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Bed rest for pressure ulcer healing in wheelchair users

Review

Intervention

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Abstract

English

Background

Pressure ulcers, which are localised injury to the skin or underlying tissue, or both, occur when people are unable to reposition themselves to relieve pressure on bony prominences. Pressure ulcers are often difficult to heal, painful, and impact negatively on the individual's quality of life. International guidelines suggest bed rest as a component of the treatment strategy to manage pressure ulcers among wheelchair users. The potential benefits and risks need to be considered when assessing the effectiveness of bed rest as an intervention for treating pressure ulcers in this population. Therefore, it was important to search and appraise existing research evidence in order to determine the impact of bed rest on the healing of pressure ulcers in wheelchair users.

Objectives

To assess the impact of bed rest on pressure ulcer healing, in wheelchair users, of any age, who are living or being cared for in any setting.

Search methods

In October 2016 we searched: the Cochrane Wounds Specialised Register; the Cochrane Central Register of Controlled Trials (CENTRAL) (the Cochrane Library); Ovid MEDLINE (including In-Process & Other Non-Indexed Citations, MEDLINE Daily and Epub Ahead of Print); Ovid EMBASE and EBSCO CINAHL Plus. We also searched clinical trials registries and conference proceedings and for ongoing and unpublished studies. There were no restrictions with respect to language, date of publication or study setting.

Selection criteria

We considered randomised controlled trials (RCTs) and cluster-RCTs that evaluated the impact of bed rest on healing pressure ulcers in wheelchair users.

Data collection and analysis

Two review authors independently assessed titles and abstracts of the studies identified by the search strategy for their eligibility.

Main results

We identified no studies that met the inclusion criteria.

Authors' conclusions

We set out to evaluate the research evidence, from randomised controlled trials, of the impact of bed rest on pressure ulcer healing in wheelchair users. No study met the inclusion criteria. It is uncertain whether bed rest makes a difference to the healing of pressure ulcers in wheelchair users. Well-designed trials addressing important clinical, quality of life and economic outcomes are required.

Plain language summary

English

Bed rest for treating pressure ulcers (bed sores) among wheelchair users

Background

Pressure ulcers (also known as bed sores) are wounds that occur on the skin or underlying tissues as a result of unrelieved pressure on bony, weight-bearing points of the body, such as the hips, heels or lower back. People at risk include those with reduced mobility. Wheelchair users are therefore at risk because they remain seated for long periods. Pressure ulcers can be difficult to heal and are prone to infection and other complications. When these wounds occur among wheelchair users, bed rest is considered important to relieve pressure on part of the body that bear weight in a seated position. This change from a sitting to a lying position is thought to improve wound healing.

Review question

We wanted to discover the impact of bed rest on the healing of pressure ulcers among people confined to a wheelchair. Eligible studies could involve wheelchair users of any age with a pressure ulcer in any setting (hospital, nursing home, person's own home etc).

What we found

In October 2016 we searched widely through the medical literature for randomised controlled trials comparing bed rest with no bed rest for the healing of pressure ulcers in wheelchair users. We did not find any trials that had been conducted in this area. This means that we cannot say whether bed rest improves the healing of pressure ulcers in wheelchair users, or what the harms and benefits of this treatment might be. Trials are needed that compare pressure ulcer healing with and without bed rest among wheelchair users.

This plain language summary is up-to-date as of October 2016.

Background

Description of the condition

A pressure ulcer is defined as a "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. A number of contributing or confounding factors are also associated with pressure ulcers; the primary of which is impaired mobility" (NPUAP 2014). Pressure is the amount of force acting on a unit of area (O'Callaghan 2007). Shear forces occur in soft tissue when these tissues are stretched, which happens when the bony structures move but the skin is stationary (Sanders 2005). Pressure ulcers commonly occur in individuals who have reduced activity and/or mobility and so are exposed to prolonged periods of exposure to sustained pressure/shear forces (Gefen 2008). Elderly with reduced activity/mobility, people with spinal cord injury and those who are sedated following trauma or surgery are at increased risk of pressure ulcer development (Moore 2011; Moore 2014), however, potentially any person of any age could develop a pressure ulcer if he/she were exposed to the causative factors, that is, sustained unrelieved pressure and shear (McLane 2004).

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

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

Category/Stage II - partial thickness: "Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough [dead tissue]. May also present as an intact or open/ruptured serum-filled or sero-sanguinous [serum and blood] filled blister. Presents as a shiny or dry shallow ulcer without slough or bruising [bruising indicates deep tissue injury]. This category should not be used to describe skin tears, tape

burns, incontinence associated dermatitis, maceration [damage through the skin being wet] or excoriation [damage through scratching/abrasion or burns]."

