Repositioning for pressure ulcer prevention in adults (Protocol)

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[Intervention Protocol]

Repositioning for pressure ulcer prevention in adults

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ABSTRACT

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

The objectives of this review are three-fold: first, to assess the effects of repositioning on the prevention of PUs in all adults, irrespective of risk, nursed in a hospital or long-term care setting; second, to ascertain the most effective repositioning schedules (i.e., timing of repositioning); and third, to ascertain the most effective positions for preventing PUs in adults, nursed in a hospital or long-term care setting. Specifically, this review addresses the following questions.

1. What is the most effective repositioning position for preventing PUs?
2. What is the most effective repositioning schedule for preventing PUs?
3. What are the incremental resource consequences and costs associated with implementing different repositioning regimens compared with alternate schedules or standard practice?

BACKGROUND

Description of the condition

A pressure ulcer (PU) (also known as pressure sore, pressure injury (PI), decubitus ulcer or bedsore), has previously been defined as “an area of localised damage to the skin and underlying tissue caused by pressure, shear and/or a combination of these” (European Pressure Ulcer Advisory Panel 1998). However, a more comprehensive and updated definition states that a PU is “a localised injury to skin or underlying tissue usually over a bony prominence as a result of pressure or pressure in combination with shear” (European Pressure Ulcer Advisory Panel 2009; NPUAP 2009). PUs occur when the soft tissue is compressed between a bony prominence and an external surface for a prolonged period of time.

PU classification systems provide an accurate and consistent means by which the severity and level of tissue injury of a PU can be described and documented (Australian Wound Management Association 2011). The words “stage” (European Pressure Ulcer Advisory Panel 2009), “grade”, and “category” may be used interchangeably to describe the levels of soft-tissue injury. The original staging system includes stages 1 through to 4. Stage 1 reflects persistent non-blanching erythema (redness) of the skin (Australian Wound Management Association 2011; European Pressure Ulcer Advisory Panel 2009). Stage 2 involves partial thickness skin loss (epidermis and dermis). Stage 3 reflects full thickness skin loss involving damage or necrosis of subcutaneous tissue whereas in Stage 4 the damage extends to the underlying bone, tendon or joint capsule. However, more recently, two additional classifications have been recognised as being part of stage 4 (“*unclassified/unstageable*” and “*deep tissue injury*”) (European Pressure Ulcer Advisory Panel 2009; Australian Wound Management Association 2011; National Pressure Ulcer Advisory Panel 2007). Integrated into these classifications is the assumption that the ulcer is due to pressure; and hence other aetiologies of wounds are not inaccurately classified as a PU (European Pressure Ulcer Advisory Panel 2009). PUs are associated with pain, an increased risk of infection and sepsis, longer hospital stay, higher hospitalisation costs and mortality (Institute for Healthcare Improvement 2008; Thomas 1996). Yet, the majority of PUs are preventable (Brandeis 2001). Despite a general consensus that PUs are preventable, hospital-acquired PUs are among the top five adverse events reported. Estimates of PU incidence in hospitalised patients have ranged from under 3% to over 30% (Nixon 2006; Queensland Health 2008; Schuurman 2009). Costs of treating PUs vary globally but similarly represent a considerable financial burden on hospital budgets. Costs to the Australian healthcare system have been estimated at AU\$285m per annum (Queensland Health 2009). The total cost for treatment of PUs in the UK was £1.4 to £2.1 billion annually (4% of total NHS expenditures) (Bennett 2004), whilst the total cost in the US is estimated at US\$11 billion per year (Institute for Healthcare Improvement 2008). Much of this cost is allocated to nursing time (Bennett 2004).

