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

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[Intervention Protocol]

Organisation of health services for preventing and treating pressure ulcers

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ABSTRACT

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

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

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" (National Pressure Ulcer Advisory Panel 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, pressure sores, and bedsores. Pressure ulcers are often diagnosed by appearance and staged: non-blanchable erythema or persistent redness 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

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a spinal cord injury, and those who are sedated following trauma or surgery are inclined to having 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 I 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 II and above) of 10.5% (Vanderwee 2007). In 2009, a USA estimate for pressure ulcer prevalence (stage II 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). Five to six per cent of patients across these settings were estimated to have a pressure ulcer in January 2014 (Durkin 2014) based on National Safety Thermometer Data. Other indicators of national pressure ulcer data are being considered as part of the National Health Service (NHS) Outcomes Framework 2014/15 (DH 2013).

Among surgical patients, pressure ulcer prevalence rates of 8.5% and 33% have been reported (Karadag 2006; Versluysen 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 2013). 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 2013). 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 effectively 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. The Cochrane Effective Practice and Organisation of Care (EPOC) Group defines four main subtypes of organisational interventions (EPOC 2015):

1. Provider-orientated interventions (e.g. changes to professional roles, multidisciplinary teams, integration of services, and inter-professional communication)
2. 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)
3. Structural interventions (e.g. changes in organisational structure, facilities, resources, records, ownership, or nature of services)
4. Regulatory interventions (e.g. changes to healthcare delivery or costs by legislation or regulation).

This review will focus 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 multi professional 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 inter-

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ventions through introduction of specialist staff roles and multi-professional care pathways (Asimus 2011; Ramos 1997).

How the intervention might work

There is some evidence 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 impact positively or negatively on 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. Dellefield 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 clearly demonstrate the effect of the team approach to wound healing, particularly in relation to clinical outcomes.This review will further consider 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 have 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 2013a; 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 have 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.

The proposed review will follow the methods outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011c. This information will also be 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 will follow EPOC 2013 guidance. Due to the nature of the intervention and difficulties associated with randomising individual participants to different service configurations, we will include a range of different study designs in this review, all of which have a control group and at least one intervention group: randomised controlled trials and appropriately analysed (or re-analysable) cluster randomised controlled trials, non-randomised controlled trials,

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controlled before-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, will be 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 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 had an existing pressure ulcer (of any stage), will be eligible for inclusion.

Types of interventions

The types of interventions that will be considered in this review are 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, e.g. 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 and/or case management (including co-ordination of assessment, treatment, and arrangement for referrals).
- Communication and case discussion between distant health professionals, e.g. telephone links or telemedicine, where there is a television/video link between specialist and remote nurse practitioners.

Types of outcome measures

As this review is concerned with both the prevention and treatment of pressure ulcers, we have separated the primary outcome into one outcome for prevention and one outcome for treatment.
We list primary and secondary outcomes below. If a study is apparently eligible (that is correct study design, population, and intervention/comparator), but does not report a listed outcome, we will contact the study authors where possible to determine whether an outcome of interest here was measured but not reported.
We will 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 will 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 will be 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 person was observed, totaled for all persons.
Incidence Proportion: Number of new cases of pressure ulcers during specified study period divided by the size of population (CDC 2012).
Treatment studies
The primary outcome for treatment studies is complete healing, but this may have been measured and reported in several ways by trial authors. Therefore, we plan to include studies that report any of the following:
• an objective 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 trial period; or healing rate (we will accept trials with any length of follow-up, we will adjust for any differences in our analyses);
• time to complete wound healing (using methods of survival analysis and expressing the intervention effect as a hazard ratio (HR)).

Secondary outcomes

All studies

1. 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 will not include ad hoc measures of quality of life that are not validated and would not be common to multiple studies).
2. Staff satisfaction
3. Patient satisfaction
4. Adverse events.

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Search methods for identification of studies

Electronic searches

We will search the following electronic databases for relevant studies:

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

The provisional search strategy to be used in CENTRAL can be found in Appendix 1. We will adapt this strategy as appropriate for other databases. In order to identify randomised trials, 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 RCT filter terms developed by the UK Cochrane Centre (Lefebvre 2011). We will combine the CINAHL searches with the RCT trial filter terms developed by the Scottish Intercollegiate Guidelines Network (SIGN 2014). We will also add additional filter terms to the searches, using controlled vocabularies and free-text strings, in order to identify the other study designs that are to be included in the review (see Types of studies). There will be no restrictions with respect to language, date of publication, or study setting.