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

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

The World Health Organization suggests that the wheelchair is one of the most commonly used assistive devices for enhancing personal mobility (WHO 2010). It is estimated that 10% of the global population - almost 650 million people - have disabilities and 10% of these individuals require the use of a wheelchair (WHO 2010). When a person is seated, body weight is loaded onto a relatively small surface area, namely the ischial tuberosities (the sitting bones), the buttocks, coccyx and upper thighs (Stockton 2002). When sitting the weight of the individual is forced against the supporting seat surface which compresses the soft tissues and increases the risk of pressure ulceration. Regular repositioning, every 15 to 30 minutes, is recommended for people confined to wheelchairs (Schofield 2013). However, protracted periods of time spent without relieving pressure on the weight bearing areas is a common problem for wheelchair users. In one study of community-dwelling wheelchair users the most frequently reported continuous sitting time was 12 hours (Stockton 2002). A further study identified that the majority of individuals confined to wheelchairs did not adhere to recommended repositioning practices, even when they had the ability to reposition themselves independently (Schofield 2013).

Stockton 2002 identified a point prevalence of pressure ulcers of 58% (stage I and above) among 136 community-dwelling wheelchair users in the UK. Another study, among 50 people with acute spinal cord injury, found a prevalence of 37% (stage I and above) (Sheerin 2011). In another study undertaken between 1986 and 2002, 27% of 3361 people with spinal cord injury had one or more episodes of pressure ulcers of stage II or above (Chen 2005). Furthermore, the prevalence of pressure ulcers significantly increased with time post injury (11.5% at year 1 rising to 21% at year 15; Chen 2005). More recently, Lala 2014 reported that 33.5% of a cohort of 1137 people with spinal cord injury developed a pressure ulcer within the first year of injury. Brienza 2010 identified an incidence of 17.6% - specifically referred to as sitting pressure ulcers - among elderly wheelchair users cared for within a nursing home setting, occurring over the ischial tuberosities or the sacral/coccyx region (stage I or above). In Africa, a study conducted at the National Spinal Injury Hospital Kenya noted a pressure

ulcer prevalence of 68% (Nangole 2009), while in a study in Thailand among wheelchair users with chronic spinal cord injuries, pressure ulcer prevalence was 26.4% (Kovindha 2015). An overall incidence of 39.2% was identified among 5995 people with spinal cord injury in Iran (Tagipoor 2009), and in Brazil 47 people within the same population showed an overall incidence of 42.5% (Nogueira 2006).

Pressure ulcers have a large impact on those affected; the ulcers can be painful, and may become seriously infected or malodorous. It has been shown that after adjustment for age, sex and co-morbidities, people with pressure ulcers have a lower health-related quality of life than those without pressure ulcers (Spilsbury 2007; Essex 2009). More specifically, when people with both spinal cord injury and pressure ulcers are compared with similar people without pressure ulcers, those with pressure ulcers had significantly lower scores (worse health status) on all SF-36 sub scales (Lourenco 2014). The number of pressure ulcers also influences the individual's health-related quality of life; for example in one study in Canada, 10% of people with one or two pressure ulcers and 16% of individuals with three or more pressure ulcers reported their quality of life as being 'very bad' or 'bad' compared with only 6.9% of individuals without pressure ulcers (Lala 2014).

In an economically constrained health service, revenue spent on pressure ulcers is a concern, as it is suggested that many pressure ulcers can be avoided with appropriate risk assessment and use of interventions targeted at combating this risk (Moore 2014). However, despite this premise, it is estimated, in the UK, that approximately 4% of the annual healthcare budget is being spent on pressure ulcers, with nursing time accounting for 41% of these costs (Posnett 2009). Pressure ulcers have been shown to increase length of hospital stay, readmission and mortality rates (Lyder 2012), and add considerably to the cost of an episode of hospital care (Chan 2013). Figures from the USA suggest that in 2006 half a million hospital stays noted 'pressure ulcer' as a diagnosis; for adults, the total hospital costs of these stays was USD 11 billion (Russo 2008). Costs to the Australian healthcare system for treating pressure ulcers have been estimated at AUD 285 million per annum (Graves 2005). Specifically, for those with a spinal cord injury coupled with a pressure ulcer cared for within a community care setting in Canada, the added cost is approximately CAD 4800 a month or almost CAD 57,000 annually (Chan 2013).

Description of the intervention

The 2014 pressure ulcer prevention and management guidelines recommend periods of bed rest to promote ulcer healing if a pressure ulcer is located on area of the body that bears weight during sitting, such as the ischial or sacral area (NPUAP 2014). This involves confining the individual to bed for varying periods of time, and restricting his/her normal activities either partially or completely. This can be devastating for the person, whose participation in usual daily activities will be restricted if he/she is unable to spend a normal amount of time sitting (Norton 2004). However, sometimes the use of bed rest as part of the management plan is seen as unavoidable due to the extensive nature of these pressure ulcers.