Immobility and physical inactivity are considered to be major risk factors for PU development in hospitalised patients (Allman 1995; Institute for Healthcare Improvement 2008; Lindgren 2004), however, the aged and individuals who have severely compromised states of health are particularly at risk (Institute for Healthcare Improvement 2008). For example, of the 3.55 million hospital admissions in Australia each year (excludes day cases), 50% of patients will be at risk of PUs and 10% or more will develop an ulcer (Queensland Health 2009). Screening tools based on individuals’ levels of activity and mobility scores have been widely used for the assessment of PU risk (Braden 2005; Jalali 2005; Thompson 2005). Various methods have been shown to reduce the incidence of PUs, the most common of these is the introduction and use of various mattresses or overlays (Nixon 2006; Reddy 2006; Vanderwee 2005) and position changes (Buss 2002; Krapfl 2008; Reddy 2006).

Description of the intervention

A central issue around pressure injury prevention (PIP) relates to repositioning. Manual repositioning regimens are used in pressure injury risk-prevention programs to alternate areas of pressure distribution between the body and the bedding through manually altering body posture (Manorama 2010).

Best practice guidelines developed in Europe, USA and Australia advocate routine repositioning of people at risk of PUs; often, but not universally, these guidelines advocate two-hour repositioning (Defloor 2005; European Pressure Ulcer Advisory Panel 1998; Australian Wound Management Association 2011; Queensland Health 2009). Such recommendations appear to be based on early small studies comparing repositioning schedules either to other repositioning schedules or to spontaneous bodily movements leading to the recommendation of a two-hour repositioning schedule for people at risk (Exton-Smith 1961; Norton 1962; Palmén 1987; Smith 1990). These initial studies were undertaken with very small samples and were not conducted as rigorous randomised controlled trials (RCTs). They were also conducted when hospital mattresses were of a much poorer quality than currently.

How the intervention might work

Pressure, from lying or sitting on a particular part of the body results in oxygen deprivation to the particular area (Defloor 2005). Normally, this results in pain and discomfort which stimulates the person to change position. However, if the person is unable to reposition themselves, assistance will be required. Repositioning is believed to reduce the length of time that the tissue is under pressure and decreases the likelihood of the development of PUs (Catania 2007). Thus, the theoretical premise underlying repositioning is that it reduces pressure, thereby maintaining an ade-

quate supply of oxygen and nutrients to the area; preventing tissue death (Braden 1987).

Negative aspects of frequent repositioning

Whilst frequent repositioning underpins current practice guidelines, it may also be associated with negative consequences for patients, nursing staff and health care (Australian Institute of Health and Welfare 2009; Bureau of Labor Statistics 2002; Carskadon 2005; Dawson 2007; Humphries 2008; Raymond 2004; Vieira 2009).

Repositioning can lead to disruption of sleep, particularly sleep fragmentation (Humphries 2008). In acutely ill people, disruption of sleep can lengthen recovery, suppress immune function and pre-dispose these people to infection (Carskadon 2005; Raymond 2004). A sleep cycle, which has light and deep stages of sleep, occurs about every 90 minutes. Consequently if repositioning is undertaken every two-hours, it may result in fragmentation of sleep at a detrimental stage of the sleep cycle (Dawson 2007).

Other negative effects of repositioning include possible increases in patient-pain perception. Although regular movement is important, unnecessary repositioning may cause increased discomfort for people with wounds, stiff joints, bony pain or contractures.

In addition to people experiencing the negative effects of repositioning, nurses experience musculoskeletal disorders at a rate exceeding that of workers in construction, mining, and manufacturing (Bureau of Labor Statistics 2002). These injuries are attributed partly to repeated manual patient handling activities, often associated with repositioning patients and working in extremely awkward postures (Bureau of Labor Statistics 2002; Vieira 2009). Back pain and injury have a major impact on the efficiency of the nursing workforce (Trinkoff 2001). Registered nurses rank seventh across all occupations for back injuries involving days away from work in private industry (Bureau of Labor Statistics 2002). Back injuries and resultant workers' compensation claims in nurses are expensive (Dawson 2007). For example, injuries in the healthcare sector cost Australia over AU\$4.3b in 2005 to 2006 (Australian Safety and Compensation Council 2009). Reducing the amount of manual handling undertaken by nurses when repositioning patients could have major nursing and hospital benefits.