We will also search the following clinical trials registries for ongoing studies:

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

Searching other resources

We will search reference lists of all included studies and other relevant publications, such as systematic reviews and guidelines. We will contact experts in the field and the authors of relevant publications to identify any completed or ongoing trials. We will also perform 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

Selection of studies

Two review authors 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 to be potentially relevant. Two review authors will independently check the full papers for eligibility; disagreements will be resolved by discussion and, where required, with the input of a third review author. Where the eligibility of a study is unclear, we will attempt to contact study authors. We will record all reasons for exclusion of studies for which we had obtained full copies. 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. Whilst we will include the study only once in the review, we will extract data from all reports in order to ensure that we obtain all available relevant data.

Data extraction and management

Two review authors (PJ and ZM) will independently extract data from eligible studies using a data extraction sheet developed for this purpose. Specifically, we will extract 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
- outcomes data for primary and secondary outcomes (by group)
- funding source.

We will resolve any differences in opinion by discussion and, where necessary, by referencing Cochrane Wounds editorial base. If data are missing from reports, we will attempt to contact study authors in order to obtain the missing information. In order to extract the maximal amount of information, we will include multiple reports of the same study, ensuring that data are not duplicated. One review author (PJ) will enter data into Review Manager 5.3 software (RevMan 2014), with a second review author (ZM) verifying accuracy.

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Assessment of risk of bias in included studies

We will assess included randomised controlled trials using the Cochrane tool for assessing risk of bias (Appendix 2). This tool addresses six specific domains: sequence generation, allocation concealment, blinding, incomplete data, selective outcome reporting, and other issues. For trials using cluster randomisation, we will assess the risk of bias using the following domains: recruitment bias, baseline imbalance, loss of clusters, incorrect analysis, and comparability with individually randomised trials (Higgins 2011a; Higgins 2011b).

Where possible, we will present 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 trial for all 'Risk of bias' items.

To assess bias in regards to non-randomised results, we will use the ACROBAT-NRSI tool (Sterne 2014) (Appendix 3).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 measurement of interventions; bias due to departures 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 (for example proportion of participants with a pressure ulcer), we will calculate 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. A RR of 1 means there is no difference in risk between the two groups; a RR of less than 1 means the event is less likely to occur in the experimental group than in the control group; and a 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 continuously distributed outcome data (for example pain), if all trials use the same assessment scale, we will use the mean difference (MD) with 95% CIs. If trials use different assessment scales, we will 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 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 with 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. An SMD of 0 means that in a clinical trial the intervention and the control have equivalent effects (Deeks 2011). We will report time-to-event data (for example 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 2011). 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 2011). For statistically significant effects in binary outcomes, we will calculate number needed to treat to benefit or number needed to treat to harm. If we suspect skewness, and if scale data have finite upper and lower limits, we will use the easy 'rule of thumb' calculation to test for skewness, that is if the standard deviation, when doubled, is greater than the mean, it is unlikely that the mean is the centre of the distribution (Altman 1996), and we will not enter the data into any meta-analysis. If we find relevant data that are skewed, we will present the data in 'Other data' tables.

Unit of analysis issues

We anticipate main unit of analysis issues occurring in cluster trials when allocation occurs at the level of the organisation or the team and data are collected from individual patients. Where a cluster trial has been conducted and correctly analysed, effect estimates and their standard errors may be meta-analysed using the generic inverse-variance method in Review Manager 5.3 (RevMan 2014). We will record where a cluster-randomised trial has been conducted but incorrectly analysed 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 (Reeves 2011), 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.

If we cannot analyse the study data, we will extract and present, but not further analyse and not include, outcome data in any otherwise relevant meta-analysis we might conduct.

Dealing with missing data

It is often the case that data is missing from studies. Excluding participants post 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 are missing, we will contact the relevant study authors to enquire whether these data are available.

Where data for 'proportion of wounds healed' remain missing, we will assume that if participants were not included in an analysis, their wound did not heal (that is they would be considered in the denominator but not the numerator).

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In a time-to-healing analysis using survival analysis methods, dropouts should be accounted for as censored data, so we will take no action regarding missing data.

For continuous variables and all secondary outcomes, we will present the data available from the study reports/study authors and will not impute missing data. Where possible, we will calculate missing measures of variance if not reported using the total N at the start of the study. Where these measures of variation are not available, we will exclude the study from any relevant meta-analyses we might conduct.

Assessment of heterogeneity

Assessment of heterogeneity can be a complex, multifaceted process. Firstly, we will consider 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 with information regarding statistical heterogeneity assessed using the Chi² test (we will consider a significance level of P less than 0.10 to indicate statistically significant heterogeneity) in conjunction with I^2 measure (Higgins 2003). I^2 examines the percentage of total variation across randomised controlled trials that is due to heterogeneity rather than chance (Higgins 2003). Very broadly, we will consider that I^2 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 2011). Where there is evidence of high heterogeneity, we will attempt to explore this further; see Data synthesis section.

