Patient and lay carer education for preventing pressure ulceration in at-risk populations (Protocol)

AUTHOR(S)

Tom O'Connor, Zena EH Moore, Jo C. Dumville

Cochrane Library

Cochrane Database of Systematic Reviews

Patient and lay carer education for preventing pressure ulceration in at-risk populations (Protocol)

O'Connor T, Moore ZEH, Dumville JC, Patton D

O'Connor T, Moore ZEH, Dumville JC, Patton D.
Patient and lay carer education for preventing pressure ulceration in at-risk populations.
Cochrane Database of Systematic Reviews 2015, Issue 12. Art. No.: CD012006.
DOI: 10.1002/14651858.CD012006.

www.cochranelibrary.com

WILEY

TABLE OF CONTENTS

[Intervention Protocol]

Patient and lay carer education for preventing pressure ulceration in at-risk populations

Tom O'Connor[1], Zena EH Moore[1], Jo C Dumville[2], Declan Patton[1]

[1]School of Nursing & Midwifery, Royal College of Surgeons in Ireland, Dublin, Ireland. [2]School of Nursing, Midwifery and Social Work, University of Manchester, Manchester, UK

Contact address: Tom O'Connor, School of Nursing & Midwifery, Royal College of Surgeons in Ireland, 123 St Stephen's Green, Dublin, Ireland. tomoconnor@rcsi.ie.

Editorial group: Cochrane Wounds Group.
Publication status and date: New, published in Issue 12, 2015.

Citation: O'Connor T, Moore ZEH, Dumville JC, Patton D. Patient and lay carer education for preventing pressure ulceration in at-risk populations. *Cochrane Database of Systematic Reviews* 2015, Issue 12. Art. No.: CD012006. DOI: 10.1002/14651858.CD012006.

ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess whether patient and lay carer education for preventing pressure ulceration affects the incidence of pressure ulceration in at-risk people, in any care setting.

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). Pressure is the amount of force acting on a unit of area (O'Callaghan 2007), whereas, shear forces occur in soft tissue when these tissues are stretched, as happens when the bony structures move but the skin remains stationary (Sanders 2005). Pressure ulcers commonly occur in people with limited functional mobility or capacity for activity and as such are exposed to prolonged periods of exposure to sustained pressure/shear forces from lying or sitting in one position for a long time (Gefen 2008). Whereas it is acknowledged that there are numerous potential risk factors it has been postulated that some specific factors play a key role in the development of pressure ulcers, such as impaired activity and mobility (Moore 2011; Moore 2014). Healthy people regularly change their position while seated or recumbent. Indeed, there are normally a number of stimulators, during sleep and while awake, that motivate the person to move (Defloor 2005; Krapfl 2008). However, this is affected by the person's ability to feel pain and the person's actual physical ability to move or reposition themselves (Defloor 2005). Therefore, those who cannot reposition themselves are at risk of pressure ulcer damage, because they are unable to relieve pressure/shear over bony prominences, resulting in ongoing cell deformation and inevitable tissue damage (Loerakker 2010). Mino 2001 found a four-fold greater risk ratio (RR) for the development of pressure ulcers in people who have an inability to turn over in bed (RR 4.09). Papanikolaou 2003 compared the probability of pressure ulcer occurrence among people with varying levels of mobility and found that pressure ulcer development was five times more likely among people with limited mobility (odds ratio (OR) 5.41 95% confidence interval (CI) 2.00 to 14.63; P value = 0.001). Furthermore, a systematic review by

Coleman 2013 noted that risk factors emerging most frequently as independent predictors of pressure ulcer development were mobility/activity, perfusion and skin/pressure ulcer status.

Pressure ulcers vary in severity. One of the most widely recognised systems for categorising pressure ulcers is that of the National Pressure Ulcer Advisory Panel (NPUAP), which is summarised below (NPUAP 2014).

Category/Stage I - non-blanchable erythema: "Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its colour may differ from the surrounding area. The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Category I may be difficult to detect in people with dark skin tones. May indicate "at risk" persons."

Category/Stage II - partial thickness: "Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough [dead tissue]. May also present as an intact or open/ruptured serum-filled or sero-sanguinous filled blister. Presents as a shiny or dry shallow ulcer without slough or bruising (bruising indicates deep tissue injury). This category should not be used to describe skin tears, tape burns, incontinence associated dermatitis, maceration [damage through the skin being wet] or excoriation [damage through scratching/abrasion or burns]."

Category/Stage III - full thickness skin loss: "Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunnelling. The depth of a Category/Stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput [back of the head] and malleolus [ankle] do not have (adipose) subcutaneous tissue and Category/Stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Category/Stage III pressure ulcers. Bone/tendon is not visible or directly palpable."

Category/Stage IV - full thickness tissue loss: "Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar [scabbing] may be present. Often includes undermining and tunnelling. The depth of a Category/Stage IV pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have (adipose) subcutaneous tissue and these ulcers can be shallow. Category/Stage IV ulcers can extend into muscle and/or supporting structures (e.g. fascia, tendon or joint capsule) making osteomyelitis [bone infection] or osteitis [inflammation of bone] likely to occur. Exposed bone/muscle is visible or directly palpable."

The presence of pressure ulcers among people in the care of health professionals is often used as an indicator of the quality of healthcare provided (NICE 2014). Therefore, in order to place the problem of pressure ulcers into context, the number of pressure ulcers within a given clinical care setting is measured and reported as prevalence or incidence figures (Moore 2013).

Prevalence is a determination of the number of people with an existing pressure ulcer, at a given point in time, whereas, incidence is a determination of the number of people that develop a new pressure ulcer over a given time (Beaglehole 1993). Prevalence and incidence estimates vary according to the population being assessed, the data collection methods used and decisions about whether or not stage I pressure ulcers should be included (since there is no open wound at this stage but evidence of possible tissue damage) (NPUAP 2014). One review noted mean pressure ulcer prevalence rates in various settings of 8.9% in Iceland (one study), 17% in Norway (three studies), 16% in Ireland (six studies), 15% in Denmark (five studies) and 25% in Sweden (17 studies) (Moore 2013). These studies were conducted in acute care (23 studies); long stay (five studies); hospice (one study), community care (two studies) and a centre for rare diseases (one study). Not all studies clearly delineated between categories of pressure ulcer. Furthermore, different classification systems were used, including self developed classification systems, the European Pressure Ulcer Advisory Panel (EPUAP) pressure ulcer classification system, the EPUAP/NPUAP guidelines and sometimes none at all (Moore 2013). In one study from Jordan, across two care settings, a prevalence of 12% (Stage I and above) (EPUAP) was noted (Tubaishat 2011). Conversely, mean pressure ulcer prevalence across 198 nursing homes in Japan was 9.6% (Stage I and above) (Igarashi 2013). The lowest figure was reported from China, where data were gathered from one university hospital and 11 general hospitals and there was a prevalence of 1.58% (Stage I and above, including "unstageable" and "suspected deep tissue injury") (Jiang 2014). From one Canadian perspective, a detailed literature review identified a prevalence of 26% (staging not described) among 14,102 people residing in 18 acute-care facilities, 23 non-acute care facilities, 19 mixed healthcare settings and five community-care agencies (Woodbury 2004). Results from the Victorian state-wide prevalence in Australia noted a prevalence of 17.6% (Stage I and above) (Victorian Quality Council 2006). Conversely, a USA estimate for pressure ulcer prevalence (Stage II and above) across acute-care, long-term care and rehabilitation settings was 9%, with prevalence highest in long-term acute-care settings (26%) (VanGilder 2009).

