results, the confidence intervals are wide. This indicates a high level of uncertainty around the effect size. Further research is, therefore, very likely to have an important impact on the confidence of the estimate of the effect of the organisation of health services on the prevention and treatment of pressure ulcers. Although altogether the four studies reported each of the outcomes proposed in the methods section, the certainty of the evidence would have been enhanced had each individual study reported all of the outcomes. Due to the absence of sufficient data we were unable to carry out a meta-analysis.

Publication bias

We feel confident that our comprehensive electronic searches identified all existing, published RCTs addressing the review question. It is theoretically possible, though unlikely, that we did not manage to locate some potentially eligible studies that have been published. There is always the risk that there are unpublished studies available that we have not been able to locate. In line with Cochrane policy, we will update this review again in future, and will include any further studies identified that meet the inclusion criteria at that stage.

Potential biases in the review process

We followed clearly described procedures to prevent potential bias in the review process. This included a careful literature search, and the methods that we used were transparent and reproducible. It is possible that studies published in journals that were outside our search strategy may have been missed.

Agreements and disagreements with other studies or reviews

There are no other reviews relating to the organisation of health services for preventing and treating pressure ulcers. Therefore, we cannot say if the outcomes of this review agree or disagree with other studies or reviews.

AUTHORS' CONCLUSIONS

Implications for practice

Pressure ulcers are common and costly, with a negative impact on the individual and on the health service as a whole. It is thought that the way in which the delivery of health care is organised,

be this in the home, or in a hospital setting, can influence the development of pressure ulcers among people at risk, and also influence the healing of these wounds.

The overall certainty of the evidence is very low, as the findings of the studies included in this review were inconsistent, there was one non-RCT, the studies had wide confidence intervals around the effect size and were at high risk of bias, meaning that additional research is required to confirm these results. Therefore, there is insufficient evidence from independently funded clinical studies to support or refute the use of different types of organisation of healthcare delivery, for the prevention of pressure ulcers. The organisation of health care is very much culturally and socially bounded and this demands special attention while the results of analysis are summarised and discussed.

Implications for research

The evidence base for the organisation of health services for preventing and treating pressure ulcers is very limited. Further, high-quality, RCTs are needed to provide the evidence to underpin these treatment and preventative practices. Further studies are justified, based on the incidence of pressure ulcers and the high costs associated with pressure ulcer prevention and management. Future studies should be large enough to show meaningful differences to assist healthcare managers to make decisions about the most effective methods of care delivery. The interventions could include teams that include new professional roles or new teams where new disciplines work together.

Selection should include people of any age, in any care setting (hospitals, nursing homes, residential care, rehabilitation centres), who are at risk of developing a pressure ulcer (as identified through either a structured or unstructured risk assessment, or by clinical judgement alone), or who have an existing pressure ulcer (of any stage).

