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Pressure redistributing static chairs for preventing pressure ulcers (Review)

Stephens M, Bartley C, Dumville JC

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[Intervention Review]

Pressure redistributing static chairs for preventing pressure ulcers

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ABSTRACT

Background

Sitting can be viewed as a therapeutic intervention and an important part of a person's recovery process; but the risk of ulceration must be mitigated. Interventions for ulcer prevention in those at risk from prolonged sitting include the use of specialist cushions and surfaces, especially for wheelchair users. Whilst there is interest in the effects of different pressure redistributing cushions for wheelchairs, the benefits of pressure redistributing static chairs, compared with standard chairs, for pressure ulcer development in at-risk people are not clear.

Objectives

To assess the effects of pressure redistributing static chairs on the prevention of pressure ulcers in health, rehabilitation and social care settings, and places of residence in which people may spend their day.

Search methods

In June 2021 we searched the following electronic databases to identify reports of relevant randomised clinical trials: the Cochrane Wounds Specialised Register, the Cochrane Central Register of Controlled Trials (CENTRAL), Ovid MEDLINE, Ovid Embase and EBSCO CINAHL Plus (Cumulative Index to Nursing and Allied Health Literature). We also searched clinical trials registers for ongoing and unpublished studies, and reference lists of relevant systematic reviews, meta-analyses and health technology reports. There were no restrictions by language, date of publication or study setting.

Selection criteria

We sought to include published or unpublished randomised controlled trials that assessed pressure redistributing static chairs in the prevention or management of pressure ulcers.

Data collection and analysis

Two review authors independently performed study selection. We planned that two review authors would also assess the risk of bias, extract study data and assess the certainty of evidence according to GRADE methodology.

Main results

We did not identify any studies that met the review eligibility criteria, nor any registered studies investigating the role of pressure redistributing static chairs in the prevention or management of pressure ulcers.

Authors' conclusions

Currently, there is no randomised evidence that supports or refutes the role of pressure redistributing static chairs in the prevention or management of pressure ulcers. This is a priority area and there is a need to explore this intervention with rigorous and robust research.

PLAIN LANGUAGE SUMMARY

Do pressure redistributing static chairs help to prevent pressure ulcers?

Key messages

Despite a comprehensive search, we did not find any studies that looked at whether pressure redistributing static chairs help to prevent or manage pressure ulcers. This is an important topic area and high quality research is needed to determine whether or not such chairs benefit people at risk of developing pressure ulcers.

What are pressure ulcers?

Pressure ulcers are injuries to the skin and underlying tissue that can be caused by prolonged pressure. Sitting can be an important part of a person's recovery process, but sitting for long periods can increase the risk of developing pressure ulcers.

How are pressure ulcers managed?

Specialist cushions and surfaces aim to redistribute pressure on the skin when people have to stay sitting for long periods of time. There has been more research into the effects of using pressure redistributing cushions in wheelchairs than in standard chairs.

We do not currently know how effective pressure redistributing static chairs are, compared with standard chairs, for preventing or managing pressure ulcers in at-risk people.

Pressure redistributing static chairs range from standard hospital chairs and chairs used in residential settings with no cushion or manual/dynamic function, to those with integrated pressure redistributing surfaces and recline, rise or tilt function when the person is sitting in it. These can be produced to a standard design or a bespoke design tailored to the needs of the person.

What did we want to find out?

We wanted to find out how effective pressure redistributing static chairs are for preventing or managing pressure ulcers in health, rehabilitation and social care settings, and residential places where people may spend their day.

What did we do?
We searched for published and unpublished studies that assessed pressure redistributing static chairs for preventing or managing pressure ulcers. There were no restrictions on language, date of publication or study setting.

What did we find?

We did not find any eligible completed or registered studies investigating the effects of pressure redistributing static chairs for preventing or managing pressure ulcers.

There is no current high-quality evidence that supports or refutes the role of pressure redistributing static chairs for preventing or managing pressure ulcers.

This is a priority area and there is a need to explore this intervention with rigorous and robust research.

How up to date is this evidence?

This evidence in this Cochrane Review is up to date to June 2021.

BACKGROUND

Description of the condition

Pressure ulcers are a global patient safety issue with serious consequences for those affected and for health systems more widely. A pressure ulcer is defined as "localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear" (EPUAP 2019). Historically, the term pressure ulcer has changed from bedsore, decubitus ulcer, and pressure sore, to pressure ulcer and pressure injury. In Europe the term pressure ulcer has been adopted; whilst in North America, Asia, and Australasia the term pressure injury is preferred.