Pressure ulcer incidence figures also vary across countries and settings. For example, the single incidence study from Norway noted a figure of 16.4%, whereas mean incidence in Denmark was 1.8% (two studies), 11% in Ireland (four studies) and 20% in Sweden (12 studies) (Moore 2013). In one study from Australia, incidence was 4.6% (Stage I and above) (Graves 2005). A further study from the USA collected data from 242,745 hospital discharges from 15 general and tertiary-care hospitals, and identified a pressure ulcer incidence of 2.68% (Gardiner 2014). One study from Australia noted an incidence of 16.6% within the acute-care setting (Jolley 2004), whereas, in long-term care in Canada this figure was 11.7% (Stage I and above) (Davis 2001). Prevalence and incidence figures are consistently highest in acute-care and hospice settings, and lowest in the care of the older person setting (Moore 2013);

however, it is interesting to note that a prevalence of between 4% and 27% has been identified in acutely ill paediatric populations (McLane 2004; Schlüer 2009), reflecting the figures noted across other clinical care settings.

The point prevalence of pressure ulceration in the total adult population of Leeds, UK, was estimated using a cross-sectional survey in 2011. Of the total adult population of 751,485, the point prevalence of pressure ulceration was 0.31 per 1000 (Hall 2014). UK pressure ulcer prevalence estimates specifically for community settings have reported rates of 0.77 per 1000 adults in a UK urban area (Stevenson 2013).

Pressure ulcers have a large impact on those affected; the ulcers can be painful, and may become seriously infected or malodorous. A number of studies conducted in the USA (Langemo 2000), the UK (Fox 2002: Spilsbury 2007; Essex 2009; Gorecki 2009), and the UK and Belgium (Hopkins 2006) have explored the impact of pressure ulcers on the people's lives. After adjustment for age, sex and co-morbidities, people with pressure ulcers had a lower health-related quality of life than people without pressure ulcers (Essex 2009). Pressure ulcers impacted on four health-related quality of life domains, namely, symptoms, physical functioning, psychological well-being and social functioning (Gorecki 2009). Participants report a preoccupation with their pressure ulcer with pain regarded as one of the most overwhelming aspects of their experience (Langemo 2000; Fox 2002; Hopkins 2006). Worryingly, treatments, repositioning and equipment often served to worsen the patient's experience rather than improve it Hopkins 2006. Furthermore, movement increased pain; therefore, participants were inclined to keep as still as possible. However, this was not always possible and repositioning regimens initiated by staff, or spontaneous movements during sleep, brought on the pain cycle (Hopkins 2006). The use of pressure redistribution devices, particularly alternating surfaces were also problematic, as when the cells inflated, they appeared to 'stick into' the pressure ulcer, exacerbating the pain experience (Hopkins 2006). One systematic review exploring the impact of pressure ulcers on quality of life in older people also identified that people feel that they are a burden to others and generally have a lack of knowledge about pressure ulcers (Gorecki 2009).

Pressure ulcers not only affect the patient themselves but also have a wider effect on families and lay carers (Hopkins 2006; Gorecki 2009). In their systematic review of the impact of pressure ulcer on quality of life, Gorecki 2009 found that pressure ulcers imposed additional care burdens on families and lay carers (such as skin inspections and help with activities of daily living) while and also causing emotional distress.

In an economically constrained health service, revenue spent on pressure ulcers is a concern, as it is suggested that many pressure ulcers can be avoided with appropriate risk assessment and use of interventions targeted at combating this risk (Moore 2014). However, despite this premise, it is estimated that approximately 4% of the annual healthcare budget is being spent on pressure ulcers, with nursing time accounting for 41% of these costs (Posnett 2009). Pressure ulcers increase length of hospital stay, re-admission and mortality rates (Lyder 2012), and add considerably to the cost of an episode of hospital care (Chan 2013). Figures from the USA suggested that for half a million hospital stays in 2006, 'pressure ulcer' was noted as a diagnosis; for adults, the total hospital costs of these stays was USD 11 billion (Russo 2008). Costs to the Australian healthcare system for treating pressure ulceration have been estimated at AUD 285 million per annum (Graves 2005).

Description of the intervention

The World Health Organization (WHO) considers that health education is not limited to the dissemination of health-related information but also "fostering the motivation, skills and confidence (self-efficacy) necessary to take action to improve health" (WHO 2012a). Patient involvement in healthcare and the rights of patients to have a central part in the healthcare process have for some time been seen as important aspects of healthcare provision (Nilsen 2006; McCormack 2006; Coulter 2008; European Commission 2012). The benefits of patient involvement are thought to include increased motivation and knowledge about health and illness among patients, resulting in patients having increased capacity to monitor and look after themselves, increased patient safety and ultimately patients having better health outcomes (Elwyn 2000; Davis 2011; European Commission 2012).

However, patient involvement is a vague concept and can be taken to mean a number of different factors and includes a range of activities or interventions (Aharony 1993). In one qualitative investigation into the concept, the European Commission identified differences between health practitioners and patients with regard to what patient involvement means. Practitioners were reported to consider patient involvement to be about compliance, patients taking more interest in their healthcare or taking steps to inform themselves about their health status. Further, practitioners considered involvement to be about them providing information or education to patients and the patient feeding back relevant information to their practitioner regarding their health status. Patients also emphasised being compliant as an element of their involvement but also equated involvement with taking responsibility for their health and health information needs. Such constructs of involvement were often considered to be passive (i.e. following health practitioner orders) but patients with chronic diseases highlighted their more active involvement (European Commission 2012). This was seen to be necessary as they were most familiar with themselves and their own disease processes (European Commission 2012). A further factor is the increased potential for patients to be knowledgeable and involved in their disease processes is the accessibility of information via the world wide web, fraught as that is with problems of misinformation and misinterpretation (Anderson 2008).

While there may be many facets to patient involvement, it is clear that central tenets are the provision of information and education in order to prompt patients to either take action themselves or to engage with health practitioners in relation to their health needs. Such responses are aimed at preventing disease, preventing further exacerbation of disease or alleviating existing disease (Smith 2009). The provision of education and information is standard practice in many situations in healthcare ranging from the single supply of medicine information leaflets to extensive and repeated education programmes for people with chronic illness such as diabetes (Radhakrishnan 2012) and cardiovascular disease (Holland 2014).

The prevention of pressure ulcers has traditionally been largely practitioner led (Asimus 2011). The increased move towards community-based care, coupled with the increasing need for patient control over their health processes points to a requirement for people who are at risk of pressure ulcers to be more involved in their care (WHO 2014). Involvement in pressure ulcer risk assessment necessitates certain knowledge and skills on behalf of the patients requiring information provision or educational interventions.