Why it is important to do this review

PU's may be painful, distressing and life-threatening (causing infection, sepsis and even death), yet many are preventable (Allman 1997; Schuurman 2009). Manual repositioning regimens are used in PU risk-prevention programs to alternate areas of pressure distribution between the body and the bedding support surfaces, including when sitting in a chair or lying in a chair through manually altering posture of the body in a bed or shifting of weight in a chair (Manorama 2010). Both of these factors have major implications for repositioning hospitalised patients and warrant investigation.

Whilst the negative aspects of repositioning have been described, it is uncertain what evidence is available to support the efficacy of repositioning as an intervention or the relative efficacy of different repositioning schedules. Yet, repositioning has a good face value, and the rationale for its use is logical as it is reasonable to suggest that PU's occur because of prolonged exposure to externally applied mechanical forces. Thus, alleviating these forces should have a positive effect and should be balanced against possible negative effects. Nevertheless, the exact timing and mechanism for repositioning is unknown. International best practice guidelines currently recommend regular repositioning. However, it is noteworthy that, more recently, the National Pressure Ulcer Advisory Panel 2007 and the European Pressure Ulcer Advisory Panel 2009 Guidelines did not advocate two-hourly repositioning as best practice due to a lack of empirical evidence. Pressure injury prevention (PIP) is one of the most frequently applied healthcare interventions needing quality evidence on which to base clinical practice. The review results will be of interest to nursing and health administration professionals and the findings may have a significant impact on international health practice. Accordingly, a rigorous systematic review is required, to summarise current evidence for the effects of repositioning of adults, the optimal repositioning schedules and to ensure that future trials are based on the best available evidence.

OBJECTIVES

The objectives of this review are three-fold: first, to assess the effects of repositioning on the prevention of PU's in all adults, irrespective of risk, nursed in a hospital or long-term care setting; second, to ascertain the most effective repositioning schedules (i.e., timing of repositioning); and third, to ascertain the most effective positions for preventing PU's in adults, nursed in a hospital or long-term care setting. Specifically, this review addresses the following questions.

1. What is the most effective repositioning position for preventing PU's?
2. What is the most effective repositioning schedule for preventing PU's?
3. What are the incremental resource consequences and costs associated with implementing different repositioning regimens compared with alternate schedules or standard practice?

METHODS

Criteria for considering studies for this review

Types of studies

All trials using random allocation of individual adult patients in hospital or long-term care to two or more alternative interventions for PU prevention will be eligible (RCTs). We will also include cluster-randomised trials, irrespective of the cluster group (i.e., patient, nurse, hospital). Cross-over trials (even if randomised) and quasi-randomised studies, e.g., treatment allocation alternate or by date of birth, will be ineligible.

The critical review of health economic evidence will include comparative full and partial economic evaluations conducted within the framework of eligible RCTs (i.e. cost-effectiveness analyses, cost-utility analyses, cost-benefit analyses and cost-analyses of a repositioning intervention and a relevant comparator), as well as RCTs reporting more limited information, such as estimates of resource use or costs associated with repositioning and a comparator. The review will consider only health economics studies conducted alongside effectiveness studies included in the effectiveness component of the review.

Types of participants

Any adult admitted to any healthcare or long-term care setting, will be eligible.

Types of interventions

We anticipate that likely comparisons will include repositioning regimens compared with other standard practices or with alternative repositioning schedules. We will include studies evaluating the following comparisons.

- Comparisons between the frequencies of repositioning, for example two-hourly turning, three-hourly turning, four-hourly turning etc. where the only systematic difference between groups is the frequency of repositioning.
- Comparisons between different positions for repositioning, for example 30-degree recumbent tilt, 90-degree lateral rotation, where the only systematic difference between groups is the positioning.
- Comparisons of the repositioning regimen with standard practice (as defined by the author/s).

Types of outcome measures

Primary outcomes

The proportion of new PU of any grade, stage or category using previously defined criteria ([European Pressure Ulcer Advisory Panel 2009](#); [European Pressure Ulcer Advisory Panel 1998](#); [National Pressure Ulcer Advisory Panel 2007](#)) or however defined by the trial authors, anywhere on the body following recruitment into the study.