Pressure ulcer severity is staged or categorised from I to IV (EPUAP 2019; NPIAP 2016; WHO 2018). The higher the category the more significant the pressure ulcer and damage to the skin and underlying tissues, with stage/category I indicating superficial damage with no open wound and stage/category IV indicating significant damage through the layers of the skin, soft tissue, and muscle, often exposing bone.

- **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/stage I may be difficult to detect in individuals with dark skin tones. May indicate “at risk” individuals (a heralding sign of risk).
- **Category/stage II: partial thickness skin loss**. Partial thickness loss of dermis presenting as a shallow open ulcer with a red-pink wound bed, without slough. May also present as an intact or open/ruptured serum filled blister. Presents as a shiny or dry shallow ulcer without slough or bruising.* This category/stage should not be used to describe skin tears, tape burns, perineal dermatitis, maceration or excoriation. *Bruising indicates suspected deep tissue injury.
- **Category/stage III**:**full thickness skin 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 and malleolus do not have 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 may be present on some parts of the wound bed. Often include 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 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 possible. Exposed bone/tendon is visible or directly palpable.
- **Unstageable: depth unknown.** Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, grey, green or brown) and/or eschar (tan, brown or black) in the wound bed. Until enough slough and/or eschar is removed to expose the base of the wound, the true depth, and therefore category/stage, cannot be determined. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heels serves as ‘the body’s natural (biological) cover’ and should not be removed.
- **Suspected deep tissue injury: depth unknown**. Purple or maroon localised area of discoloured intact skin or blood-filled blister due to damage of underlying soft tissue from pressure or shear (or both). The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue. Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered by thin eschar. Evolution may be rapid exposing additional layers of tissue even with optimal treatment.

Prevalence estimates for pressure ulceration vary according to the population being assessed, the data collection methods used, and decisions about whether or not category I pressure ulcers should be included (since there is no open wound at this stage but evidence of possible tissue damage). In a retrospective analysis of the 2011 to 2016 International Pressure Ulcer Prevalence data, estimates of the global prevalence of hospital acquired pressure ulcers were recorded as 3.06% (Kayser 2019). In England, the National Stop the Pressure Ulcer audit of over ten thousand patients in England across 36 hospitals in 18 NHS Trusts recorded an overall point prevalence of 9.04% (NHS England & NHS Improvement 2020). UK pressure ulcer prevalence estimates specifically for community settings have reported rates of 0.77 per 1000 adults in a UK urban area (Stevenson 2013).

The financial implications of pressure ulceration to health services is large, with estimates across countries that range from EUR 12.58 million to EUR 240.94 million for prevention, and from EUR 121.44 million to EUR 2.59 billion for treatment (Demarré 2015). A recent retrospective cohort analysis found that UK National Health Service (NHS) community costs of pressure ulcer treatment ranged from GBP 1400 for a category I ulcer to over GBP 8500 for the other categories (Guest 2018). In the USA, adult inpatient pressure ulcer management cost USD 11.0 billion in 2006 (Russo 2006). On a personal level, pressure ulcers represent a major burden to patients. Gorecki 2014, in a systematic review of the literature, found that the burden of pressure ulcers on patients included negative psychological, physical, and social consequences affecting health, well-being, and health-related quality of life (HRQL).

Being seated with no or limited movement increases the risk of pressure ulceration as soft tissues are compressed between two surfaces, the seat and the bones of the pelvis, for long periods (Krouskop 1983; Schubert 1994). This starves the area of oxygen and nutrients and, if pressure is unrelieved, skin begins to break down (Kosiak 1959). The risk of ulceration and rate of development can vary, as high pressures over a short period of time can be as destructive as low pressures over a longer period (Gefen 2008). Damage from shear occurs when layers of the skin are laterally shifted in relation to each other because of limited movement across a surface. Immobilisation or reduced mobility are risk factors for pressure ulceration, as is reduced bodily sensation; other

suggested risk factors include unmanaged incontinence (resulting in constantly moist skin), poor circulation, and poor nutrition (Bartley 2017; Bhattacharya 2015). A pressure ulcer can begin with inflamed, sore, painful skin. However, if a person has reduced bodily sensation, the initial feelings of soreness are not felt and an open wound could be the first signs of skin damage.