For the purposes of this review, patient, family and lay carer involvement will concentrate on lay people becoming more knowledgeable and active in their prevention of pressure ulcers. Therefore, we will include any intervention that involves:

- the provision of information to patients, family and lay carers regarding the prevention of pressure ulcers;
- educational programmes aimed at increasing patient, family, lay carer, or a combination of these, involvement in the prevention of pressure ulcers;
- strategies that encourage patients, their family, lay carers, or a combination of these, to become more knowledgeable about pressure ulcer prevention.
- the use of sensors or pressure monitoring devices aimed at encouraging patients to move to relieve pressure or be helped to move be families or lay carers

How the intervention might work

This intervention falls within the broader domain of knowledge concerning health literacy and its benefits for health. Health literacy concerns patients' capacities to access, process and understand information so that they can actively and knowledgeably participate in decisions and actions relating to their health (Ratzan 2000; Nielsen-Bohlman 2004; Martensson 2012). A significant body of research has demonstrated the link between lower levels of health literacy and poorer health outcomes (Gazmararian 2003; Berkman 2011; Bostock 2012). Evidence to support the benefits of introducing strategies to increase health literacy for better health outcomes is also beginning to emerge (Pignone 2005). Thus, interventions aimed at increasing health literacy are likely to lead to better health outcomes. The health literacy intervention in this context is aimed at making patients more knowledgeable and active in the prevention of pressure ulcers. This is likely to lead to:

- an increased capacity to self manage;
- an increased level of awareness of risk factors in pressure ulcer development;
- an increased ability to act on risk;
- a decrease in pressure ulcers development.

Why it is important to do this review

Patient safety is at the heart of healthcare delivery, and as such, avoidance of unnecessary complications associated with clinical care is considered to be a fundamental patient right (WHO 2012b). Therefore, as pressure ulcers remain an important issue, adopting strategies aimed at reducing their occurrence makes both human and economic sense (Moore 2014). Patients, their families and lay carers are central to the success of any interventions adopted, as the majority of people are not nursed within a care setting where there is ready access to trained health professionals (CDC 2011). The WHO stresses the importance of enhancing the contribution of the patient and their wider personal network to their own health and well-being (WHO 2012c). In this way, the patient may be empowered to making more informed decisions pertaining to the type of healthcare delivery most suited to their clinical needs (WHO 2012c). As pressure ulcers are a key concern for the patient, their family and lay carers their involvement in pressure ulcer prevention is important and recommended in guidelines for prevention (NICE 2014). However, the precise impact of patient, family and lay carer involvement on pressure ulcers has not been systematically reviewed which is the rational for the current review.

OBJECTIVES

To assess whether patient and lay carer education for preventing pressure ulceration affects the incidence of pressure ulceration in at-risk people, in any care setting.

METHODS

Criteria for considering studies for this review

Types of studies

We will include published and unpublished randomised controlled trials (RCTs), including cluster RCTs, irrespective of language of report. We will exclude cross-over trials and studies using quasi-randomisation.

Types of participants

We will include RCTs recruiting people of any age at risk of pressure ulceration, or RCTs recruiting people who informally care for someone at risk of pressure ulceration.

Types of interventions

We will include studies where the only systematic difference between study groups was the specific use of an intervention aiming to educate patients, lay carers (carers and family members), or both, in pressure ulcer prevention. Interventions could be provision of information on the prevention of pressure ulcers, or could be educational programmes aimed at increasing patient or family/lay carer knowledge of the prevention of pressure ulcers, or strategies that encourage people to become more knowledgeable about pressure ulcer prevention such as pressure monitoring systems or technology which prompts action to prevent pressure ulcers for patient or lay person use. We will include interventions that are based on the provision of eduction via written (e.g. information leaflets), verbal (e.g. teaching sessions), multimedia (e.g. web-based programmes or audiovisual aids), skill based (e.g. practical demonstrations) methods. We will consider educational interventions that are singular, one-off interventions or delivered multiple times. The comparisons of interest for this review will be usual care, no educational interventions or an attention control e.g., an educational intervention on a different topic.

Types of outcome measures

We will analyse outcomes at the latest time point available (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 is different from the latest time point available). For all outcomes, we will class assessment of outcomes as:

- short term: less than one week to eight weeks;
- medium term: greater than eight weeks to 26 weeks;
- long term: greater than 26 weeks.

Primary outcomes

- risk of pressure ulceration - defined as a new ulcer of any grade developing during the study period. We will regard the following as adequate measures of this outcome:
    - time to occurrence of a new ulcer;
    - proportion of participants developing a new ulcer.

We will accept authors' assessment/measurement processes when classifying a new ulcer.

Secondary outcomes

- Grade/category of pressure ulcer, as reported by the study author.
- Patient/lay carer knowledge of pressure ulcer risk and prevention.
- Measures of acceptability of interventions to users where the study systematically recorded this.

Search methods for identification of studies

Electronic searches

We will search the following electronic databases to retrieve reports of relevant RCTs:

- Cochrane Wounds Group Specialised Register;
- Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library)* (latest issue);
- Ovid MEDLINE (1946 to search date);
- Ovid MEDLINE (In-Process & Other Non-Indexed Citations) (latest issue);
- Ovid EMBASE (1974 to search date);
- EBSCO CINAHL Plus (1937 to search date);
- Ovid PsycINFO (1806 to search date).

We will use the following provisional search strategy in CENTRAL:

#1 MeSH descriptor: [Education] explode all trees
#2 MeSH descriptor: [Pamphlets] explode all trees
#3 ((educat* or train* or learn* or teach*) near/3 (self* or patient* or carer* or cargiver* or famil* or partner* or friend*)):ti,ab,kw
#4 ((educat* or train* or learn* or teach*) near/3 (program* or model* or system* or intervention*)):ti,ab,kw
#5 ((educat* or train* or learn* or teach*) near/3 (technol* or multimedia or web or audiovisual or audio-visual or online or internet or app* or e-learning or elearning or written or printed or oral or face-to-face or "face to face")):ti,ab,kw
#6 ((patient or health) near/3 (information or literacy)):ti,ab,kw
#7 (leaflet* or booklet* or pamphlet* or poster* or brochure*) .ti,ab,kw
#8 ((written or printed or oral or online or audiovisual or audio-visual or Internet or web or online or telephon*) near/3 information):ti,ab,kw
#9 academic detailing:ti,ab,kw
#10 (algorithm* or decision tree*):ti,ab,kw
#11 {or #1-#10}
#12 MeSH descriptor: [Pressure Ulcer] explode all trees
#13 (pressure near (ulcer* or sore* or injur*)):ti,ab,kw
#14 (decubitus near (ulcer* or sore*)):ti,ab,kw
#15 (bedsore* or bed sore*):ti,ab,kw
#16 {or #12-#15}
#17 {and #11, #16} in Trials

We will adapt this strategy to search Ovid MEDLINE, Ovid EMBASE, EBSCO CINAHL and Ovid PsycINFO. We will combine 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 will combine the EMBASE search with the Ovid EMBASE filter developed by the UK Cochrane Centre (Lefebvre 2011). We will combine the CINAHL search with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN 2012). We will apply no restrictions with respect to language, date of publication or study setting.

We will also search the following clinical trials registries:

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

Searching other resources

We will try to identify other potentially eligible trials or ancillary publications by searching the reference lists of retrieved included trials, as well as relevant systematic reviews, meta-analyses and Health Technology Assessment reports.

Data collection and analysis

Selection of studies

Two review authors (TOC and ZM) will independently assess the titles and abstracts of the citations retrieved by the searches for relevance. After this initial assessment, we will obtain full-text copies of all studies considered potentially relevant. Two review authors (TOC and ZM) will independently check the full papers for eligibility; we will resolve disagreements by discussion and, where required, the input of a third review author (JD). Where required and possible, we will contact study authors where the eligibility of a study is unclear. We will record all reasons for exclusion of studies for which we had obtained full copies and present them in a 'Characteristics of excluded studies' table. We will complete a PRISMA flowchart to summarise this process (Liberati 2009).