Secondary outcomes

- Health-related quality of life (HR QoL) (however reported by the authors)
- Procedural pain (however reported by the authors)
- Patient satisfaction (however reported by the authors).
- Cost (including: utility scores representing health-related quality of life; costs of PU prevention; costs of related health practitioner time or visits; costs avoided by PU prevention (e.g. treatment costs per patient per PU wound; costs to treat adverse events, infections or complications of PU; duration or costs of hospital stay for PU wound healing, adverse events and complications; indirect costs to society associated with PU such as lost productivity);
- Incremental cost per event avoided such as per additional PU prevented; incremental cost per life year gained; incremental cost per quality adjusted life year (QALY) and cost-benefit ratio).

Search methods for identification of studies

Electronic searches

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

- The Cochrane Wounds Group Specialised Register;
- The Cochrane Central Register of Controlled Trials (CENTRAL) (latest issue);
- Ovid MEDLINE (1948 to Current);
- Ovid MEDLINE (Current);
- Ovid EMBASE (1974 to Current);
- EBSCO CINAHL (1982 to Current)

We will search the Cochrane Central Register of Controlled Trials (CENTRAL) using the following exploded MeSH headings and keywords:

#1	MeSH descriptor Pressure Ulcer explode all trees
#2	pressure NEXT (ulcer* or sore*):ti,ab,kw
#3	decubitus NEXT (ulcer* or sore*):ti,ab,kw
#4	(bed NEXT sore*) or bedsore*:ti,ab,kw
#5	(#1 OR #2 OR #3 OR #4)
#6	MeSH descriptor Posture explode all trees
#7	(reposition* or re-position*):ti,ab,kw
#8	position*:ti,ab,kw
#9	(turn* NEAR/5 patient*):ti,ab,kw
#10	(turn* NEAR/5 interval*):ti,ab,kw
#11	(turn* NEAR/5 frequen*):ti,ab,kw
#12	(body NEAR/5 postur*):ti,ab,kw
#13	turning:ti,ab,kw
#14	(pressure NEXT relie*):ti,ab,kw
#15	(mobilis* or mobiliz*):ti,ab,kw
#16	(#6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15)

#17 (#5 AND #16).

We will adapt this strategy to search Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL. 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 and CINAHL searches with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN 2011).

We will conduct separate searches to identify economic studies in the following databases:

- NHS Economic Evaluation Database (*The Cochrane Library*) (latest issue);
- Ovid MEDLINE (1948 to Current); Ovid MEDLINE (Current);
- Ovid EMBASE (1974 to Current);
- EBSCO CINAHL (1982 to Current);
- EURONHEED (<http://infodoc.inserm.fr/euronheed/>);
- Health Economics Evaluations Database HEED (<http://onhttp://onlinelibrary.wiley.com/book/>).

We will use the economics search strategy shown in Appendix 1 to search Ovid MEDLINE and adapt this strategy to search other databases.

We will also search the following clinical trials registries for details of relevant protocols and contact the relevant research team:

- Clinical trials.gov.
- International Clinical Trials Registry Platform search Portal.
- Australian and New Zealand Clinical Trials Registry.
- Current Controlled Trials.

We will not restrict searches by time, language, study setting, date of publication or publication status. We will make every effort to obtain translations of papers not published in English.

Searching other resources

We will search the reference lists of included studies and any systematic reviews identified by the search process and contact corresponding authors of identified studies. We will attempt to contact experts in the field (e.g., council members of the European Wound Management Association, the National Pressure Ulcer Advisory Panel, the World Union of Wound Healing Societies, and the Australian Wound Management Association) to ask for information about any unpublished studies. We will include conference proceedings or programme abstracts in our search. However, if we are unable to obtain details of the full study after contacting the author(s), we will exclude these studies that are available only in abstract form.

Data collection and analysis

Selection of studies

Two review authors (BG, EM) will independently assess all titles and abstracts of studies retrieved from searching. Full reports of all potentially relevant trials will be retrieved for further assessment of eligibility based on the inclusion criteria. Differences of opinion will be resolved by consensus or referral to a third review author (WC). We will record reasons for exclusion. We will not blind study authorship.