There are approximately 131,800,000 wheelchair users worldwide who are not ambulant and are at increased risk for the development of a pressure ulcer (Wheelchair Foundation 2016). Also at risk of ulceration are those who have limited mobility and sit in static chairs for extended periods of time, for example elderly and frail populations: the number of people in this at-risk group is difficult to estimate but is likely to be very large. For some patients, sitting can be viewed as a therapeutic intervention and an important part of the person's recovery process; but the risk of ulceration also has to be mitigated. Interventions for ulcer prevention in those at risk from prolonged sitting include the use of specialist cushions and surfaces (such as reactive and active, powered and non-powered devices (NPIAP 2019), especially in wheelchair users (Bartley 2017; Stephens 2017). There is also increased interest in the effects of different pressure redistributing static chairs on pressure ulcer development in at-risk people.

Description of the intervention

Pressure redistributing static chairs are devices for those who remain seated for extended periods of time due to short- or long-term mobility issues, or both. These chairs are used in many settings, including hospitals, care homes, and people's own homes. They are an essential part of the 24-hour postural management programme for many patient groups, and are considered a key assistive device for promoting independence and function (Bartley 2017; Harrand 2016; Stephens 2017).

There is no one standard definition of a pressure redistributing static chair. For the purpose of this review, this can be described as specifically designed seating that has integrated pressure redistributing surfaces and adjustable-angle seats, backrests, leg supports and footrests that can be combined with a manual or powered facility, providing the functionality to support, tilt, recline, rise, or elevate parts of, or the whole of the body, to meet the postural and pressure redistributing needs of the user.

There are many different types of static chair available for use in health and social care contexts, with various levels of pressure redistributing technology: ranging from standard hospital chairs and chairs used in residential settings with no pressure redistribution function, to those that include foam, gel, air, or water with the aim of reducing pressure on soft tissue. These can include:

- static arm chair, also known as a high-back chair, which is a high-seat chair with an upright seating position. It comes with additional lumbar support, optional wings (side pieces projecting from the back of the chair) and arms that can be upholstered in antimicrobial vinyls and fabric upholstery options, and a removable seat cushion;
- recliner chair: a high-back chair, which is a high-seat chair with a sculpted or waterfall (sloping) back that reclines when the occupant lowers the chair's back and raises its front. It has a backrest that can be tilted back, and often a footrest that may be extended by means of a lever on the side of the chair, or may extend automatically when the back is reclined. It can also have lift and tilt actions;
- riser: a recliner chair (single motor/action) is a high-back chair, which is a high-seat chair with a sculpted or a waterfall back that provides a two-way, tilt-in-space action that gives high leg elevation as the seat-to-back angle remains constant. The tilt in space can be controlled manually or through a handset. It can also have lift and tilt actions;
- riser: a recliner chair (dual motor/action) is a high-back chair, which is a high-seat chair with a sculpted or waterfall back, utilising two motors, operated by a handset to allow independent leg rest and backrest operation. The backrest can be reclined virtually flat as the backrest opens away from the seat. It can also have lift and tilt actions;
- hybrid specialist seating: manual or dynamic seating systems that provide positioning and postural management for people who are at risk of developing an asymmetrical body shape, are unable to maintain a midline position and require additional postural support. The seating can be adjusted for the correct seat height, seat depth, seat width, arm height, and back height combined with headrest angle adjustment, back angle recline, tilt-in-space, and leg rest elevation. Pressure redistributing seat cushions can be integrated into the chair;
- bespoke custom-configured seating to accommodate more complex postures or skin integrity needs that cannot be met with off-the-shelf seating solutions;
- bespoke custom-moulded seating to accommodate the fixed asymmetrical posture of people who require significant postural support.

The number of different static chairs with pressure redistributing elements has increased exponentially since the publication of the Tissue Viability Society 2008 guidelines, despite no standardised terminology. For example, the UK NHS Supply Chain currently lists 307 static chairs ranging in cost from GBP 270 to GBP 2500 (NHS Supply Chain 2022), and this excludes bespoke equipment such as moulded seat inserts fitted to the person's requirements.