Where studies have been reported in multiple publications/reports, we will obtain all publications. While we will include the study only once in the review, we will extract data from all reports to ensure maximal relevant data are obtained.

Data extraction and management

We will extract and summarise details of the eligible studies using a data extraction sheet and present them in a 'Characteristics of included studies' table. Two review authors (TOC and ZM) will extract data independently and will resolve disagreements by discussion, drawing on a third review author where required. Where data are missing from reports, we will attempt to contact the study authors to obtain this information. Where a study meets the eligibility criteria and where more than two intervention arms are included, we will extract only data from intervention and control groups relevant to the primary and secondary outcomes of interest.

We will extract the following data where possible by treatment group for the pre-specified interventions and outcomes in this review. We will collect outcome data for relevant time points as described in Types of outcome measures section as follows:

- country of origin;
- unit of randomisation
- unit of analysis;
- trial design (e.g. parallel, cluster);
- care setting;
- number of participants randomised to each trial arm;
- eligibility criteria and key baseline participant data;
- details of intervention regimen received by each group;
- duration of intervention;
- details of any co-interventions;
- primary and secondary outcome(s) (with definitions);
- outcome data for primary and secondary outcomes (by group);
- duration of follow-up;
- number of withdrawals (by group);
- publication status of study;
- source of funding for trial.

Assessment of risk of bias in included studies

Two review authors (TOC and ZM) will independently assess included studies using the Cochrane 'Risk of bias' tool (Higgins 2011a). This tool addresses six specific domains: sequence generation, allocation concealment, blinding, incomplete data, selective outcome reporting and other issues. In this review, we will record issues with unit of analysis, for example, where a cluster trial has been undertaken but analysed at the individual level in the study report (Appendix 1). We will assess blinding and completeness of outcome data for each of the review outcomes separately. We will present our assessment of risk of bias using two 'Risk of bias' summary figures; one that is a summary of bias for each item across all studies, and a second that shows a cross-tabulation of each trial by all of the 'Risk of bias' items. We will class studies with an assessment of high risk of bias for selection bias, detection bias or attrition bias (or a combination of these) as being at overall high risk of bias (for specified outcome).

For trials using cluster randomisation, we will also consider the risk of bias in terms of: recruitment bias, baseline imbalance, loss of clusters, incorrect analysis and comparability with individually randomised trials (Higgins 2011b) (Appendix 2).

Measures of treatment effect

Where data allow, for dichotomous outcomes (e.g. pressure ulcer present, yes or no), we will calculate the RR with 95% CI. The RR 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, whereas 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 2011). For continuous outcomes (e.g. health-related quality of life), we will use the mean difference (MD) with 95% CIs, if all trials use the same or similar assessment scale. If trials use different assessment scales, we will use the standardised mean difference (SMD) with 95% CIs. The MD is a standard statistic that measures the absolute difference between the mean value in two groups in a clinical trial. It estimates the amount by which the experimental intervention changes the outcome on average compared with the control. Interpretation of the results is the same as RR except the point of no effect is 0 rather than 1 (Deeks 2011). The SMD expresses the size of the intervention effect in each study relative to the variability observed in that study and an SMD of zero means that the intervention and the control have equivalent effects (Deeks 2011).

We will report time-to-event data (e.g. time-to-ulceration) as hazard ratios (HR) where possible in accordance with the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011). If studies reporting time-to-event data (e.g. time to incident ulcer) do not report an HR, then, where feasible, we will estimate this using other reported outcomes, such as the numbers of events, through the application of available statistical methods (Parmar 1998). We will only consider mean or median time to new ulceration without survival analysis as a valid outcome in the unlikely event that a report specifies that all participants developed a wound (i.e. if the trial authors regarded time to incident ulcer as a continuous measure as there is no censoring).

Unit of analysis issues

Where studies randomise at the participant level and measure outcomes at the wound level (e.g. number of pressure ulcers), we will treat the participant as the unit of analysis when the number of pressure ulcers assessed appears equal to the number of participants (e.g. one pressure ulcer per person).

Particular unit of analysis issues in wound care trials can occur when 1) studies randomise at the participant level, use the allocated treatment on multiple wounds per participant and then analyse outcomes per wound, or 2) studies undertake multiple assessments of an outcome over time per participant. These approaches should be treated as cluster trials, alongside more standard cluster designs (such as delivery of interventions at an organisational level).

Where a cluster trial has been conducted and correctly analysed (i.e. using methods that adjust for clustering), effect estimates and their standard errors will be meta-analysed using the generic inverse variance method in Review Manager 5 (RevMan 2014).

We will record where a cluster randomised trial has been conducted but incorrectly analysed. This will be recorded as part of the 'Risk of bias' assessment. If possible, we will approximate the correct analyses based on *Cochrane Handbook for Systematic Reviews of Interventions* guidance using information on (Higgins 2011a):

- the number of clusters (or groups) randomised to each intervention group; or the 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 (ICC).

If we cannot analyse the study data correctly, we will extract and present outcome data.

We will also note when randomisation has used a split-site or split-body design. We will assess whether the correct paired analysis has been undertaken in the study. Again, we will record issues in the 'Risk of bias' section. If an incorrect analysis has been undertaken, we will try to approximate a correct analysis if the required data are available from the study report or the study authors. If this is not possible, we will extract and present the relevant outcome data but not analyse them further.

Dealing with missing data

It is common to have data missing from trial reports. Excluding participants post-randomisation from the analysis, or ignoring those participants who are lost to follow-up compromises the randomisation, and potentially introduces bias into the trial. Where there are missing data we think should be included in the analyses, we will contact the study authors to request whether these data are available.

Where data remain missing for the outcome 'risk of pressure ulceration' we will compare the effects of assuming both a best and worst case scenario for participants with a missing outcome.

For continuous variables (e.g. health-related quality of life measures), and for all secondary outcomes, we will present available data from the study reports/study authors and do not plan to impute missing data. Where measures of variance are missing, we will calculate these wherever possible. If calculation is not possible, we will contact the study authors. Where these measures of variance are not available, we will exclude the study from any relevant meta-analyses that we conduct.

Assessment of heterogeneity

Assessment of heterogeneity will comprise initial assessment of clinical and methodological heterogeneity: that is, the degree to which the included studies vary in terms of participant, intervention, outcome and characteristics such as length of follow-up. We

will supplement this assessment of clinical and methodological heterogeneity by information regarding statistical heterogeneity - assessed using the Chi^2 test (a significance level of P value < 0.10 will indicate statistically significant heterogeneity) in conjunction with the I^2 statistic (Higgins 2003). The I^2 statistic examines the percentage of total variation across RCTs that is due to heterogeneity rather than chance (Higgins 2003). In general, I^2 values of 25% or less may mean a low level of heterogeneity (Higgins 2003), and values of more than 75% indicate very high heterogeneity (Deeks 2011). Where there is evidence of high heterogeneity, we will attempt to explore this further: see Data synthesis section.