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Bloemen-Vrencken 2007

Methods	<p>Study design: controlled before-and-after study</p> <p>Study grouping: parallel</p> <p>Ethics and informed consent: not reported</p> <p>Follow-up period: 12 months</p> <p>Sample size estimate: no, but inclusion of 60 experimental and 60 control was expected</p> <p>ITT analysis: no; met criteria: 149; number analysed: 115</p> <p>Funding: the study was supported by: ZonMw, the Netherlands Organisation for Health Research and Development, ZonMw, Rehabilitation programme, grant numbers. 01432030 & 14350003; and the healthcare insurance companies Agis and CZ</p>
Participants	<p>Country: Netherlands</p> <p>Setting: spinal cord Injury</p> <p>Number: 62 (intervention group 31 participants); (control group: 31 participants)</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • 18-65 years of age • Spinal cord injury, both tetraplegia and para-plegia • American Spinal Injury Association(ASIA) impairment scale A-D, 15 in some way wheelchair dependent • The injury itself is stable (no progressive disease) • Receiving rehabilitation treatment for the first time (no re-admissions) <p>Exclusion criteria</p> <ul style="list-style-type: none"> • None stated <p>Pre-treatment: (reported for N = 31 intervention and N = 31 matched controls)</p> <ul style="list-style-type: none"> • Age, mean, years (SD); intervention: 37.8 (13.8); control: 36.1 (13.6) • Men (N): intervention: 24; control: 24 • Complete tetraplegia (C1-C5) (N): intervention: 2; control: 2 • Incomplete tetraplegia (C1-C5) (N): intervention: 1; control: 2 • Complete tetraplegia (C6-T1) (N): intervention: 5; control: 5 • Incomplete tetraplegia (C6-T1) (N): intervention: 5; control: 4 • Complete paraplegia (N): intervention: 15; control: 15 • Incomplete paraplegia (N): intervention: 3; control: 3 • Cause of injury (N): traumatic: intervention: 27; control: 26; non-traumatic (N): intervention:4; control: 5 • Average clinical rehabilitation, days (SD): intervention: 270.7 (123.6); control: 294.1 (168.2)
Interventions	<p>Intervention characteristics</p> <p>Intervention</p> <ul style="list-style-type: none"> • In addition to the usual follow-up care by the rehabilitation doctor at the rehabilitation centre, the participants in the intervention group had access to transmurial care for at least 1 year after discharge <ul style="list-style-type: none"> • The core component of the transmurial care consisted of a transmurial nurse as liaison between people with spinal cord injury living in the community, primary care professionals and the rehabilitation centre • The transmurial nurse was a member of the clinical rehabilitation team (also worked as a nurse at the spinal cord unit) and was engaged for 8 h/week to perform 4 main tasks: <ul style="list-style-type: none"> ◦ to support people with spinal cord injury and their partner/family with their health problems, within the scope of the nursing discipline ◦ to support primary care professionals with the specific care of people with spinal cord injury

	<ul style="list-style-type: none"> ○ to promote continuity of care between primary care professionals and the rehabilitation team ○ to give feedback and initiate improvements in care for the rehabilitation team, based on the experiences with participants <p>Control</p> <ul style="list-style-type: none"> ● The participants in the usual follow-up-care group were able to make use of periodic outpatient visits to the rehabilitation doctor at their rehabilitation centre ● During these visits a comprehensive assessment of functioning (i.e. physical, psychological, social and communicative functioning, and functioning regarding ADL) was performed and, if necessary, interventions were applied or other forms of support given.
Outcomes	<p>Primary outcome <i>PU incidence:</i></p> <ul style="list-style-type: none"> ● outcome type: dichotomous outcome ● reporting: fully reported ● unit of measure: numbers ● direction: lower is better ● data value: endpoint <p>Secondary outcomes <i>Participant satisfaction:</i></p> <ul style="list-style-type: none"> ● outcome type: continuous outcome ● reporting: fully reported ● unit of measure: numbers ● direction: higher is better ● data value: endpoint <p><i>Adverse events: readmission to clinical rehabilitation due to PUs:</i></p> <ul style="list-style-type: none"> ● outcome type: dichotomous outcome ● reporting: fully reported ● unit of measure: numbers ● direction: lower is better ● data value: endpoint
Identification	<p>Sponsorship source: the study was supported by ZonMw, the Netherlands Organisation for Health Research and Development, ZonMw, Rehabilitation programme, grant numbers. 01432030& 14350003; and the health care insurance companies Agis and CZ</p> <p>Country: Netherlands</p> <p>Setting: spinal cord rehabilitation centres</p> <p>Comments: none</p> <p>Author's name: Bloemen-Vrencken JHA</p> <p>Institution: Rehabilitation Centre Hoensbroeck, Hoensbroeck</p> <p>Email: j.bloemen@srl.nl</p> <p>Address: HA Bloemen-Vrencken, Rehabilitation Centre Hoensbroeck, Hoensbroeck, PO Box 88,6430 AB Hoensbroeck, The Netherlands</p>
Notes	See Table 1 for 'Risk of bias' assessment for this study