Assessment of reporting biases

We will assess reporting bias using guidelines in the *Cochrane Handbook for Systematic Reviews of Interventions* (Stern 2011). If enough studies are available for a meaningful assessment of publication bias, we will construct a funnel plot of primary outcomes to test for asymmetry. We will also consider selective reporting (that is reporting some outcomes and not others) in our assessment of reporting bias.

Data synthesis

We will 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 will consider clinical and methodological heterogeneity and undertake pooling only when studies appear appropriately similar in terms of intervention type, study design, duration of treatment, and outcome assessment, and when we can clearly interpret data. We will present randomised controlled trials and non-randomised studies separately.

In terms of meta-analytical approach, in the presence of clinical heterogeneity (review author 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 believe clinical heterogeneity to be minimal and estimate statistical heterogeneity as non-statistically significant for the Chi² value and 0% for the I^2 assessment (Kontopantelis 2013). 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 2012). Where we believe clinical heterogeneity to be acceptable or of interest, we may meta-analyse even when statistical heterogeneity is high, but we will attempt to interpret the causes for this heterogeneity and will consider using meta-regression for that purpose, if possible (Thompson 1999; Thompson 2002).

We will present data using forest plots where possible. For dichotomous outcomes, we will present the summary estimate as a RR with 95% CI. Where continuous outcomes are measured in the same way across studies, we plan to present a pooled MD with 95% CI; we plan to pool SMD estimates where studies measure the same outcome using different methods. For time-to-event data, we plan 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 5.3 (RevMan 2014). Where time to healing 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 or use data in any meta-analysis.

'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 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. 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:

- Ulcer incidence
- Ulcer healing
- Adverse events.

Where data are not pooled, we will conduct the GRADE assess-

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ment for each comparison and present this narratively within the Results section without presenting separate 'Summary of findings' tables.

Subgroup analysis and investigation of heterogeneity

If substantial heterogeneity exists between studies for the primary outcomes, we will explore reasons for heterogeneity. We envisage that the number of studies meeting our inclusion criteria may be low. Consequently, in order to avoid type 1 errors we plan to conduct a minimal number of subgroup analyses, including the following, if possible:

- The setting for which service delivery is taking place: hospital, community nursing home, or the patient's home.

Sensitivity analysis

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

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. The Cochrane Central Register of Controlled Trials (CENTRAL) provisional search strategy

#1 MeSH descriptor: [Pressure Ulcer] explode all trees
#2 (pressure next (ulcer* or sore* or injur*)):ti,ab,kw
#3 (decubitus next (ulcer* or sore*)):ti,ab,kw
#4 ((bed next sore*) or bedsore*):ti,ab,kw
#5 {or #1-#4}
#6 MeSH descriptor: [Role] explode all trees
#7 MeSH descriptor: [Physician's Practice Patterns] explode all trees
#8 MeSH descriptor: [Nurse's Practice Patterns] explode all trees
#9 ((shift* or chang* or replac* or substitut* or transfer* or delegat* or expand* or extend* or increas* or empower*) near/4 (role? or boundar* or pattern? or professional? or practice? or responsibilit*)):ti,ab,kw

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#10 ((nurse? or physician? or practitioner? or pharmacist? or therapist?) near/4 (role? or skill? or duty or duties or task* or responsibilit* or charg*)):ti,ab,kw
#11 {or #6-#10}
#12 MeSH descriptor: [Patient Care Team] explode all trees
#13 MeSH descriptor: [Interprofessional Relations] explode all trees
#14 (interdisciplinar* or multidisciplinar* or interprofessional*):ti,ab,kw
#15 {or #12-#14}
#16 MeSH descriptor: [Patient Care Management] explode all trees
#17 MeSH descriptor: [Continuity of Patient Care] explode all trees
#18 MeSH descriptor: [Health Planning] explode all trees
#19 MeSH descriptor: [Delivery of Health Care] explode all trees
#20 pathway*:ti,ab,kw
#21 ((integrat* or comprehensive or "patient centered" or continu*) near/4 (care or system?)):ti,ab,kw
#22 {or #16-#21}
#23 MeSH descriptor: [Personal Satisfaction] explode all trees
#24 MeSH descriptor: [Reinforcement (Psychology)] explode all trees
#25 MeSH descriptor: [Motivation] explode all trees
#26 MeSH descriptor: [Reward] explode all trees
#27 MeSH descriptor: [Reimbursement, Incentive] explode all trees
#28 {or #23-#27}
#29 MeSH descriptor: [Health Personnel] explode all trees
#30 {and #28-#29}
#31 MeSH descriptor: [Job Satisfaction] explode all trees
#32 MeSH descriptor: [Workplace] explode all trees
#33 {or #30-#32}
#34 ((nurse? or physician? or practitioner? or pharmacist? or therapist?) near/4 (satisfaction* or incentiv* or reward* or reinforcem* or motivation*)):ti,ab,kw
#35 organi?ational:ti,ab,kw
#36 {or #34-#35}
#37 {or #11, #15, #22, #33, #36}
#38 {and #5, #37} in Trials

Appendix 2. Risk of bias criteria - individually randomised controlled trials

1. Was the allocation sequence randomly generated?

Low risk of bias

The investigators describe 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 describe 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

Insufficient information about the sequence generation process to permit judgement of low or high risk of bias.