Assessment of reporting biases

Reporting biases arise when the dissemination of research findings is influenced by the nature and direction of results. Publication bias is one of a number of possible causes of 'small-study effects', that is, a tendency for estimates of the intervention effect to be more beneficial in smaller RCTs. Funnel plots allow a visual assessment of whether small-study effects may be present in a meta-analysis. A funnel plot is a simple scatter plot of the intervention effect estimates from individual RCTs against some measure of each trial's size or precision (Sterne 2001). We will present funnel plots for meta-analyses comprising 10 RCTs or more using Review Manager 5 (RevMan 2014).

Data synthesis

We will combine details of included studies in a narrative review according to type of comparator, possibly by location/type of wound and then by outcomes by time period. We will consider clinical and methodological heterogeneity and undertake pooling when studies appear appropriately similar in terms of wound type, intervention type, duration of follow-up and outcome type.

In terms of meta-analytical approach, in the presence of clinical heterogeneity (review author's judgement) or evidence of statistical heterogeneity (or both), we will use the random-effects model. We will only use a fixed-effect approach when we consider clinical heterogeneity minimal and estimate statistical heterogeneity as non-statistically significant for the Chi^2 value and 0% for the I^2 assessment (Kontopantelis 2012). We will adopt this approach as it is recognised that statistical assessments can miss potentially important between-study heterogeneity in small samples, hence the preference for the more conservative random-effects model (Kontopantelis 2013). Where we consider clinical heterogeneity acceptable or of interest, we may meta-analyse even when statistical heterogeneity is high, but we will attempt to interpret the causes behind this heterogeneity and will consider using meta-regression for that purpose, if possible (Thompson 1999).

We will present data using forest plots where possible. For dichotomous outcomes, we will present the summary estimate as an RR with 95% CI. Where continuous outcomes are measured in the same way across studies, we will present a pooled MD with 95% CI; we will pool SMD estimates where studies measure the same outcome using different methods. For time-to-event data, we will 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 (RevMan 2014). Where time to incident ulcer is analysed as a continuous measure but it is not clear if all wounds healed, we will document use of the outcome in the study but will not summarise data or used them in any meta-analysis.

We will obtain pooled estimates of treatment effect using Review Manager 5 software (RevMan 2014).

'Summary of findings' tables

We will present the main results of the review in 'Summary of findings' tables. These tables present key information concerning the quality of the evidence, the magnitude of the effects of the interventions examined and the sum of the available data for the main outcomes (Schünemann 2011a). The 'Summary of findings' tables also include an overall grading of the evidence related to each of the main outcomes using the GRADE (Grades of Recommendation, Assessment, Development and Evaluation) approach (Schünemann 2011a). The GRADE approach defines the quality 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 quality of a body of evidence involves consideration of within-trial risk of bias (methodological quality), directness of evidence, heterogeneity, precision of effect estimates and risk of publication bias (Schünemann 2011b). We plan to present the following outcomes in the 'Summary of findings' tables:

- time to development of a new ulcer;
- risk of developing a new ulcer during follow up.

Subgroup analysis and investigation of heterogeneity

Where there is evidence of between-trial heterogeneity, we will conduct the following subgroup analyses where feasible:

- type of interventions being evaluated (e.g. the provision of information to patients, families, lay carers, or a combination of these, regarding the prevention of pressure ulcers; educational programmes aimed at increasing involvement in the prevention of pressure ulcers; strategies that encourage patients, families, lay carers, or a combination of these, to become more knowledgeable about pressure ulcer prevention;
- provision of information to patients versus provision to lay carers;
- studies at low risk of selection bias versus studies at unclear or high risk of bias.

Sensitivity analysis

We will perform a sensitivity analysis by excluding studies assessed as having a high risk of bias in the key domains of 'generating the randomisation sequence', 'allocation concealment' and 'blinding of outcome assessment'. We will explore the effect of unpublished studies, small studies (fewer than 100 participants) and cluster trials, where the analysis was not at the same level as the allocation (i.e. allocation by cluster and analysis by participant).

ACKNOWLEDGEMENTS

The review authors would like to acknowledge the contribution of the peer reviewers: Sonya Osborne, Gemma Villaneuva, Evangelos Kontopantelis, Sasha Shepherd, Patricia Davies, Janet Gunderson and Jodi Kay Duke. Thanks in addition for the contribution of the Copy Editor, Anne Lawson; the Cochrane Wounds Group Managing Editors, Gill Rizzello and Sally Bell-Syer; and the Trials Search Co-ordinator, Reetu Child. We would also like to thank Paul Mountain for his invaluable comments.

REFERENCES

Additional references

Aharony 1993
Aharony L, Strasser S. Patient satisfaction: what we know about and what we still need to explore. *Medical Care Review* 1993;**50**:49–79.

Anderson 2008
Anderson A, Klemm P. The Internet: friend or foe when providing patient education?. *Clinical Journal of Oncology Nursing* 2008;**12**:55–63.

Asimus 2011
Asimus M, Maclellan L, Li PI. Pressure ulcer prevention in Australia: the role of the nurse practitioner in changing practice and saving lives. *International Wound Journal* 2011; **8**(5):508–13.

Beaglehole 1993
Beaglehole R, Bonita R, Kjellstrom T. Measuring health and disease. *Basic Epidemiology*. Geneva: World Health Organization, 1993:13–20.

Berkman 2011
Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Crotty K. Low health literacy and health outcomes: an updated systematic review. *Annals of Internal Medicine* 2011;**155**:97–107.

Bostock 2012
Bostock S, Steptoe A. Association between low functional health literacy and mortality in older adults: longitudinal cohort study. *BMJ* 2012;**344**:e1602.

CDC 2011
Centers for Disease Control and Prevention. Health literacy. www.cdc.gov/healthliteracy/ (accessed 21 August 2015).

Chan 2013
Chan B, Nanwa N, Mittmann N, Bryant D, Coyte PC, Houghton PE. The average cost of pressure ulcer management in a community dwelling spinal cord injury population. *International Wound Journal* 2013;**10**:431–40.

Coleman 2013
Coleman S, Gorecki C, Nelson EA, Closs SJ, Defloor T, Halfens R, et al. Patient risk factors for pressure ulcer development: systematic review. *International Journal of Nursing Studies* 2013;**50**:974–1003.

Coulter 2008
Coulter A, Parsons S, Askham J. Where are the patients in decision-making about their own care?. World Health Organization Regional Office for Europe and European Observatory on Health Systems and Policies, Copenhagen 2008.

Davis 2001
Davis CM, Caseby NG. Prevalence and incidence studies of pressure ulcers in two long-term care facilities in Canada. *Ostomy and Wound Management* 2001;**47**:28–34.

Davis 2011
Davis RE, Sevdalis N, Vincent CA. Patient involvement in patient safety: how willing are patients to participate?. *BMJ Quality & Safety* 2011;**20**:108–14.

Deeks 2011
Deeks JJ, Higgins JPT, Altman DG. Chapter 9: Analysing data and undertaking meta-analyses. In: Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions. 5.1.0 [Updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Defloor 2005
Defloor T, De Bacquer D, Grypdonck MH. The effect of various combinations of turning and pressure reducing devices on the incidence of pressure ulcers. *International Journal of Nursing Studies* 2005;**42**:37–46.

Elwyn 2000
Elwyn G, Edwards A, Kinnersley P, Grol R. Shared decision making and the concept of equipoise: the competences of involving patients in healthcare choices. *British Journal of General Practice.* 2000;**50**(460):892–9.