<p>Methods</p>	<p>Study design: RCT Study grouping: parallel group Ethics and informed consent: not reported Follow-up period: 28 days Sample size estimate: yes, the study had a power of 80% and an alpha of ≤ 0.05, to detect a 20% difference in the occurrence of complications ITT analysis: yes; number randomised 100: number analysed:100 Funding: the study was supported by a grant from the Commonwealth Department of Health and Family Services - Hospital Access (National Projects) Programme</p>
<p>Participants</p>	<p>Country: Australia Setting: tertiary hospital Number: 100 (intervention group 51 participants; control group: 49 participants) Inclusion criteria</p> <ul style="list-style-type: none"> ● Patients > 65 years ● Including those living in nursing homes ● Accepted younger patients if they had been assessed as requiring admission by the relevant medical or surgical team <p>Exclusion criteria</p> <ul style="list-style-type: none"> ● Evidence of shock (systolic blood pressure, 100 mmHg) ● Required oxygen (PaO₂, 60 mmHg) ● Judged too unwell by the study team ● Had no available care ● Lived outside the local area ● Their home was unsuitable for home treatment (lack of running water, electricity or an inside toilet, concerns about safety, or dangerous pets) <p>Pretreatment</p> <ul style="list-style-type: none"> ● Age: median (range): intervention: 73 (17-111); control: 79 (22-97) ● male/female: intervention: 21/30; control: 24/25 ● Barthel index (max 20) (range): intervention: 15.2 (13.3-17.1); control: 14.8 (12.8-16.8) ● Instrumental ADL (max 12) (range): intervention: 6.8 (5.5-8.1); control: 6.2 (4.7-7.7) ● Mental status questionnaire (max 10) (range): intervention: 7.1 (6.1-8.1); control: 6.9 (5.8-8.0)
<p>Interventions</p>	<p>Intervention characteristics HIH service</p> <ul style="list-style-type: none"> ● HIH participants were treated according to the presenting diagnosis by the hospital community outreach team. The range of treatments included administration of parenteral antibiotics and other medications and blood transfusions <p>Control group</p> <ul style="list-style-type: none"> ● Admitted to hospital and treated according to the usual standards of the hospital
<p>Outcomes</p>	<p>Primary outcome <i>PU incidence rate:</i></p> <ul style="list-style-type: none"> ● outcome type: dichotomous outcome ● reporting: fully reported ● unit of measure: numbers

	<ul style="list-style-type: none"> ● direction: lower is better ● data value: endpoint <p>Secondary outcomes</p> <p><i>Participants' carers and GPs' satisfaction:</i></p> <ul style="list-style-type: none"> ● outcome type: continuous outcome ● reporting: fully reported ● unit of measure: numbers ● direction: higher is better ● data value: endpoint <p><i>Adverse events: deaths</i></p> <ul style="list-style-type: none"> ● outcome type: dichotomous outcome ● reporting: fully reported ● unit of measure: numbers ● direction: lower is better ● data value: endpoint <p><i>Adverse events: unplanned readmission:</i></p> <ul style="list-style-type: none"> ● outcome type: dichotomous outcome ● reporting: fully reported ● unit of measure: numbers ● direction: lower is better ● data value: endpoint 	
Identification	<p>Sponsorship source: supported by a grant from the Commonwealth Department of Health and Family Services - Hospital Access (National projects) Programme</p> <p>Country: Australia</p> <p>Setting: a tertiary referral hospital affiliated with the University of New South Wales</p> <p>Comments: none</p> <p>Author's name: Caplan GA</p> <p>Institution: Prince of Wales Hospital, Sydney</p> <p>Email: g.caplan@unsw.edu.au</p> <p>Address: Post Acute Care Services, Prince of Wales Hospital, Sydney, NSW</p>	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "allocation sequence was achieved using computer-generated random numbers"
Allocation concealment (selection bias)	Unclear risk	Used sealed envelopes, but the nature of these envelopes in terms of sequential numerical coding, or opaqueness, was not described
Blinding of participants and personnel (performance bias)	High risk	Staff and participants knew who was in the HIH group as they were cared for either at

Caplan 1999 (Continued)

All outcomes		home or in the hospital
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Independent reviewers assessed outcomes
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses to follow-up
Selective reporting (reporting bias)	Unclear risk	Protocol for the study not registered, therefore, unclear if all outcomes were reported
Other bias	High risk	There was a difference in the length of time spent in the ED, with those in the control group spending longer than those in the experimental group ($P < 0.003$). In addition, those in the intervention group had a longer mean length of stay in hospital at baseline (10.1 days; 95% CI 7.7 to 12.5) compared with the control group (7.4 days; 95% CI 10.1 to 14.3)