How the intervention might work

To reduce pressure ulcer risk when seated, static chairs aim to reduce seating pressure around the ischial tuberosities (bony parts of the buttocks), greater trochanters (widest part of the thigh), and sacral region (area at the top of the buttock crease) (Reddy 2006). However, attention should also be paid to other bony prominences, such as shoulder blades, spinal processes, back of head, elbows, and heels (Stephens 2017). The aim is that the support provided by the chair minimises constant pressure, allowing good blood flow to the soft tissues, maintaining the metabolic needs of local cells, and reducing the risk of ulceration (Jan 2010). Several approaches are used in the development of static chairs to redistribute pressure and prevent shear or friction forces. Features such as seat cushion design; tilt-in-space or recline function, or both; and use of elevated leg rests are all used in an attempt to address these concepts (Jan 2010; Jan 2013; Michael 2007; NICE 2014; RESNA 2009; Stinson 2003). However, much of the testing of these features has been undertaken in wheelchair design and not static chair design.

Why it is important to do this review

Currently, there is no systematic review focused on the evidence for different types of static chairs in pressure ulcer prevention; there is a potential over-reliance on marketing material, case studies and pilot studies to inform decision-making in this area. Given the widespread use of static chairs with pressure redistributing technology in health and social care settings, it is important to systematically review current evidence for their effects. Whilst previous reviews have focused on cushions and wheelchairs, this Cochrane Review considers the different types of static chairs and related seat moulds used in health and social care contexts, the evidence for the effectiveness of these, and any outstanding uncertainty that may shape future research and use of healthcare finances.

OBJECTIVES

To assess the effects of pressure redistributing static chairs on the prevention of pressure ulcers in health, rehabilitation and social care settings, and places of residence in which people may spend their day.

METHODS

Criteria for considering studies for this review

Types of studies

In this review we intended to include published and unpublished randomised controlled trials (RCTs), including cluster-randomised trials and cross-over RCTs, irrespective of language of report. We planned to exclude studies using quasi-randomisation.

Types of participants

We intended to include studies in adults who remain seated for extended periods of time, undertaken in any care setting: this might have included health, rehabilitation and social care settings, and places of residence in which people may spend their day. We planned to include people at risk of developing new pressure ulcers, which may have included those with existing pressure ulcers at baseline when pressure ulcer incidence was measured in the study. We excluded children and people whose only form of seating was a wheelchair or seat cushion.

Types of interventions

We planned to include any type of pressure redistributing static chair. This could have included, but would not have been limited to, static arm chairs, riser recline chairs, tilt-in-space chairs, recline chairs, and hybrid chairs. We did not plan to consider comparisons of static chairs with wheelchairs, or of different wheelchairs with each other in this review, as wheelchairs are mobility aids. Nor was the focus of this review the effects of different types of pressure redistributing cushions, as these are included in a Cochrane Review focused on support surfaces (McInnes 2015). We intended to include trials where the only systematic difference between trial arms was the use of a specific static chair type.

We anticipated that comparisons might include but not be limited to:

- pressure redistributing chairs compared with a standard chair (used in a ward or residential setting), which may have included:
  - pressure redistributing static chair compared with standard chair;
  - pressure redistributing recline chair compared with standard chair;
  - pressure redistributing riser recline chair compared with standard chair;
  - pressure redistributing tilt-in-space chair compared with standard chair;
  - pressure redistributing hybrid chair compared with standard chair;
- comparison of different types of pressure redistributing chairs, which may have included, but not been limited to, any combination of the chair types noted above.

Classification of intervention type would have been based on information presented in the paper. Standard chairs used in a ward or residential setting can have a high or low back, arm rests, front cross bars (horizontal support element joining the legs), removable seat cushions, custom-moulded seat inserts, with or without wings and side infill. We planned to use the authors' definition of standard chair unless it was clear this was very different to this general definition.

Types of outcome measures

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 would have contacted the study authors where possible to establish whether an outcome of interest here was measured but not reported.

We intended to report outcome measures at the latest time point available (assumed to be length of follow-up if not specified) and the time point specified in the methods as being of primary interest (if this was different from the latest time point available). For all outcomes we would have classed assessment of outcome measures as:

- < 1 week to 8 weeks as short term;
- > 8 weeks to 26 weeks as medium term; and
- > 26 weeks as long term.

Primary outcomes

Pressure ulcer incidence

- Proportion of participants developing a new pressure ulcer. This data would have included all incidence ulcers regardless of grade/category (I to IV);
- Time to pressure ulcer development, correctly analysed using survival, time-to-event approaches. We would not have extracted mean time-to-event data unless it was clear that all participants in the study developed an ulcer (a scenario which we anticipated being highly unlikely).