Essex 2009
Essex HN, Clark M, Sims J, Warriner A, Cullum N. Health-related quality of life in hospital inpatients with pressure ulceration: assessment using generic health-related quality of life measures. *Wound Repair and Regeneration* 2009;**17**: 797–805.

European Commission 2012
European Commission. Eurobarometer qualitative study: patient involvement, 2012. ec.europa.eu/health/

healthcare/docs/eurobaro_patient_involvement_2012_en.pdf (accessed 13 May 2015).

Fox 2002
Fox C. Living with a pressure ulcer: a descriptive study of patients' experiences. *British Journal of Community Nursing* 2002;**7**:10, 12, 14, 16, 20, 22.

Gardiner 2014
Gardiner JC, Reed PL, Bonner JD, Haggerty DK, Hale DG. Incidence of hospital-acquired pressure ulcers - a population-based cohort study. *International Wound Journal* 2014;**11**(6).

Gazmararian 2003
Gazmararian JA, Williams MV, Peel J, Baker DW. Health literacy and knowledge of chronic disease. *Patient Education Counseling* 2003;**51**:267–75.

Gefen 2008
Gefen A, van Nierop B, Bader DL, Oomens CW. Strain-time cell-death threshold for skeletal muscle in a tissue-engineered model system for deep tissue injury. *Journal of Biomechanics* 2008;**41**:2003–12.

Gorecki 2009
Gorecki C, Brown JM, Nelson EA, Briggs M, Schoonhoven L, Dealey C, et al. Impact of pressure ulcers on quality of life in older patients: a systematic review. *Journal of the American Geriatrics Society* 2009;**57**:1175–83.

Graves 2005
Graves N, Birrell F, Whitby M. Effect of pressure ulcers on length of hospital stay. *Infection Control Hospital Epidemiology* 2005;**26**:293–7.

Hahn 2005
Hahn S, Puffer S, Torgerson DJ, Watson J. Methodological bias in cluster randomised trials. *BMC Medical Research Methodology* 2005;**5**:10.

Hall 2014
Hall J, Buckley HL, Lamb KA, Stubbs N, Saramago P, Dumville JC, et al. Point prevalence of complex wounds in a defined United Kingdom population. *Wound Repair and Regeneration* 2014;**22**(6):694–700.

Higgins 2003
Higgins JPT, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *BMJ* 2003;**327** (7414):557–60.

Higgins 2011a
Higgins JPT, Altman DG, Sterne, JAC. Chapter 8: Assessing risk of bias in included studies. In: Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Higgins 2011b
Higgins JPT, Deeks JJ, Altman DG. Chapter 16: Special topics in statistics. In: Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions. Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Holland 2014
Holland C, Carthron DL, Duren-Winfield V, Lawrence W. An experiential cardiovascular health education program for African-American college students. *ABNF Journal* 2014;**25**: 52–6.

Hopkins 2006
Hopkins A, Dealey C, Bale S, Defloor T, Worboys F. Patient stories of living with a pressure ulcer. *Journal of Advanced Nursing* 2006;**56**(4):345–53.

Igarashi 2013
Igarashi A, Yamamoto-Mitani N, Gushiken Y, Takai Y, Tanaka M, Okamoto Y. Prevalence and incidence of pressure ulcers in Japanese long-term-care hospitals. *Archives of Gerontology and Geriatrics* 2013;**56**:220–6.

Jiang 2014
Jiang Q, Li X, Qu X, Liu Y, Zhang L, Su C, et al. The incidence, risk factors and characteristics of pressure ulcers in hospitalized patients in China. *International Journal of Clinical Experimental Pathology* 2014;**7**:2587–94.

Jolley 2004
Jolley DJ, Wright R, McGowan S, Hickey MB, Campbell DA, Sinclair RD, et al. Preventing pressure ulcers with the Australian Medical Sheepskin: an open-label randomised controlled trial. *Medical Journal of Australia* 2004;**180**: 324–7.

Kontopantelis 2012
Kontopantelis E, Reeves D. Performance of statistical methods for meta-analysis when true study effects are non-normally distributed: a simulation study. *Statistical Methods in Medical Research* 2012;**21**(4):409–26.

Kontopantelis 2013
Kontopantelis E, Springate DA, Reeves D. A re-analysis of the Cochrane Library data: the dangers of unobserved heterogeneity in meta-analysis. *PLoS One* 2013;**8**(7): e69930.

Krapfl 2008
Krapfl L, Gray M. Does regular repositioning prevent pressure ulcers?. *Journal of Wound, Ostomy, and Continence Nursing* 2008;**36**:571–7.

Langemo 2000
Langemo D K, Melland H, Hanson D, Olson B, Hunter S. The lived experience of having a pressure ulcer: a qualitative analysis. *Advances in Skin and Wound Care* 2000;**13**: 225–35.

Lefebvre 2011
Lefebvre C, Manheimer E, Glanville J. Chapter 6: Searching for studies. In: Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions. Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Liberati 2009
Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JP, et al. The PRISMA statement for reporting

systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *PLoS Medicine* 2009;**6**:e1000100.

Loerakker 2010
Loerakker S, Stekelenburg A, Strijkers GJ, Rijpkema JJM, Baaijens FPT, Bader DL, et al. Temporal effects of mechanical loading on deformation-induced damage in skeletal muscle tissue. *Annals of Biomedical Engineering* 2010;**38**:2577–87.

Lyder 2012
Lyder CH, Wang Y, Metersky M, Curry M, Kliman R, Verzier NR, et al. Hospital-acquired pressure ulcers: results from the national Medicare Patient Safety Monitoring System study. *Journal of the American Geriatric Society* 2012; **60**(9):1603–8.

Martensson 2012
Martensson L, Hensing G. Health literacy - a heterogeneous phenomenon: a literature review. *Scandinavian Journal of Caring Sciences* 2012;**26**:151–60.

McCormack 2006
McCormack B, McCance TV. Development of a framework for person-centred nursing. *Journal of Advanced Nursing* 2006;**56**:472–9.

McLane 2004
McLane KM, Bookout K, McCord S, McCain J, Jefferson LS. The 2003 national pediatric pressure ulcer and skin breakdown prevalence survey: a multisite study. *Journal of Wound, Ostomy and Continence Nursing* 2004;**31**:168–78.

Mino 2001
Mino Y, Morimoto S, Okaishi K, Sakurai S, Onishi M, Okuro M, et al. Risk factors for pressure ulcers in bedridden elderly subjects: importance of turning over in bed and serum albumin level. *Geriatrics and Gerontology International* 2001;**1**:38–44.

Moore 2011
Moore Z, Cowman S, Conroy R. A multi-centre, pragmatic, randomised controlled trial of repositioning for the prevention of pressure ulcers. *Journal of Clinical Nursing* 2011;**20**(17-18):2633–44.

Moore 2013
Moore Z, Johanssen E, van Etten M. A review of PU prevalence and incidence across Scandinavia, Iceland and Ireland (Part I). *Journal of Wound Care* 2013;**22**:1–7.

Moore 2014
Moore Z, Cowman S. Risk assessment tools for the prevention of pressure ulcers. *Cochrane Database of Systematic Reviews* 2014, Issue 2. [DOI: 10.1002/14651858.CD006471.pub3]

NICE 2014
National Institute for Health and Care Excellence. Pressure ulcers: prevention and management of pressure ulcers: clinical guideline 179. www.nice.org.uk/guidance/cg179 (accessed 31 May 2015).