Stern 2014

Methods	<p>Study design: pragmatic, cluster-randomised trial</p> <p>Study grouping: stepped wedge</p> <p>Ethics and informed consent: ethics not reported but consent obtained from facility leader</p> <p>Follow-up period: 14 months</p> <p>Sample size estimate: yes</p> <p>ITT analysis: yes; number randomised 181; number analysed: 161</p> <p>Funding: the study was funded by the Canadian Patient Safety Institute, the Central Community Care Access Center, and the Ministry of Health and Long Term Care</p>
Participants	<p>Country: Canada</p> <p>Setting: LTC</p> <p>Number: 161 (intervention group 94 participants; control group: 67 participants)</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> ● Facilities: <ul style="list-style-type: none"> ○ had a minimum of 100 beds ○ were within 100 km from the hospital housing the expert wound team ○ had a PU prevalence > the provincial average (5.5%, based on data collected from LTC facilities in Ontario by the Canadian Institute of Health Research in 2009) ○ the facility administrator provided consent ● Participants: <ul style="list-style-type: none"> ○ the study population was residents with \geq Stage 2 PUs ○ residing in eligible LTC facilities situated within 2 geographic regions <p>Exclusion criteria</p> <ul style="list-style-type: none"> ● Stage 1 and deep tissue injury PUs

	<p>Pretreatment</p> <ul style="list-style-type: none"> • Age: mean (SD): intervention: 81 (12); control: 83 (12) • Sex (female): N (%): intervention: 43 (64.2); control: 65 (69.1) • Incontinence (urine): N (%): intervention: 66 (98.5%); control: 91 (96.8%) • Incontinence (stool): intervention: 58 (86.6); control 79 (84.0) • Bedbound N (%): intervention: 49 (81.7); control: 71 (87.7) • Mental status (not alert/not oriented): N (%): intervention: 52 (77.6); control: 78 (83.0) • Nutritional supplement: N (%): intervention: 55 (82.1); control: 80 (85.1) • Tube feed N (%): intervention: 5 (7.5); control: 7 (7.4) • BMI: mean (SD): intervention: 25 (8); control: 24 (6)
<p>Interventions</p>	<p>Intervention characteristics</p> <p>Intervention</p> <ul style="list-style-type: none"> • The EMDT consisted of APNs who provided outreach to LTC facilities, and were linked to a hospital based expert wound care team • They visited LTC facilities to educate staff on the prevention and treatment of PUs, consulting with a hospital-based expert wound care team via email, telephone, or video link following a referral rubric • The intervention was implemented in 2 phases at each LTC facility • Phase 1 was 3 months in length at each facility and focused on training of LTC staff • Phase 2 (1-11 months in length), involved primarily remote support of the facility wound care lead by the APNs via email and telephone • This process was repeated every 2 weeks for all PUs until healed, or until the end of the study period, whichever came first. <p>Control</p> <ul style="list-style-type: none"> • Wound care within LTC facilities was typically provided by registered nurses, registered practical nurses, personal support workers, and nutritionists, who may or may not have had expertise in wound care • Access to other disciplines (e.g. enterostomal therapists, physiotherapists, occupational therapists) was available, typically on a reactive basis
<p>Outcomes</p>	<p>Primary outcome</p> <p><i>PU incidence rate:</i></p> <ul style="list-style-type: none"> • outcome type: continuous outcome • reporting: fully reported • unit of measure: numbers • direction: lower is better • data value: endpoint <p><i>Number of wounds healed:</i></p> <ul style="list-style-type: none"> • outcome type: dichotomous outcome • reporting: fully reported • unit of measure: probability of healing, expressed as a percentage • direction: higher is better • data value: endpoint <p><i>Reduction in PU surface area</i></p> <ul style="list-style-type: none"> • outcome type: dichotomous outcome • reporting: fully reported