How the intervention might work

Wound healing is a normal response to injury. It is initiated after the skin's integrity has been interrupted, for example, by the development of a pressure ulcer (Martin 1997). The

purpose of the healing process is to replace the tissue that has been damaged with living tissue, and to restore the continuity of the skin (Tarnuzzer 1996). Open wounds, including pressure ulcers, heal through formation of granulation tissue and epithelialisation (Slavin 1996). Granulation tissue is characterised by a high density of blood vessels, capillaries and many different types of cells, so the metabolic need of the wounded area is great (Krishnamoorthy 2001). Normal cellular metabolism requires an adequate supply of oxygen and nutrients, and also an effective elimination of waste metabolites (Tarnuzzer 1996). Pressure and shear cause cell deformation, impede normal osmosis and diffusion, and alter tissue perfusion (the process through which a body delivers blood to capillary beds). Therefore when an individual actually develops a pressure ulcer he/she should not bear weight on the affected area, as perfusion is central to cell repair (Tarnuzzer 1996). This is why bed rest is thought to be advantageous, in that it allows for the individual to offload pressure/shear from the affected area, and so increase perfusion of the wound bed with the aim of enhancing wound healing potential in that area.

It is important to note that there might also be other adverse issues associated with bed rest - it can represent a large lifestyle change for patients and may have a psychological impact. Long periods of bed rest may increase the risk of chest infections, as well as cause muscular degeneration, which can require a long recovery period (Norton 2004). Bed rest can also cause what is known as deconditioning of the body (Stuempfle 2007); deconditioning is defined as the loss of muscle tone and endurance due to chronic disease, immobility, or loss of function and is thought to affect all of the organs of the body. This is caused by a number of mechanisms, including a reduced hydrostatic pressure gradient within the cardiovascular system, unloading of forces on skeletal muscles and bones, and reduced total energy expenditure (Stuempfle 2007). Bed rest has a negative economic impact on the person and his/her dependents due to making work impossible. This inability to work can result in a loss of the work habit, and reduce the likelihood of the person eventually returning to work (Andersson 1989). Therefore, the potential benefits and risks need to be considered when assessing the effectiveness of bed rest as an intervention for treating pressure ulcers in wheelchair users.

Why it is important to do this review

Pressure ulcers commonly occur amongst wheelchair users, therefore identification of strategies which reduce recovery time is important (Moore 2014). Bed rest may or may not be an effective treatment for pressure ulcers in wheelchair users; the balance of benefits and risks associated with bed rest must be assessed systematically. Although there have been many reports of bed rest as a modality for pressure ulcer management, many of these reports appear to have been underpinned by anecdotal evidence, or have been subjected to little critical scrutiny (NPUAP 2014), so overall, the precise impact of bed rest is unclear. Therefore, it was important to search and appraise the literature systematically in order to determine the impact of bed rest on the management of pressure ulcers in wheelchair users.

Objectives

To assess the impact of bed rest on pressure ulcer healing in wheelchair users, of any age, who are living or being cared for in any setting.

Methods

Criteria for considering studies for this review

Types of studies

Published and unpublished randomised controlled trials (RCTs), including cluster-RCTs were eligible for inclusion, irrespective of language of report. Cross-over trials were eligible if outcome data were available from the end of the first treatment period prior to cross-over. Studies using quasi-randomisation were to be excluded.

Types of participants

People of any age, in any setting (hospitals, nursing homes, residential care, rehabilitation centres, living at home) who are wheelchair users and have an existing pressure ulcer (of any stage), were eligible for inclusion.

Types of interventions

The intervention of interest was bed rest (as defined by study authors, but should have involved a period of non-seated time, so may have included complete bed rest or periodic bed rest, or both) used for the treatment of pressure ulcers in wheelchair users. The comparison was to be normal sitting behaviour or another control intervention.

Types of outcome measures

Primary outcomes

We list primary and secondary outcomes below. If a study was otherwise eligible (i.e. correct study design, population and intervention/comparator) but did not report a listed outcome then we planned to contact the study authors, where possible, to establish whether an outcome of interest to the review was measured but not reported.

We planned to 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). For all outcomes we planned to categorise outcomes as follows:

- SHORT TERM: those occurring before eight weeks;
- MEDIUM TERM; those occurring between eight and 26 weeks; and
- LONG TERM: those occurring after 26 weeks.

The primary outcomes for this review were complete wound healing and adverse events.

Complete wound healing

For this review we regarded the following as providing the most relevant and rigorous measures of outcome:

- time to complete wound healing: we planned to record whether this has been correctly analysed using censored data and with adjustment for prognostic covariates such as baseline size;
- the proportion of ulcers healed (frequency of complete healing).

Where both the outcomes above were reported we planned to present all data in a summary outcome table for reference. Where equal amounts of information were available we anticipated focusing on time to healing as the key outcome measure. We planned to accept authors' definitions of what constituted a healed wound.

Adverse events (specified as important by our consumer advisors)

- Incidence of a new pressure ulcer;
- Incidence of chest infection;
- Reports of muscle deterioration;
- Time to recovery following period of bed rest.

Secondary outcomes

- Mean pain scores (measured at any time with any validated instrument e.g. Visual Analogue Scale).
- Mean health-related quality of life (using any validated measure such WHOQOL-BREF, SF-36, SF-12).
- Cost (including resources associated with the team and those associated with dressings and other additional interventions, where reported).
- Adverse events (generic). Reported data were to be extracted on adverse events classed as 'serious adverse events' and 'non-serious adverse events' where a clear methodology for the collection of adverse event data was provided. This methodology would have been needed to make it clear whether events were reported at the participant level or, where multiple events/person were reported, that an appropriate adjustment had been made for data clustering. Individual types of adverse events such as pain or infection that required specific assessment were not planned to be extracted under this outcome - rather this was to be the assessment of any event classed as adverse by the patient and or health professional during the trial.