Secondary outcomes

- **Participant health-related quality of life/health status:** we planned to report on studies that measured health-related quality of life using a standardised generic questionnaire such as EQ-5D (Herdman 2011), Short Form (SF)-36, (Ware 1992),

SF-12 (Ware 1996), or SF-6 (Brazier 2002)). We would not have included ad hoc measures of health-related quality of life that were unlikely to be validated and would not be common to multiple trials.

- **Participant comfort:** we planned to report on comfort as a secondary outcome measure. However, as we are not aware of any validated scale for patient comfort, we planned to accept the study authors reports of this measure.
- **Cost effectiveness:** we intended to report on within-trial cost-effectiveness analysis comparing mean differences in effects with mean cost differences between the two arms. Any data extracted would have been incremental mean cost per incremental gain in benefit (incremental cost-effectiveness ratios), or other combined measures of cost and effects.
- **All reported adverse events:** we planned to consider data where study authors had specified a clear method for collecting adverse event data. Where available, we planned to extract data on all serious and all non-serious adverse events as an outcome. We intended to record where it was clear that events were reported at the participant level or whether multiple events per person were reported, and then if appropriate adjustments were made for data clustering. We intended to consider the assessment of any event in general defined as adverse by participants, health professionals, or both.

Search methods for identification of studies

Electronic searches

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

- the Cochrane Wounds Specialised Register (searched 23 June 2021);
- the Cochrane Central Register of Controlled Trials (CENTRAL; 2021, Issue 5) in the Cochrane Library (searched 23 June 2021);
- Ovid MEDLINE including In-Process & Other Non-Indexed Citations (1946 to 23 June 2021);
- Ovid Embase (1974 to 23 June 2021);
- EBSCO CINAHL Plus (Cumulative Index to Nursing and Allied Health Literature; 1937 to 23 June 2021).

The search strategies for the Cochrane Wounds Specialised Register, CENTRAL, Ovid MEDLINE, Ovid Embase and EBSCO CINAHL Plus can be found in Appendix 1. We combined the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity-maximising version (2008 revision) (Lefebvre 2021). We combined the Embase search with the Ovid Embase filter terms developed by the UK Cochrane Centre (Lefebvre 2021). We combined the CINAHL Plus search with the trial filter developed by Glanville 2019. There were no restrictions of the searches by language, date of publication or study setting.

We also searched the following clinical trials registries:

- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov) (searched 23 June 2021);
- World Health Organization (WHO) International Clinical Trials Registry Platform (who.int/clinical-trials-registry-platform) (searched 23 June 2021).

Search strategies for clinical trial registries can be found in Appendix 1.

Searching other resources

- **Searching reference lists of included trials and relevant reviews:** we aimed to identify other potentially eligible trials or ancillary publications by searching the reference lists of retrieved included trials, as well as relevant systematic reviews, meta-analyses and health technology assessment reports.
- **Searching by contacting individuals or organisations:** when necessary, we planned to contact authors of key papers and abstracts to request further information about their trials.
- **Adverse effects:** we did not perform a separate search for adverse effects of interventions used, we considered adverse effects described in included studies only.

Data collection and analysis

We planned to carry out data collection and analysis according to the methods stated in the published protocol (Stephens 2020), which were based on the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019).

Selection of studies

Two review authors independently assessed the titles and abstracts of the citations retrieved by the searches for relevance. After this initial assessment, we obtained full-text copies of all studies considered to be potentially relevant. Two review authors independently checked the full papers for eligibility; they resolved disagreements by discussion and, where required, with the input of a third review author. We did not need to contact study authors to query any study details with regard to eligibility. We recorded all reasons for exclusion of studies obtained as full text and most relevant to the review. We completed a PRISMA flowchart to summarise this process (Liberati 2009).

Where studies had been reported in multiple publications/reports, we planned to obtain all available publications. Whilst we planned to include each study once in the review, we planned to extract data from all reports to ensure we would obtain maximal relevant data.

Data extraction and management

We intended to extract and summarise details of the eligible studies using a data extraction sheet. Two review authors would have extracted data independently and would have resolved disagreements by discussion, consulting a third review author where required. If data were missing from reports, we intended to contact the study authors to obtain these. If we had included a study with more than two intervention arms, we planned to only extract data from intervention and control groups that met the eligibility criteria.