	<ul style="list-style-type: none"> ● unit of measure: pixels, converted to cm² ● direction: lower is better ● data value: endpoint <p><i>Time to complete healing (in days):</i></p> <ul style="list-style-type: none"> ● outcome type: continuous outcome ● reporting: fully reported ● unit of measure: random-effects model - changes in slope ● direction: values < 1 indicate benefit ● data value: endpoint <p>Secondary outcomes:</p> <p><i>Health-related quality of life</i></p> <ul style="list-style-type: none"> ● outcome type: continuous outcome ● reporting: fully reported ● unit of measure: numbers ● direction: lower is better ● data value: endpoint <p><i>Adverse events: hospitalisation:</i></p> <ul style="list-style-type: none"> ● outcome type: continuous outcome ● reporting: fully reported ● unit of measure: numbers ● direction: lower is better ● data value: endpoint <p><i>ED visits:</i></p> <ul style="list-style-type: none"> ● outcome type: continuous outcome ● reporting: fully reported ● unit of measure: numbers ● direction: lower is better ● data value: endpoint 	
<p>Identification</p>	<p>Sponsorship source: the study was funded by the Canadian Patient Safety Institute, the Central Community Care Access Center, and the Ministry of Health and Long Term Care</p> <p>Country: Canada</p> <p>Setting: LTC facilities in Canada</p> <p>Comments: none</p> <p>Author's name: Stern A</p> <p>Institution: ELLICSR, University Health Network</p> <p>Email: anita.stern@rmp.uhn.ca</p> <p>Address: 200 Elizabeth Street, Munk Building, BCS021, Toronto, Ontario M5G 2C4, Canada</p>	
<p>Notes</p>		
<p>Risk of bias</p>		
<p>Bias</p>	<p>Authors' judgement</p>	<p>Support for judgement</p>
<p>Random sequence generation (selection bias)</p>	<p>Low risk</p>	<p>Quote: "LTC facilities were randomised to start date of the intervention by a researcher"</p>

		external to the study team, using a computer generated random number sequence”
Allocation concealment (selection bias)	Low risk	Quote: “computer generated random number sequence”
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: “blinding of facility staff or residents was not possible due to the nature of the intervention”
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The primary outcome was assessed using standard photographs by an assessor blinded to facility allocation
Incomplete outcome data (attrition bias) All outcomes	High risk	Loss to follow-up N = 11 (control); N = 23 (intervention period)
Selective reporting (reporting bias)	Low risk	Protocol for the study was registered and outcomes were reported
Other bias	High risk	The follow-up differed for each facility. The baseline characteristics were not similar across the groups

Vu 2007

Methods	<p>Study design: quasi-experimental cluster trial</p> <p>Study grouping: parallel groups</p> <p>Ethics and informed consent: yes</p> <p>Follow-up period: 20 weeks</p> <p>Sample size estimate: yes</p> <p>ITT analysis: yes; number randomised: 176 residents located in 44 homes; number analysed: 176 residents located in 44 homes</p> <p>Funding: this project was funded by the Australian Government Department of Health and Ageing under the Third Community Pharmacy Agreement Research and Development Grants Programme that is managed by the Pharmacy Guild of Australia (Community Pharmacy Agreement Research and Development Grant No. 5002553/99)</p>
Participants	<p>Country: Australia</p> <p>Setting: high-care nursing homes</p> <p>Number: 176 residents located in 44 homes (intervention group 21 homes and 94 participants; control group: 23 homes and 82 participants)</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> Residents with leg or pressure wounds who could provide informed consent <p>Exclusion criteria</p> <ul style="list-style-type: none"> Residents with infected wounds or diabetes Those undergoing long-term corticosteroid therapy chemotherapy or treatment with immunosuppressants