Data extraction and management

For eligible studies, two of the five review authors (BG, EM) will independently extract data using a pre-designed data collection tool while a third review author (WC) will adjudicate where there are differences of opinion. For studies where there is an economic component included, JW (Health Economist) will extract the relevant data. We will include studies published in duplicate but maximally extract data and identify the primary reference for the purpose of this review. If data are missing from reports, we will attempt to contact the trial authors to obtain the missing information. One review author (BG) will enter the data into Review Manager software (RevMan 5.1) and data will be checked for accuracy by other review authors. Abstracted data will include the following information.

- Author, title, journal title, year of publication, country.
- Healthcare setting.
- Inclusion/exclusion criteria.
- Sample size.
- Patient characteristics by treatment group.
- Methods (number eligible and randomised, adequacy of randomisation, allocation concealment, blinding, completeness of follow-up).
- Treatment of missing values (e.g., use of intention-to-treat, per protocol or other imputation method).
- Intervention details.
- Types of outcome measures in relation to primary (location and stage of PU) and secondary outcomes.
- Analysis; results and conclusions relevant to review.
- Funding sources.

For economic studies, additional data extracted will include the following.

- Estimates of specific items of resource use per person.
- Estimates of unit costs (extracted separately to resource use).
- Price year and currency.
- Decision-making jurisdiction.
- Analytic perspective.
- Both a point estimate and a measure of uncertainty (e.g. standard error or confidence interval) for measures of incremental resource use, costs and cost-effectiveness, if reported.
- Details of any sensitivity analyses undertaken, and any information regarding the impact of varying assumptions on the magnitude and direction of results.

Assessment of risk of bias in included studies

Two of the five review authors will independently assess the quality of eligible trials (BG, EM) using The Cochrane Collaboration tool for assessing risk of bias (Higgins 2011b). This tool addresses six specific domains; namely sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other issues which may potentially bias the study (see Appendix 2 for details of the criteria on which the judgment will be based). Items will be rated as low risk of bias, high risk of bias or unclear (unknown) risk of bias. In assessing bias, the review authors will not be blinded to the names of trial authors, institutions, or journal.

In assessing the risk of bias, we will distinguish between primary subjective outcomes (proportion of new PU and patient satisfaction), and secondary subjective outcomes (HR-QoL, procedural pain), and the objective outcome (economic). As the primary outcomes for this review, however measured, are subject to potential observer/measurement biases; allocation concealment, blinding of outcome assessment, and incomplete outcomes data are important. Similarly we will make separate judgements for secondary outcomes for the domain of incomplete outcome data. We will classify trials as being at overall high risk of bias if they are rated as 'high' for any one of three key domains (allocation concealment, blinding of outcome assessors and completeness of outcome data). Where there is a high risk of bias in any of these key domains, we will endeavour to contact the trial authors, asking open-ended questions about the design and conduct of the study.

Disagreements between review authors will be resolved by consensus or referral to another review author (WC). We will contact investigators of included trials to resolve any ambiguities. We will report bias, and within economic evaluations, use the Drummond checklist as recommended by The Cochrane Collaboration (Shemilt 2011) to assess the methodological quality of full and partial economic evaluations.

We will present assessment of risk of bias a 'Risk of bias' summary figure, which presents all the judgments in a cross-tabulation of study by entry. If sufficient studies are identified, we will assess reporting bias using forest plots.

Measures of treatment effect

Where possible, we will report the outcomes of each trial using 95% confidence intervals (CI). We will report estimates for dichotomous outcomes (e.g., PU developed during time period) as risk ratio (RR). We will use the RR rather than odds ratio (OR), since ORs (may be misinterpreted as RR) and can give an inflated impression of the effect size when event rates are greater than 20% (Deeks 2002). For individual trials, we will extract the numbers with an event for each treatment group and use them to calculate the RR with its 95% CI. RR is the PU incidence rate in the experimental group divided by the incidence rate in the control group and indicates the likelihood of pressure ulcer development

on a turning regimen compared with a standard treatment. We will report continuous data (e.g. pain) as mean difference (MD) and overall effect size (with 95% CI) will be calculated. We will use MD as a summary statistic in meta-analysis when outcome measurements in all studies are made on the same scale. Standardised mean difference (SMD) will be used as a summary statistic in meta-analysis when the studies all assess the same outcome but measure it in a variety of ways.