Search methods for identification of studies

Electronic searches

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

- The Cochrane Wounds Specialised Register (searched 10 October 2016);
- The Cochrane Central Register of Controlled Trials (CENTRAL) *(The Cochrane Library)* (2016, Issue 9);
- Ovid MEDLINE (including In-Process & Other Non-Indexed Citations, MEDLINE Daily and Epub Ahead of Print) (1946 to 10 October 2016);
- Ovid EMBASE (1974 to 10 October 2016);
- EBSCO CINAHL Plus (1937 to 10 October 2016).

The search strategies for CENTRAL, Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL Plus can be found in Appendix 1. We combined the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version (2008 revision) (**Lefebvre 2011**). We combined the EMBASE search with the Ovid EMBASE filter developed by the UK Cochrane Centre (**Lefebvre 2011**). We combined the CINAHL searches with the trial filters developed by the Scottish Intercollegiate Guidelines Network (**SIGN 2015**). We did not restrict studies with respect to language, date of publication or study setting.

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

- Clinical Trials.gov (www.clinicaltrials.gov) (searched 11th October 2016);
- WHO International Clinical Trials Registry Platform (ICTRP) apps.who.int/trialsearch/Default.aspx) (searched 11th October 2016);
- The EU Clinical Trials Register (www.clinicaltrialsregister.eu) (searched 11th October 2016).

Searching other resources

We planned to search reference lists of all included studies. We searched other relevant publications, such as systematic reviews and guidelines. We contacted experts in the field and planned to contact the authors of relevant publications to identify any completed or ongoing trials. We also performed manual searches of conference proceedings, namely the National Pressure Ulcer Advisory Panel Conference, USA; the European Pressure Ulcer Advisory Panel meeting; the Pan Pacific Pressure Injury Alliance meeting; and the World Union of Wound Healing Societies meeting, to identify authors and papers related primarily to bed rest for the treatment of pressure ulcers.

Data collection and analysis

We performed this systematic review according to instructions in the *Cochrane Handbook for Systematic Reviews of Interventions* (**Green 2011**).

Selection of studies

Two review authors (ZM and MvE) independently assessed the titles and abstracts of the citations retrieved by the searches for relevance. After this initial assessment, we planned to

obtain full text copies of all studies felt to be potentially relevant. Independently, two review authors planned to check the full papers for eligibility; disagreements were to be resolved by discussion and, where required, the input of a third review author. We planned to record all reasons for the exclusion of studies for which we had obtained full copies. We completed a PRISMA flowchart to summarize this process (Liberati 2009).

Where studies were reported multiple times we planned to obtain all publications. Whilst the study would have been included only once in the review, we planned to extract data from all reports to ensure we obtained the maximal amount of relevant data.

Data extraction and management

We planned to extract and summarize details of the eligible studies. Two review authors were to extract data independently and resolve disagreements by discussion, drawing on a third review author where required. Where data were missing from reports, we planned to attempt to contact the study authors to obtain this information. Where a study with more than two intervention arms would have been included, only data from intervention and control groups that meet the eligibility criteria were to be extracted.

We planned to extract the following data, where possible by treatment group, for the prespecified interventions and outcomes in this review using a data extraction sheet developed for this purpose:

- author, title, source;
- date of study, country of origin;
- care setting;
- inclusion and exclusion criteria;
- baseline participant characteristics (ulcer grade and size);
- number of participants randomised to each arm;
- study design details;
- risk of bias;
- intervention details (specifically team composition and focus of the intervention), concurrent intervention(s);
- type of surface the person was lying on;
- 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.

One review author (ZM) was to enter data into Review Manager 5 (RevMan 5) 5.3 software (RevMan 2014), with a second author (MvE) verifying accuracy.

Assessment of risk of bias in included studies

Two review authors (ZM and MvE) planned to use the Cochrane 'Risk of bias' tool to independently assess the risk of bias of the included studies (Higgins 2011a). This tool addresses six specific domains, namely: sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other issues (e.g. extreme baseline imbalance, which might inform decisions about selection bias). Appendix 2 contains details of the criteria on which this assessment was to be based. We were to assess blinding and completeness of outcome data for each outcome separately (for example, blinding is important for subjective outcomes such as pressure ulcer healing and pain). We planned to present our assessment of risk of bias using a 'Risk of bias' summary figure that shows a summary of all of the 'Risk of bias' items. For studies using cluster randomisation, we were also to assess the following domains for risk of bias: recruitment bias, baseline imbalance, loss of clusters, incorrect analysis and comparability with individually randomised trials (Higgins 2011b).