	<p>Pretreatment</p> <ul style="list-style-type: none"> • Mean (SD) age (years): intervention 83.0 (9.1); control: 83.7 (8.9) 0.635 • Mean (SD) days in nursing home: intervention: 681.5 (877.2); control: 731.7 (973.0) 0.749 • Women: intervention: 60 (63.8%); control: 64 (78.0%) 0.039 • Underweight: intervention: 46 (48.9%); control: 17 (20.7%) 0.000 • History of previous leg or PUs: yes: intervention 40 (42.6%); control: 49 (62.0%) 0.011; no: intervention: 54 (57.4%); control: 30 (38.0%) • Ability to describe pain or discomfort: yes: intervention: 62 (66.0%); control: 57 (69.5%) 0.615; no: intervention: 32 (34.0%); control: 25 (30.5%) • Urinary incontinence: significant: intervention: 38 (40.4%); control: 25 (30.5%) • Faecal incontinence: significant: intervention: 32 (34.0%); control: 18 (21.9%)
Interventions	<p>Intervention characteristics</p> <p>Intervention</p> <ul style="list-style-type: none"> • Multidisciplinary team of pharmacists and nurses • Study staff developed a standard treatment protocol for use in the intervention arm based on the colour, depth and exudate method for assessing wounds and their academic and clinical experience • Before the study commenced, training was provided to nurses and pharmacists in the intervention arm in both how to use the protocol and documentation procedures for data collection purposes <p>Control</p> <ul style="list-style-type: none"> • Residents in the control arm received usual care from nurses
Outcomes	<p>Primary outcome</p> <p><i>Number of wounds healed:</i></p> <ul style="list-style-type: none"> • outcome type: dichotomous outcome • reporting: fully reported • unit of measure: numbers • direction: higher is better • data value: endpoint <p><i>Time to complete healing:</i></p> <ul style="list-style-type: none"> • outcome type: continuous outcome • reporting: fully reported • unit of measure: numbers • direction: lower is better • data value: endpoint
Identification	<p>Sponsorship source: funded by the Australian Government Department of Health and Ageing under the Third Community Pharmacy Agreement Research and Development Grants Program that is managed by the Pharmacy Guild of Australia</p> <p>Country: Australia</p> <p>Setting: nursing homes in Melbourne, Australia</p> <p>Comments: none</p> <p>Authors name: Vu, T</p> <p>Institution: Centre for Health Economics, Monash University</p> <p>Email: vu@buseco.monash.edu.au</p> <p>Address: Clayton, Victoria, Australia</p>

Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Non-random component in the sequence generation process: quote: "The first nursing home to accept our invitation was assigned to the intervention arm, and the second with similar resident numbers from the same region allocated to the control arm"
Allocation concealment (selection bias)	High risk	Alternation or rotation employed: quote: "The first nursing home to accept our invitation was assigned to the intervention arm, and the second with similar resident numbers from the same region allocated to the control arm"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not mentioned in the paper, however, blinding not possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not mentioned in the paper
Incomplete outcome data (attrition bias) All outcomes	High risk	Outcomes reported per wound, and some wounds lost to follow-up
Selective reporting (reporting bias)	Unclear risk	Protocol for the study not registered, therefore, unclear if all outcomes were reported
Other bias	High risk	Difference in baseline characteristics for nutrition and history of previous PU. Differences in wound characteristics at baseline. In the intervention arm, the wounds are bigger, producing more exudate and are more painful. No analysis for the effect of clustering undertaken by the study authors

ADL: activities of daily living; **APN:** advanced practice nurse; **BMI:** body mass index; **ED:** emergency department; **EMDT:** enhanced multidisciplinary team; **HIH:** hospital-in-the-home; **ITT:** intention-to-treat; **LTC:** long-term care; **PU:** pressure ulcer; **RCT:** randomised controlled trial

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

Study	Reason for exclusion
Abadi 2017	Non-eligible study design
Al Awamleh 2012	Non-eligible intervention
Alvarez 1993	Non-eligible study design
Anderson 2009	Non-eligible study design
Anonymous 1994	Non-eligible intervention
Arora 2017	Non-eligible intervention
Bensmail 2012	It is a description of a programme, not an original study
Berlowitz 2007	Non-eligible intervention
Biji 2014	Non-eligible patient population
Brosolo 1989	Non-eligible study design
Chaboyer 2016	Non-eligible intervention
Charrier 2008	Non-eligible study design
Elliott 2008	Non-eligible study design
Ellis 2006	Non-eligible study design
Futtrup 2013	Non-eligible study design
Hart 2011	Non-eligible study design
Houser 2012	Non-eligible intervention
Jones 1993	Non-eligible intervention
Kapoor 2008	Non-eligible study design
Liu 2016	Non-eligible study design
O'Leary 2011	Non-eligible study design
Rantz 2012	Non-eligible intervention

(Continued)

Rodney 2015	Non-eligible study design
Van Gaal 2011	Non-eligible intervention
Warshawsky 2013	Non-eligible intervention
Yap 2013	Non-eligible intervention
Zarchi 2015	Wrong study population

Characteristics of studies awaiting assessment [ordered by study ID]