Review of economic evaluations

We will present a tabled analysis of the identified economic data in accordance with current guidance on the use of economics methods in the preparation of Cochrane reviews (Shemilt 2011). We will classify economic evaluations according to the framework in Drummond 2005, and assess the methodology using the checklist published by Drummond and colleagues. We will tabulate the main characteristics and results of the identified economic evaluation studies and expand these with a narrative description. This will discuss the methods used and compare the key results of those studies.

The results of economic evaluations will likely vary according to the particular circumstances of each study. For instance, the comparator treatment, such as standard care, may differ for different groups of people and in different settings. Given the likely lack of direct comparability in resource use and cost data between different healthcare contexts and settings, caution is advised in pooling economic outcomes, and it is not our intention to pool the economic data. Our review will place the results of the economic studies in context and will entail a discussion of key drivers and impact of assumptions on the available economic evaluations, scenarios that are likely to lead to the most and least cost-effective use of repositioning for pressure ulcer prevention, as well as guidance on future research that might be required to assess the economic value of repositioning as an intervention for PU prevention.

Costs

All substantial costs that are observed to differ between people repositioned for pressure ulcer prevention and people administered standard care are intended to be captured and reported as part of the review of economic evaluations.

We will report resource utilisation and unit costs separately, along with the currency and price year in each original study. These costs will then be converted to 2011 values by employing a web-based conversion tool that applies implicit price deflators for GDP (gross domestic product) of that currency and then converted into the currency most frequently observed in the articles reviewed using GDP Purchasing Power Parities (Shemilt 2010). This will allow readers of the review to make meaningful comparisons between costs in studies that may have been conducted in different countries and at different times.

The main costs are likely to be those associated with the development of PUs, specialist and other practitioner costs as measured by time or number of visits, potential cost-savings from a change in the number of bed days in hospital, and costs stemming from differing rates of adverse events and complications (including procedures initiated due to the failure of wounds to heal, such as amputation). The key cost drivers will be identified from the studies included. This will enable users of the review to gain a clear understanding of the nature of resource use associated with repositioning for PU prevention.

Health state utility weights

We will examine information on the change in health-related quality of life (HR-QoL) reported by included trials via utilities measured by a multi-attribute utility instrument (MAUI) or other approaches (such as the time trade-off, standard gamble). The utility data will need to be assessed for comparability and representativeness considering issues such as the stages of PU, the patient populations, timing of the baseline point and follow-up collection, the MAUI used and the algorithm for scoring the MAUI. Discussion of the potential impact on HR-QoL attributable to the intervention will be presented as part of the review.

Unit of analysis issues

In all trials included in our review, the person will be the unit of analysis and we will take into account the level at which randomisation occurred. The number of observations will match up with the number of 'units' (people) who are randomised. For a parallel group design, we will collect and analyse a single measurement from each outcome from each person. In these types of studies, it is possible that the unit of analysis may be the pressure injury rather than the individual person. In trials where the unit of analysis is the PU and not the person or group, we will exclude the study. We will consider where there are multiple observations on the same outcome. Where this occurs we will first use the PU that is the most advanced in relation to its staging. If this is cannot be determined, then we will contact the trial author(s). For cluster-randomised trials, we will adjust sample sizes using methods as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011) using an estimate of the intra-cluster correlation coefficient (ICC) derived from the trial if possible, or from a similar trial. Therefore, for cluster-RCTs that are included, the person will be adjusted for in the cluster as the unit of analysis.