Measures of treatment effect

For dichotomous outcomes (e.g. proportion of participants with a pressure ulcer healed) we planned to calculate the risk ratio (RR) with 95% confidence intervals (CI). For continuously distributed outcome data (e.g. pain), when all trials used the same assessment scale we planned to use the mean difference (MD) with 95% CIs. If trials used different assessment scales, we planned to use the standardised mean difference (SMD) with 95% CIs. We planned to report time-to-event data (e.g. time to complete wound healing) as hazard ratios (HR) where possible, in accordance with the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011). For statistically significant effects in binary outcomes we planned to calculate number needed to treat for an additional beneficial outcome (NNTB), or number needed to treat for an additional harmful outcome (NNTH). Where skewness was suspected, and if scale data had finite upper and lower limits, we planned to use the easy 'rule of thumb' calculation to test for skewness. That is, if the standard deviation (SD), when doubled, was greater than the mean, it would be unlikely that the mean was the centre of the distribution (Altman 1996), and we planned not to enter the data into any meta-analysis. If we found relevant data that were skewed, we planned to present the data in 'Other data' tables.

Unit of analysis issues

Where studies were randomised at the participant level and measured outcomes at the wound level, for example for wound healing, and the number of wounds appeared to be equal to the number of participants, we planned to treat the participant as the unit of analysis. We anticipated a possible unit of analysis issue if individual participants with multiple wounds were randomised, the allocated treatment implemented and then data presented and analysed by wound not person. This is a type of clustered data and presents a unit of analysis error that inflates precision. In cases where included studies contained some or all clustered data we planned to report this alongside whether data had been (incorrectly)

treated as being independent. We planned to record this as part of the 'Risk of bias' assessment. We did not plan to undertake further calculation to adjust for clustering in these cases.

Dealing with missing data

Where possible, we planned to perform all analyses using the intention-to-treat (ITT) principle, that is, all randomised participants should have been analysed according to their allocated treatment group. Where it appeared that data were excluded from the analyses, we planned to contact authors for these missing data. If data remained missing, despite our best efforts to obtain them, we planned to assume that those missing from the analysis of dichotomous data had a negative outcome (e.g. did not heal completely). For continuous data, if standard deviations were missing, where possible, we planned to compute them from standard errors (SE) using the formula SD = SE x √N (**Higgins 2011c**). If this were not possible, and trial authors were not able to provide data, we would have been unable to present these data. Where results were reported for all participants, but it was unclear how many people were originally randomised, we planned to use an available-case analysis.

Assessment of heterogeneity

Assessment of heterogeneity can be a complex, multi-faceted process. Firstly, we planned to consider clinical and methodological heterogeneity: that is the degree to which the included studies varied in terms of participant, intervention, outcome and characteristics such as length of follow-up. This assessment of clinical and methodological heterogeneity was to be supplemented by information regarding statistical heterogeneity - assessed using the Chi^2 test (a significance level of $P < 0.10$ was to be considered to indicate statistically significant heterogeneity) in conjunction with the I^2 statistic (**Higgins 2003**). I^2 examines the percentage of total variation across RCTs that is due to heterogeneity rather than chance (**Higgins 2003**). In general I^2 values of 25% or less may mean a low level of heterogeneity (Higgins 2003), and values of 75% or more indicate very high heterogeneity (**Deeks 2011**). Where there was evidence of high heterogeneity we planned to attempt to explore this further: see Data synthesis.

Assessment of reporting biases

Reporting bias was to be assessed using guidelines in the *Cochrane Handbook for Systematic Reveiws of Interventions* (**Stern 2011**). If enough studies were available for a meaningful assessment of publication bias, we planned to construct a funnel plot of primary outcomes to test for asymmetry. We also planned to consider selective reporting (i.e. reporting some outcomes and not others) in our assessment of reporting bias.

Data synthesis

We planned to combine details of included studies in a narrative review according to type of comparator, possibly by location/type of wound and then by outcomes and time period. We planned to consider clinical and methodological heterogeneity and undertake pooling when studies appeared to be appropriately similar in terms of wound type, intervention type, duration of follow-up and outcome type, that is, when synthesis was considered viable. Our

standard approach for meta-analytical analyses was to employ a random-effects model. The basis for our preference for the more conservative random-effects model was that statistical assessments can miss potentially important between-study heterogeneity in small samples (Kontopantelis 2012). We planned to only use a fixed-effect analysis when, in our judgement, there was minimal clinical heterogeneity and this was also supported by an Chi^2 value that was estimated to be statistically non-significant and an I^2 of 0% (Kontopantelis 2013). In all other circumstances a random-effects model was to be adopted. Where clinical heterogeneity was thought to be acceptable, or of interest, we planned to meta-analyse even when statistical heterogeneity was high, but would have attempted to interpret the causes behind this heterogeneity and would have considered using meta-regression for that purpose, if possible (Thompson 1999; Thompson 2002).

Data were to be presented using forest plots where possible. For dichotomous outcomes we planned to present the summary estimate as a RR with 95% CIs. Where continuous outcomes were measured in the same way across studies, we planned to present a pooled MD with 95% CIs; we planned to pool SMD estimates where studies measured the same outcome using different methods. For time-to-event data, we planned to plot and, if appropriate, pool estimates of hazard ratios and 95% CIs as presented in the study reports using the generic inverse variance method in RevMan 5.3 (RevMan 2014). Where time to healing was analysed as a continuous measure, but it was not clear if all wounds healed, use of the outcome in the study would have been documented, but we would not have summarised or used data in any meta-analysis. We planned to obtain pooled estimates of treatment effect by using the Cochrane RevMan 5.3 software (RevMan 2014).