Nielsen-Bohlman 2004
Nielsen-Bohlman L, Panzer AM, Kindig DA (editors). Health Literacy: a Prescription to End Confusion. National Academies Press 2004.

Nilsen 2006
Nilsen ES, Myrhaug HT, Johansen M, Oliver S, Oxman AD. Methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material. *Cochrane Database of Systematic Reviews* 2006, Issue 3. [DOI: 10.1002/14651858.CD004563.pub2]

NPUAP 2014
National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance. In: Haesler Emily editor(s). *Prevention and Treatment of Pressure Ulcers: Quick Reference Guide*. Perth, Australia: Cambridge Media, 2014.

O'Callaghan 2007
O'Callaghan M, Reilly S, Seery A. Pressure. In: Duffy K editor(s). *Exploring Science*. Dublin: Education Company, 2007:270–7.

Papanikolaou 2003
Papanikolaou P, Lyne PA, Lycett EJ. Pressure ulcer risk assessment: application of logistic analysis. *Journal of Advanced Nursing* 2003;**44**:128–36.

Parmar 1998
Parmar MK, Torri V, Stewert L. Extracting summary statistics to perform meta-analysis of the published literature for survival endpoints. *Statistics in Medicine* 1998;**17**: 2815–34.

Pignone 2005
Pignone M, DeWalt DA, Sheridan S, Berkman N, Lohr KN. Interventions to improve health outcomes for patients with low literacy. *Journal of General Internal Medicine* 2005; **20**(2):185–92.

Posnett 2009
Posnett J, Gottrup F, Lundgren H, Saal G. The resource impact of wounds on health-care providers in Europe. *Journal of Wound Care* 2009;**18**:154–61.

Radhakrishnan 2012
Radhakrishnan K. The efficacy of tailored interventions for self-management outcomes of type 2 diabetes, hypertension or heart disease: a systematic review. *Journal of Advanced Nursing* 2012;**68**:496–510.

Ratzan 2000
Ratzan SC, Parker R. National Library of Medicine current bibliographies in medicine: health literacy (introduction). National Institutes of Health 2000.

RevMan 2014 [Computer program]
The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan) 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014.

Russo 2008
Russo CA, Steiner C, Spector W. Hospitalizations related to pressure ulcers among adults 18 years and older. *Statistical*

Brief #64. Healthcare Cost and Utilization Project (HCUP). Rockville (MD): Agency for Health Care Policy and Research (US), 2008.

Sanders 2005
Sanders J. Stump-socket interface pressures. In: Bader DL, Bouten CVC, Colin D, Oomen CWJ editor(s). *Pressure Ulcer Research: Current and Future Perspectives*. Heidelberg, Germany: Springer, 2005:129–148.

Schlüer 2009
Schlüer AB, Cignacco E, Müller M, Halfens RJ. The prevalence of pressure ulcers in four paediatric institutions. *Journal of Clinical Nursing* 2009;**18**:3244–52.

Schünemann 2011a
Schünemann HJ, Oxman AD, Higgins JPT, Vist GE, Glasziou P, Guyatt GH. Chapter 11: Presenting results and 'Summary of findings' tables. In: Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Schünemann 2011b
Schünemann HJ, Oxman AD, Higgins JPT, Deeks JJ, Glasziou P, Guyatt GH. Chapter 12: Interpreting results and drawing conclusions. In: Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

SIGN 2012
Scottish Intercollegiate Guidelines Network (SIGN). Search filters. www.sign.ac.uk/methodology/filters.html#random (accessed 15 June 2014).

Smith 2009
Smith SK, Dixon A, Trevena L, Nutbeam D, McCaffery KJ. Exploring patient involvement in healthcare decision making across different education and functional health literacy groups. *Social Science and Medicine* 2009;**69**(12): 1805–12.

Spilsbury 2007
Spilsbury K, Nelson A, Cullum N, Iglesias C, Nixon H, Mason S. Pressure ulcers and their treatment and effects on quality of life: hospital inpatient perspectives. *Journal of Advanced Nursing* 2007;**57**:494–504.

Sterne 2001
Sterne JA, Egger M. Funnel plots for detecting bias in meta-analysis: guidelines on choice of axis. *Journal of Clinical Epidemiology* 2001;**54**:1046–55.

Stevenson 2013
Stevenson R, Collinson M, Henderson V, Wilson L, Dealey C, McGinnis E, et al. The prevalence of pressure ulcers in community settings: an observational study. *International Journal of Nursing Studies* 2013;**50**:1550–7.

Thompson 1999
Thompson SG, Sharp SJ. Explaining heterogeneity in meta-analysis: a comparison of methods. *Statistics in Medicine* 1999;**18**:2693–708.

Tubaishat 2011
Tubaishat A, Anthony D, Saleh M. Pressure ulcers in Jordan: a point prevalence study. *Journal of Tissue Viability* 2011; **20**:14–9.

VanGilder 2009
VanGilder C, Amlung S, Harrison P, Myer S. Results of the 2008-2009 International Pressure Ulcer Prevalence Survey and a 3-year, acute care, unit-specific analysis. *Ostomy Wound Management* 2009;**55**:39–45.

Victorian Quality Council 2006
Victorian Quality Council. Victorian Quality Council State wide PUPPS2 report - 2004, 2006. www.health.vic.gov.au/qualitycouncil/downloads/pupps2/pupps2_report.pdf. Me, (accessed 31 May 2015).

WHO 2012a
World Health Organization. *Health Education: Theoretical Concepts, Effective Strategies and Core Competencies*. Cairo: World Health Organization: Regional Office for the Eastern Mediterranean, 2012.

WHO 2012b
World Health Organization. *Unsafe Medical Care is a Major Source of Morbidity and Mortality Throughout the World*. Geneva: World Health Organization, 2012.

WHO 2012c
World Health Organization. Right to health. www.who.int/mediacentre/factsheets/fs323/en/ (accessed 04 June 2015).

WHO 2014
World Health Organization. *A Universal Truth: No Health Without a Workforce*. Geneva: World Health Organization, 2014.

Woodbury 2004
Woodbury MG, Houghton PE. Prevalence of pressure ulcers in Canadian healthcare settings. *Ostomy and Wound Management* 2004;**50**:22-4, 26, 28, 30, 32, 34, 36-8.