Dealing with missing data

If some outcome data remain missing despite our attempts to obtain complete outcome data from authors, we will perform an available-case analysis, based on the numbers of people for whom outcome data are known. We will also conduct best-case and worst-case analysis. If standard deviations (SD) are missing, we will impute them from other studies or, where possible, compute them

from standard errors (SE) using the formula $SD = SE \times \sqrt{N}$, where these are available (Higgins 2011c).

Assessment of heterogeneity

We will consider clinical and statistical heterogeneity in relation to the primary outcomes, PU incidence and patient satisfaction, and secondary outcomes such as HR-QoL and procedural pain. For cluster-trials, we will assess the outcome at the same level as the group allocation (Deeks 2011).

We will assess clinical heterogeneity by examining the types of participants and/or groups, interventions and their duration, and the outcomes of each study. If appropriate, we will pool data using meta-analysis (using RevMan 5.1). We will not pool studies for economic outcomes as the variability in, and generalisability of, these outcomes are considered problematic.

Statistical heterogeneity will be assessed visually and by using the χ^2 statistic with significance being set at $P < 0.10$. In addition, we will investigate the degree of heterogeneity by calculating the I^2 statistic (Deeks 2002). The I^2 test examines the percentage of total variation across studies due to heterogeneity rather than by chance. Values over 50% indicate a substantial level of heterogeneity. In the absence of clinical heterogeneity and in the presence of statistical heterogeneity ($I^2 > 50\%$), we plan to use a random-effects model. If there were sufficiently similar studies to consider pooling, we plan to use a fixed-effect model for low to moderate levels of heterogeneity (I^2 0% to 50%). However, we will not pool studies where heterogeneity exceeds 75% (Higgins 2011a).

Assessment of reporting biases

If 10 or more studies of varying size are included, we will assess reporting potential publication bias via funnel plots and visually assess funnel plot asymmetry (Sterne 2011).

If appropriate, we will also use a linear regression approach to measure funnel plot asymmetry or the natural logarithm scale of the OR.

Data synthesis

The method of synthesising the studies will depend on the quality, design, and degree of heterogeneity of studies identified. If there is high variability in the clinical characteristics, methodology, treatment effect or statistical heterogeneity, it may be inappropriate to perform a meta-analysis. Where studies are clinically similar and the outcome measures comparable, we will pool the results using a fixed-effect model and report the pooled estimate together with its 95% CI (Deeks 2011). If there is heterogeneity in either the intervention or comparison group, we will exclude the inconsistent controls and only include those controls where there is consistency across the intervention. In the absence of heterogeneity, we will pool studies with similar comparisons using a fixed-effect model. For statistically significant effects, we will calculate number needed to treat to benefit (NNTB) or number needed to treat to harm

(NNTH) from the risk difference (RD) where appropriate (Deeks 2011). For continuous outcomes, we will extract the mean and SD and calculate the MD. If the scale of measurement differs across trials, we will calculate the SMD with its 95% CI. For cluster-randomised trials, if possible, we will extract the number of clusters randomised to each group or the mean size of each cluster, or both; an estimate of the intra-class correlation coefficient (ICC); and the outcome data disregarding the cluster design (i.e. proportion of individuals who develop a PU during the study period). We will combine studies using a narrative overview of eligible studies where statistical synthesis of data from more than one study is not possible or considered appropriate. We will also comment on the clinical relevance where appropriate.

Subgroup analysis and investigation of heterogeneity

In undertaking subgroup analyses, we will consider the effects of prognostic and effect modifier factors. We will analyse potential sources of heterogeneity using the following subgroup analyses:

1. Type of patient (paralysis, bariatric, surgical, geriatric).
2. Type of setting (acute care, long-term care).

Sensitivity analysis

We will perform sensitivity analyses to assess whether the findings are robust to the method used to obtain them (Higgins 2011c). To address this, we will compare the results of two or more meta-analyses using different assumptions. For instance, where appropriate data are available, we will make the following comparisons:

1. If a study was excluded from a meta-analysis because it was deemed to be different either on the basis of methodological or statistical heterogeneity, its influence will be assessed in a meta-analysis and then assessed by excluding it.