Subgroup analysis and investigation of heterogeneity

If substantial heterogeneity existed between studies for the primary outcomes (that is, when the I^2 statistic exceeded 50%), we planned to explore reasons for heterogeneity. We envisaged that the number of studies meeting our inclusion criteria would have been low. Consequently, to avoid type I errors we planned to conduct a minimal number of sub analyses that were to include the following, if possible:

- type of intervention (complete bed rest versus periodic bed rest).

Sensitivity analysis

If feasible we planned to perform a sensitivity analysis by excluding those studies assessed as having a high risk of bias in the key domains of selection bias and detection bias. Again, if feasible we planned to explore the effect of excluding cluster trials, where the analysis was not at the same level as the allocation (i.e. allocation by cluster and analysis by individual).

'Summary of findings' tables

We planned to 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 planned to present the following outcomes in the 'Summary of findings' tables:

- ulcer healing;
- incidence of new pressure ulcer;
- incidence of chest infection.

Where data were not pooled we planned to conduct the GRADE assessment for each comparison and present this narratively within the results section, without the presentation of separate 'Summary of findings' tables.

Results

Description of studies

Results of the search

The search yielded 73 citations (see Figure 1). ZM and MvE examined the abstracts of all papers, independently, to assess for potential relevance. Following this assessment, no papers met the inclusion criteria. ZM contacted 19 experts in the field enquiring about further potential papers, and no further papers were identified.

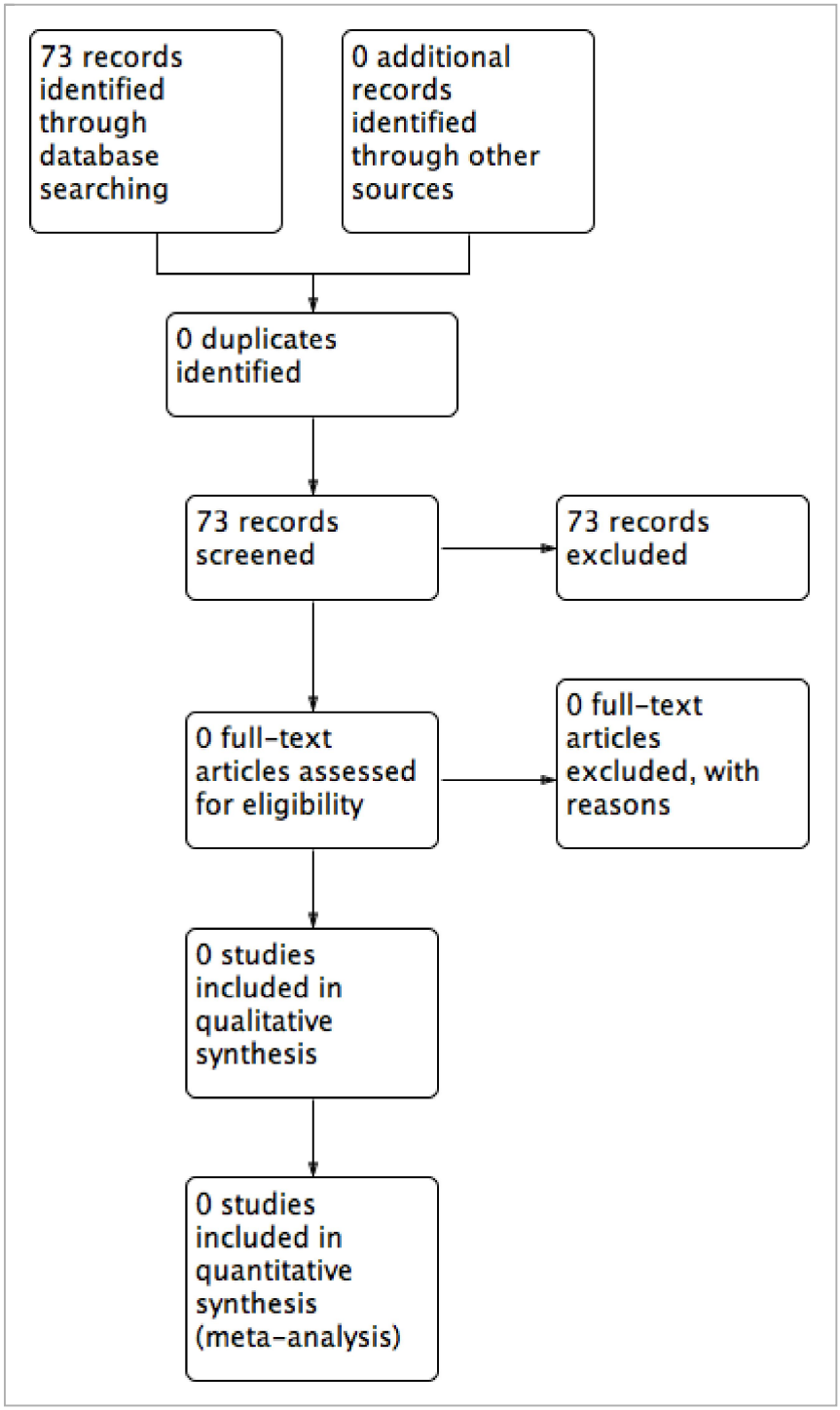

Figure 1.