* *Indicates the major publication for the study*

APPENDICES

Appendix 1. 'Risk of bias' assessment (individually randomised controlled trials)

- Was the allocation sequence randomly generated?
  - Low risk of bias:
    - the investigators described a random component in the sequence generation process such as: referring to a random number table; using a computer random number generator; coin tossing; shuffling cards or envelopes; throwing dice; drawing of lots.
  - High risk of bias:
    - the investigators described a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: sequence generated by odd or even date of birth; sequence generated by some rule based on date (or day) of admission; sequence generated by some rule based on hospital or clinic record number.
  - Unclear risk of bias:
    - insufficient information about the sequence generation process to permit judgement of low or high risk of bias.
- Was the treatment allocation adequately concealed?
  - Low risk of bias:
    - participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone, web-based and pharmacy-controlled randomisation); sequentially numbered drug containers of identical appearance; sequentially numbered, opaque, sealed envelopes.
  - High risk of bias:
    - participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: using an open random allocation schedule (e.g. a list of random numbers); assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non opaque or not sequentially numbered); alternation or rotation; date of birth; case record number; any other explicitly unconcealed procedure.
  - Unclear risk of bias:
    - insufficient information to permit judgement of low or high risk of bias. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement, for example, if the use of assignment envelopes was described, but it remained unclear whether envelopes were sequentially numbered, opaque and sealed.
- Blinding - was knowledge of the allocated interventions adequately prevented during the study?
  - Low risk of bias: any one of the following:
    - no blinding, but the review authors judged that the outcome and the outcome measurement were not likely to be influenced by lack of blinding;
    - blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken;
    - either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others unlikely to introduce bias.
  - High risk of bias: any one of the following:
    - o blinding or incomplete blinding, and the outcome or outcome measurement was likely to be influenced by lack of blinding;
    - blinding of key study participants and personnel attempted, but likely that the blinding could have been broken;
    - either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.
  - Unclear risk of bias: any one of the following:
    - insufficient information to permit judgement of low or high risk of bias.
    - The study did not address this outcome.
- Were incomplete outcome data adequately addressed?
  - Low risk of bias: any one of the following:
    - no missing outcome data;
    - reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias);
    - missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups;

◇ for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate;

◇ for continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size;

◇ missing data were imputed using appropriate methods.

- High risk of bias: any one of the following:

◇ reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups;

◇ for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate;

◇ for continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size;

◇ 'as-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation;

◇ potentially inappropriate application of simple imputation.

- Unclear risk of bias: any one of the following:

◇ insufficient reporting of attrition/exclusions to permit judgement of low or high risk of bias (e.g. number randomised not stated, no reasons for missing data provided);

◇ the study did not address this outcome.

- Were reports of the study free of suggestion of selective outcome reporting?
  - Low risk of bias: any of the following:

◇ the study protocol was available and all of the study's pre-specified (primary and secondary) outcomes that were of interest in the review were reported in the pre-specified way;

◇ the study protocol was not available but it was clear that the published reports included all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).

  - High risk of bias: any one of the following:

◇ not all of the study's pre-specified primary outcomes were reported;

◇ one or more primary outcomes were reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified;

◇ one or more reported primary outcomes were not pre-specified (unless clear justification for their reporting was provided, such as an unexpected adverse effect);

◇ one or more outcomes of interest in the review were reported incompletely so that they could not be entered in a meta-analysis;

◇ the study report did not include results for a key outcome that would be expected to have been reported for such a study.

  - Unclear risk of bias:

◇ insufficient information to permit judgement of low or high risk of bias. It is likely that the majority of studies will fall into this category.

- Were there any other sources of potential bias?
  - Low risk of bias:

◇ the study appeared to be free of other sources of bias.

  - High risk of bias: there was at least one important risk of bias. For example, the study:

◇ had a potential source of bias related to the specific study design used; or

◇ was claimed to have been fraudulent; or

◇ had some other problem.

  - Unclear risk of bias: there may be a risk of bias, but there was either:

◇ insufficient information to assess whether an important risk of bias existed; or

◇ insufficient rationale or evidence that an identified problem will introduce bias.

Appendix 2. 'Risk of bias' assessment (cluster randomised controlled trials)

In cluster-randomised trials, particular biases to consider include: recruitment bias; baseline imbalance; loss of clusters; incorrect analysis and comparability with individually randomised trials.

- Recruitment bias:
  - can occur when participants are recruited to the trial after the clusters have been randomised, as the knowledge of whether each cluster is an 'intervention' or 'control' cluster could affect the types of participants recruited.

- Baseline imbalance:
  - cluster-randomised trials often randomise all clusters at once, so lack of concealment of an allocation sequence should not usually be an issue. However, because small numbers of clusters are randomised, there is a possibility of chance baseline imbalance between the randomised groups, in terms of either the clusters or the participants. Although not a form of bias as such, the risk of baseline differences can be reduced by using stratified or pair-matched randomisation of clusters. Reporting of the baseline comparability of clusters, or statistical adjustment for baseline characteristics, can help reduce concern about the effects of baseline imbalance.

- Loss of clusters:
  - occasionally complete clusters are lost from a trial, and have to be omitted from the analysis. Just as for missing outcome data in individually randomised trials, this may lead to bias. In addition, missing outcomes for participants within clusters may also lead to a risk of bias in cluster-randomised trials.

- Incorrect analysis:
  - many cluster-randomised trials are analysed by incorrect statistical methods, not taking the clustering into account. Such analyses create a 'unit of analysis error' and produce over-precise results (the standard error of the estimated intervention effect is too small) and P values that are too small. They do not lead to biased estimates of effect. However, if they remain uncorrected, they will receive too much weight in a meta-analysis.

- Comparability with individually randomised trials:
  - in a meta-analysis including both cluster and individually randomised trials, or including cluster-randomised trials with different types of clusters, possible differences between the intervention effects being estimated need to be considered. For example, in a vaccine trial of infectious diseases, a vaccine applied to everyone in a community would be expected to be more effective than if the vaccine was applied to only half of the people. Another example is provided by a Cochrane review of hip protectors (Hahn 2005). The cluster trials showed large positive effects whereas individually randomised trials did not show any clear benefit. One possibility is that there was a 'herd effect' in the cluster-randomised trials (which were often performed in nursing homes, where compliance with using the protectors may have been enhanced). In general, such 'contamination' would lead to underestimates of effect. Thus, if an intervention effect is still demonstrated despite contamination in those trials that were not cluster-randomised, a confident conclusion about the presence of an effect can be drawn. However, the size of the effect is likely to be underestimated. Contamination and 'herd effects' may be different for different types of cluster.

CONTRIBUTIONS OF AUTHORS

Tom O'Connor: conceived the review question, developed the protocol and co-ordinated the protocol development. Wrote and edited the protocol and approved the final version prior to submission.

Zena Moore: conceived the review question, developed the protocol and co-ordinated the protocol development. Wrote and edited the protocol and approved the final version prior to submission.

Jo Dumville: developed the protocol and co-ordinated the protocol development. Wrote and edited the protocol and approved the final version prior to submission.

Declan Patton: developed the protocol; wrote and performed part of the editing of the protocol and approved the final version prior to submission.

Contributions of editorial base:

Liz McInnes edited the protocol; advised on methodology, interpretation and protocol content. Nicky Cullum edited the protocol; advised on methodology, interpretation and protocol content and approved the final protocol prior to submission.
Gill Rizzello and Sally Bell-Syer: co-ordinated the editorial process. Advised on interpretation and content. Edited the protocol.
Reetu Child:designed the search strategy and edited the search methods section.

DECLARATIONS OF INTEREST

Tom O'Connor: nothing to declare.

Zena EH Moore: Has received an honorarium for speaking at professional meetings for Vancive, Covidien and Convatec.

Jo C Dumville:nothing to declare.

Declan Patton: nothing to declare.

SOURCES OF SUPPORT

Internal sources

- Royal College of Surgeons in Ireland, Ireland.
- School of Nursing, Midwifery and Social Work, University of Manchester, UK.

External sources

- This project was supported by the National Institute for Health Research (NIHR), via Cochrane Infrastructure and Cochrane Programme Grant funding to Cochrane Wounds. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, National Health Service (NHS) or the Department of Health, UK.