2. Trials that are deemed to be most susceptible to bias (based on quality rating of 'high' and 'unclear') will be excluded in the initial meta-analysis.

Presentation of results

We will present the main results of the review in summary of findings tables, which provide key information concerning the quality of evidence, the magnitude of effect of the interventions examined, and the sum of available data on the main outcomes, as recommended by the Cochrane Collaboration (Schünemann 2011a). We plan to include the following main outcomes (both desirable and undesirable) in the summary of findings tables:

- development of a new PU
- HR-QoL
- pain
- costs
- incremental costs.

The summary of findings table includes an overall grading of the evidence related to each of the main outcomes, using the GRADE approach (Schünemann 2011b).

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* Indicates the major publication for the study

APPENDICES

Appendix I. Ovid MEDLINE Economics Search Strategy

- 1 exp Pressure Ulcer/
- 2 (pressure adj (ulcer* or sore*)).tw.
- 3 (decubitus adj (ulcer* or sore*)).tw.
- 4 (bedsore* or (bed adj sore*)).tw.
- 5 or/1-4
- 6 exp Posture/
- 7 (reposition* or re-position*).tw.
- 8 position*.tw.
- 9 (turn* adj5 patient*).tw.
- 10 (turn* adj5 interval*).tw.
- 11 (turn* adj5 frequen*).tw.
- 12 turning.tw.
- 13 (body adj5 posture*).tw.
- 14 pressure relie*.tw.
- 15 (mobilis* or mobiliz*).tw.
- 16 or/6-15
- 17 5 and 16
- 18 economics/
- 19 exp “costs and cost analysis”/
- 20 economics, dental/
- 21 exp “economics, hospital”/
- 22 economics, medical/
- 23 economics, nursing/
- 24 economics, pharmaceutical/
- 25 (economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic*).ti,ab.
- 26 (expenditure* not energy).ti,ab.
- 27 value for money.ti,ab.
- 28 budget*.ti,ab.
- 29 or/18-28
- 30 ((energy or oxygen) adj cost).ti,ab.
- 31 (metabolic adj cost).ti,ab.
- 32 ((energy or oxygen) adj expenditure).ti,ab.
- 33 or/30-32
- 34 29 not 33

35 letter.pt.
36 editorial.pt.
37 historical article.pt.
38 or/35-37
39 34 not 38
40 Animals/
41 Humans/
42 40 not (40 and 41)
43 39 not 42
44 17 and 43

Appendix 2. Risk of bias criteria

1. Was the allocation sequence adequately 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 judgment 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 (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

Insufficient information to permit judgment 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 judgment, 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 unlikely to introduce bias.

High risk of bias

- Any one of the following.
- No blinding or incomplete blinding, and the outcome or outcome measurement is 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

Any one of the following.

- Insufficient information 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 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 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 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

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.

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

Low risk of bias

Any of the following.

- The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
- The study protocol is not available but it is clear that the published reports include 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 have been reported.
- One or more primary outcomes are 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 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 to permit judgment 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
- 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.

HISTORY

Protocol first published: Issue 7, 2012

CONTRIBUTIONS OF AUTHORS

Wendy Chaboyer conceived the review question, co-ordinated and contributed to protocol development, and performed part of the writing or editing of the protocol.

Brigid Gillespie completed the first draft of the protocol, contributed to protocol development, and approved the final version prior to submission.

Elizabeth McInnes performed part of the writing or editing of the protocol, made an intellectual contribution, and approved the final version of the protocol prior to submission.

Bridie Kent made an intellectual contribution to the protocol and approved the final version prior to submission.

Jennifer Whitty made an intellectual contribution to the protocol and approved the final version prior to submission.

Contributions of editorial base:

Nicky Cullum: edited the protocol; advised on methodology, interpretation and protocol content. Approved the final protocol prior to submission.

Sally Bell-Syer: coordinated the editorial process. Advised on methodology, interpretation and content. Edited and copy edited the protocol.

Ruth Foxlee: designed the search strategy and edited the search methods section.

DECLARATIONS OF INTEREST

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