Open in figure viewer

Study flow diagram.

Included studies

No studies met the inclusion criteria.

Excluded studies

No studies were excluded.

Risk of bias in included studies

Allocation

No studies met the inclusion criteria.

Blinding

No studies met the inclusion criteria.

Incomplete outcome data

No studies met the inclusion criteria.

Selective reporting

No studies met the inclusion criteria.

Other potential sources of bias

No studies met the inclusion criteria.

Effects of interventions

No studies met the inclusion criteria.

Discussion

We identified no eligible studies despite our having made every attempt to identify all relevant studies, including contacting experts in this field and searching conference proceedings to identify studies as yet unpublished. It is theoretically possible, though unlikely, that we did not manage to locate some potentially eligible studies. In line with Cochrane policy, we will continue to undertake updates of this review and any studies identified at that stage that meet the inclusion criteria will be included.

Pressure ulcers arise in individuals who are exposed to prolonged periods of sustained pressure and shear forces on the weight bearing areas of the body. In wheelchair users, during sitting, the weight bearing areas are the sacrum (a large, triangular bone at the base of the spine) and trochanters (bony prominences toward the near end of the thighbone). The sustained forces impair the normal blood supply to tissues and disrupt the removal of waste products following cell metabolism which, if pressure and shear forces are not relieved, will inevitably lead to cell damage. In addition, unrelieved pressure and shear result in sustained cell deformation, failure of the cell membrane and disruption of the cytoskeleton, which can quickly progress to complete cell death (**Oomens 2015**). Cell death triggers an inflammatory response in the tissues, causing an influx of inflammatory cells and

an alteration in cell permeability, leading to leakage of fluids into the interstitial spaces, further impeding the blood supply to the affected tissues (Tarnuzzer 1996). For pressure ulcers to heal, an adequate supply of oxygen and nutrients are needed to promote new tissue generation, which is required to replace the damaged tissue (Gottrup 2004). Given that pressure and shear forces impair the blood supply, offloading using bed rest, is regularly recommended for those with existing pressure ulcers who are confined to a wheelchair (NPUAP 2014). However, despite good face validity, overall, there is a lack of evidence from randomised controlled trials available to support or refute the use of bed rest for pressure ulcer healing in wheelchair users. Furthermore, bed rest can represent a large lifestyle change for patients, and may have a negative physical and psychological impact. Therefore, further research is justified based on the incidence of the problem and the high costs, both personal and monetary, associated with pressure ulcer treatment.

Summary of main results

No studies met the inclusion criteria.

Overall completeness and applicability of evidence

No studies met the inclusion criteria.

Quality of the evidence

No studies met the inclusion criteria.

Potential biases in the review process

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

Agreements and disagreements with other studies or reviews

A previous non-Cochrane review identified that the literature does not contain evidence supporting the use of bed rest to facilitate healing of pressure ulcers, this review concurs with these findings (Norton 2004).

Authors' conclusions

Implications for practice

Pressure ulcers are common, costly and impact negatively on the individual's quality of life. Bed rest for the treatment of pressure ulcers in wheelchair users is often advocated; however, there is no evidence from randomised controlled trials to support or refute the use of bed rest for this purpose. Despite this,

international guidelines in the field of pressure ulcer prevention recommend the use of a bed rest for treating pressure ulcers (NPUAP 2014). Additional research is needed to demonstrate the effect bed rest on pressure ulcer healing among wheelchair users.

Implications for research

There are no trials that have explored the use of bed rest for pressure ulcer healing in wheelchair users, despite its recommendation within international pressure ulcer prevention and management guidelines (NPUAP 2014). Future trials to answer this question are justified, based on the incidence of pressure ulcers and their consequences in wheelchair users. Future trials should be large enough to show meaningful differences; include participant-related outcomes such as acceptability, adverse events and quality of life; and economic evaluations to assist healthcare managers to make rational decisions. Standard, validated tools should be used to measure outcomes such as pressure ulcer staging and quality of life.

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Data and analyses

Download statistical data

This review has no analyses.