2. 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 (for example a list of random numbers); assignment envelopes were used without

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appropriate safeguards (for example if envelopes were unsealed or nonopaque or not sequentially numbered); alternation or rotation; date of birth; case record number; any other explicitly unconcealed procedure.

Unclear

Insufficient information available 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 is described, but it remains unclear whether envelopes were sequentially numbered, opaque, and sealed.

3. 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 judge that the outcome and the outcome measurement are 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 was unlikely to introduce bias.

High risk of bias

Any one of the following.

- No 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 was likely to introduce bias.

Unclear

Either of the following.

- Insufficient information available to permit judgement of low or high risk of bias.
- The study did not address this outcome.

4. Were incomplete outcome data adequately addressed?

Low risk of bias

Any one of the following.

- No missing outcome data.
- Reasons for missing outcome data were unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias).
- Missing outcome data are 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 is 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 is not enough to have a clinically relevant impact on observed effect size.
- Missing data have been 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 the observed event risk is 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 is enough to induce clinically relevant bias in observed effect size.
- 'As-treated' analysis done with substantial departure in the intervention received from that assigned at randomisation.
- Potentially inappropriate application of simple imputation.

Unclear

Either 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.

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5. Are reports of the study free of suggestion of selective outcome reporting?

Low risk of bias

Either of the following.

- The study protocol is available and all of the study's prespecified (primary and secondary) outcomes that are of interest in the review have been reported in the prespecified way.
- The study protocol is not available, but it is clear that the published reports include all expected outcomes, including those that were prespecified (convincing text of this nature may be uncommon).

High risk of bias

Any one of the following.

- Not all of the study's prespecified primary outcomes have been reported.
- One or more primary outcomes is reported using measurements, analysis methods, or subsets of the data (e.g. subscales) that were not prespecified.
- One or more of the reported primary outcomes was not prespecified (unless clear justification for their reporting is provided, such as an unexpected adverse effect).
- One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis.
- The study report fails to include results for a key outcome that would be expected to have been reported for such a study.

Unclear

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

6. Other sources of potential bias

Low risk of bias

The study appears to be free of other sources of bias.

High risk of bias

There is 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
- had extreme baseline imbalance; or
- has been claimed to have been fraudulent; or
- had some other problem.

Unclear

There may be a risk of bias, but there is either:

- insufficient information to assess whether an important risk of bias exists; or
- insufficient rationale or evidence that an identified problem will introduce bias.

Appendix 3. Risk of bias criteria - cluster 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 individuals are recruited to the trial after the clusters have been randomly assigned, as knowledge of whether each cluster is an 'intervention' or 'control' cluster could affect the types of participants recruited.
- Cluster randomised trials often randomly assigned 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 randomly assigned, there is a possibility of chance baseline imbalance between randomly assigned groups, in terms of the clusters or the individuals. 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.
- 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 individuals within clusters may lead to risk of bias in cluster randomised trials.
- Many cluster randomised trials are analysed by incorrect statistical methods, without taking the clustering into account. Such analyses create a 'unit of analysis error' and produce overly precise results (the standard error of the estimated intervention effect is too

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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.

- 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 estimated need to be considered. For example, in a vaccine trial of infectious diseases, a vaccine applied to all individuals in a community would be expected to be more effective than vaccine applied to only half of the people. Another example is provided by a Cochrane review of hip protectors (Hahn 2005). The cluster trials showed a large positive effect, whereas individually randomised trials did not show 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 clusters.

CONTRIBUTIONS OF AUTHORS

All review authors: conceived the review question, developed the protocol, completed the first draft of the protocol, assisted in writing the protocol and approved the final version prior to submission. Jo Dumville secured funding for the protocol. Zena Moore is guarantor of the protocol.

Contributions of editorial base:

Nicky Cullum: Edited the protocol. Advised on methodology, interpretation, and protocol content.

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

Pauline Joyce: nothing to declare.

Zena Moore: has received an honorarium for speaking at professional meetings for Vancive.

Janice Christie: nothing to declare

Jo Dumville: nothing to declare.

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NOTES

Some of the content of this protocol has been used in other protocols for the Cochrane Wounds Group.

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