Onyebueke 2017

Methods	Non-RCT
Participants	Veterans with chronic spinal cord injury admitted for urinary tract infection, pressure ulcer/osteomyelitis or pneumonia
Interventions	Hospital-in-the-home (HIH) consisting of: daily registered nurse visits and daily physician oversight with follow-up visits as needed
Outcomes	Health: readmission and mortality rates; cost care: cost per bed-day; patient satisfaction: survey
Notes	Unclear about sample. Unable to source full text as yet, trying to contact study author

RCT: randomised controlled trial

DATA AND ANALYSES

Comparison 1. Transmural care versus usual follow-up care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence; follow-up 12 months	1	62	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.53, 1.64]
2 Adverse event: readmission to clinical rehabilitation; follow-up 12 months	1	62	Risk Ratio (M-H, Fixed, 95% CI)	2.0 [0.19, 20.93]

Comparison 2. Hospital-in-the-home versus hospital admission

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence; follow-up 28 days	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2 Adverse event: death; follow-up 28 days	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
3 Adverse event: hospital readmission; follow-up 28 days	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

Comparison 3. Enhanced multidisciplinary team versus usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcers healed; follow-up 14 months	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

Comparison 4. Multidisciplinary wound care versus usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcers healed; follow-up 20 weeks	1	342	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.98, 1.42]

ADDITIONAL TABLES

Table 1. ROBINS-I 'Risk of bias' table

Bloemen-Vrencken 2007	Bias due to confounding	Bias in selection of participants into the study	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	Overall bias
	Serious risk ^a	Critical risk ^b	Moderate risk ^c	Moderate risk ^d	Moderate risk ^e	Low risk ^f	Low risk ^g	Critical ^h

^aAt least one known important domain was not appropriately controlled for.

^bParticipants were not randomised. Matching between the experimental and control groups was not done until the 12-month point so as to include those for whom follow-up data was available. For this reason we judged the bias of the study to be unclear.

^cSome aspects of assignment were determined retrospectively.

^dDeviation from protocol apparent but unclear if deviation sufficient to have an effect.

^eIt is not known how many people were excluded from the study on the basis of incomplete outcome data and if this differed between the groups.

^fPrevalence of pressure ulcers unlikely to be influenced by knowledge of intervention.

^gSome multiple domain reporting, but no differences noted; no subgroup analysis (other than retrospective of participants for whom data were available).

^hWe judged the study as 'critical' risk of bias overall due to critical risk of bias in one domain.

CONTRIBUTIONS OF AUTHORS

Pauline Joyce: conceived, designed and coordinated the review; extracted data; checked the quality of data extraction; analysed or interpreted data; undertook and checked quality assessment; produced the first draft of the review; contributed to writing or editing the review; wrote to study authors/experts/companies; approved the final review prior to submission and is guarantor of the review.

Zena Moore: conceived and designed the review; extracted data; checked the quality of data extraction; analysed or interpreted data; undertook and checked quality assessment; produced the first draft of the review; contributed to writing or editing the review and approved the final review prior to submission.

Janice Christie: conceived and designed the review; analysed or interpreted data; undertook and checked quality assessment; contributed to writing or editing the review; advised on the review; performed previous work that was the foundation of the current review and approved the final review prior to submission.

Contributions of editorial base:

Nicky Cullum (Coordinating Editor): edited the protocol; advised on methodology, interpretation and content; approved the final protocol prior to publication.

Gill Norman (Editor): edited the review; advised on methodology, interpretation and content; approved the final review prior to publication.

Gill Rizzello (Managing Editor): coordinated the editorial process; advised on interpretation and content; edited the protocol and the review.

Naomi Shaw and Reetu Child (Information Specialists): designed the search strategy, ran the searches and edited the search methods section.

Ursula Gonthier (Editorial Assistant): edited the Plain language summary and reference sections of the protocol and the review.

DECLARATIONS OF INTEREST

Pauline Joyce: none known.

Zena Moore: has received an honorarium for speaking at professional meetings for Smith & Nephew and Molnlycke. The School of Nursing and Midwifery, RCSI has received a research grant from BSN Medical.

Janice Christie: none known.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

To assess bias in regards to non-randomised results, we planned to use ACROBAT-NRSI tool. However, we used the ROBINS-I tool as this is now standard practice for such studies. We have reported on all primary outcomes in the 'Summary of findings' table and added 'time to complete healing' in the 'Summary of findings' table for treatment studies.