Appendices

Appendix 1. Search strategies

The Cochrane Central Register of Controlled Trials (CENTRAL)

#1 MeSH descriptor: [Pressure Ulcer] explode all trees
#2 (pressure next (ulcer* or sore* or injur*)):ti,ab,kw (Word variations have been searched)
#3 (decubitus next (ulcer* or sore*)):ti,ab,kw (Word variations have been searched)
#4 {or #1-#3}

#5 MeSH descriptor: [Wheelchairs] explode all trees
#6 (wheelchair* or (wheel* near/3 (chair* or mobil*))):ti,ab,kw (Word variations have been searched)
#7 (mobile near/4 (seat* or chair*)):ti,ab,kw (Word variations have been searched)
#8 {or #5-#7}
#9 {and #4, #8} in Trials

Ovid MEDLINE

1 exp Pressure Ulcer/
2 (pressure adj (ulcer* or sore* or injur*)).tw.
3 (decubitus adj (ulcer* or sore*)).tw.
4 (bedsore* or bed sore*).tw.
5 or/1-4
6 Wheelchairs/
7 (wheelchair* or (wheel* adj3 (chair* or mobil*))).ti,ab,kw.
8 (mobile adj4 (seat* or chair*)).ti,ab,kw.
9 or/6-8
10 and/5,9
11 randomized controlled trial.pt.
12 controlled clinical trial.pt.
13 randomi?ed.ab.
14 placebo.ab.
15 clinical trials as topic.sh.
16 randomly.ab.
17 trial.ti.
18 or/11-17
19 exp animals/ not humans.sh.
20 18 not 19
21 10 and 20

Ovid EMBASE

1 exp decubitus/
2 (pressure adj (ulcer* or sore* or injur*)).tw.
3 (decubitus adj (ulcer* or sore*)).tw.
4 (bedsore* or bed sore*).tw.
5 or/1-4
6 exp wheelchair/
7 (wheelchair* or (wheel* adj3 (chair* or mobil*))).ti,ab,kw.
8 (mobile adj4 (seat* or chair*)).ti,ab,kw. (35)
9 or/6-8
10 and/5,9
11 Randomized controlled trials/
12 Single-Blind Method/
13 Double-Blind Method/
14 Crossover Procedure/

15 (random* or factorial* or crossover* or cross over* or cross-over* or placebo* or assign* or allocat* or volunteer*).ti,ab.
16 (doubl* adj blind*).ti,ab.
17 (singl* adj blind*).ti,ab.
18 or/11-17
19 exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/
20 human/ or human cell/
21 and/19-20
22 19 not 21
23 18 not 22
24 10 and 23

EBSCO CINAHL Plus

S24 S10 AND S23
S23 S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22
S22 TI allocat* random* or AB allocat* random*
S21 MH "Quantitative Studies"
S20 TI placebo* or AB placebo*
S19 MH "Placebos"
S18 TI random* allocat* or AB random* allocat*
S17 MH "Random Assignment"
S16 TI randomi?ed control* trial* or AB randomi?ed control* trial*
S15 AB (singl* or doubl* or trebl* or tripl*) and AB (blind* or mask*)
S14 TI (singl* or doubl* or trebl* or tripl*) and TI (blind* or mask*)
S13 TI clinic* N1 trial* or AB clinic* N1 trial*
S12 PT Clinical trial
S11 MH "Clinical Trials+"
S10 S5 AND S9
S9 S6 OR S7 OR S8
S8 TI ((mobile N4 (seat* or chair*))) OR AB ((mobile N4 (seat* or chair*)))
S7 TI ((wheelchair* or (wheel* N3 (chair* or mobil*)))) OR AB ((wheelchair* or (wheel* N3 (chair* or mobil*))))
S6 (MH "Wheelchairs+")
S5 S1 OR S2 OR S3 OR S4
S4 TI decubitus or AB decubitus
S3 TI (bed sore* or bedsore*) or AB (bed sore* or bedsore*)
S2 TI (pressure ulcer* or pressure sore*) or AB (pressure ulcer* or pressure sore*)
S1 (MH "Pressure Ulcer+")

Appendix 2. Risk of bias criteria

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 available to permit a judgement of low or high risk of bias to be made.

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: use of an open random allocation schedule (e.g. a list of random numbers); assignment envelopes without appropriate safeguards (e.g. if envelopes were unsealed, 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 a judgement of low or high risk of bias to be made. 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 a judgement of low or high risk of bias to be made.
- 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 a 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

Either 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 is reported using measurements, analysis methods or subsets of the data (e.g. sub scales) that were not pre-specified.
- One or more of the reported primary outcomes was 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 is available to permit a judgement of low or high risk of bias to be made. 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:

- has 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
- has 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.

Contributions of authors

Zena Moore: conceived, designed and coordinated the review; produced the first draft of the review; contributed to writing or editing the review; approved the final review prior to submission; and is a guarantor of the review.

Menno van Etten: designed the review; contributed to writing or editing the review; approved the final review prior to submission; and is a guarantor of the review.

Jo Dumville: conceived the review; approved the final review prior to submission; and is a guarantor of the review.

Contributions of editorial base

Nicky Cullum: edited the review, advised on methodology, interpretation and content; approved the final review prior to submission.
Gill Rizzello: co-ordinated the editorial process; advised on content; edited the review.
Reetu Child: designed the search strategy, ran searches and edited the search methods section.

Declarations of interest

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

Menno van Etten: is employed by Etac AS in Norway as a product specialist and a seating and mobility consultant.

Jo Dumville: none known.

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