We intended to extract the following data where possible by treatment group for the prespecified interventions and outcomes in this review. We planned to collect outcome data for relevant time points as described in the Types of outcome measures section:

- country of origin;
- type of setting;

- trial design and unit of randomisation: whether randomisation was undertaken at the participant level or at the level of a ward, care home, or other location;
- unit of analysis: how clustered data were addressed in the analysis;
- care setting;
- number of participants randomised to each trial arm;
- eligibility criteria and key baseline participant data (participant age, gender, and skin status where recorded);
- details of treatment regimen received by each group;
- duration of treatment;
- details of any co-interventions;
- primary and secondary outcome(s) (with definitions);
- outcome data for primary and secondary outcomes (by group);
- duration of follow-up;
- number of withdrawals (by group);
- publication status of study; and
- source of funding for trial.

Assessment of risk of bias in included studies

Two review authors planned to independently assess the risk of bias in included studies by using the Cochrane risk of bias tool RoB1 (Higgins 2017). This tool addresses six specific domains: sequence generation, allocation concealment, blinding, incomplete data, selective outcome reporting, and other issues. In this review we intended to record issues with unit of analysis, for example where a cluster-randomised trial has been undertaken but analysed at the individual level in the study report (Appendix 2).

We planned to assess blinding and completeness of outcome data for each of the review outcomes separately. We were aware that, since pressure ulcer incidence is a subjective outcome, it can be at high risk of measurement bias when outcome assessment is not blinded. Therefore, we intended to consider studies without blinded outcome assessment of ulcer incidence at high risk of detection bias. It would have been unlikely that studies were able to blind health professionals or participants to treatment received, meaning that most or all studies would have been regarded as being at high risk of performance bias. However, where studies had documented their processes to minimise differences in performance, for example with protocol-guided delivery of co-interventions, we would have considered making a judgement of unclear or low risk of bias. We planned to present our assessment of risk of bias using two risk of bias summary figures: one was to have been a summary of bias for each item across all studies, and the second would have shown a cross-tabulation of each trial by all risk of bias items. We planned to class studies with an assessment of low risk of bias for selection bias (both domains of sequence generation and allocation concealment), detection bias, and attrition bias, and no assessment of high risk of bias in any other domain, to be at overall low risk of bias (for specified outcome). Studies with a high risk of bias assessment in any domains would have been classed as being at high risk of bias.

For cluster-randomised trials, we planned to consider the risk of bias in terms of: recruitment bias, baseline imbalance, loss of clusters, incorrect analysis, and comparability with individually randomised trials (Higgins 2021; Appendix 3).

Measures of treatment effect

For dichotomous outcomes we would have sought to calculate the risk ratio (RR) with 95% confidence intervals (CI). For continuously distributed outcome data, we intended to use the mean difference (MD) with 95% CIs where trials utilised the same or similar assessment scale. Wherever trials used different assessment scales, we proposed to use the standardised mean difference (SMD) with 95% CIs. We sought to only consider mean time to healing without survival analysis as a valid outcome if reports specified that all wounds healed (i.e. if the trial authors regarded time to healing as a continuous measure as there was no censoring). We intended to report time-to-event data (e.g. time to pressure ulceration), as hazard ratios (HR) where possible, in accordance with the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2021). If studies reporting time-to-event data did not report a HR, then, where feasible, we planned to estimate this using other reported outcomes, such as the numbers of events, through the application of available statistical methods (Parmar 1998); however, this was not necessary.

Unit of analysis issues

Where studies randomised by participant, but analysed by wound outcome, with the numbers of participants and wounds being equal (i.e. one wound per participant), we intended to treat the participant as the unit of analysis. There may have been instances of clustered data, where a proportion of trial participants had outcome data collected and reported on multiple wounds. Since not all participants would have multiple wounds this is not a cluster trial per se, but rather a trial that incorrectly includes a mixture of individual and clustered data (Schultz 2010). We planned to note such trials and record the issue in the risk of bias assessment. Data would have been extracted and presented but would not have been the subject of any further analyses.

We intended to only incorporate correctly designed and analysed full cluster-randomised trials into meta-analyses. If it had been possible, we intended to approximate the correct analyses with guidance from the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2021), using information on:

- the number of clusters randomised to each intervention, or the mean size of each cluster;
- outcome data ignoring cluster design for the total number of individuals; and
- an estimate of the intracluster correlation coefficient (ICC).

If we could not analyse the study data correctly, we planned to extract and present the data without further analysis.

We aimed to ensure there were no unit of analysis issues with double counting of controls when using studies with multiple intervention arms.

Where repeated observations were recorded on the same participant (e.g. discomfort scales over time), we intended to define time points and analyse accordingly. Where multiple recordings were available within these time points, we planned to incorporate all available data for an overall mean where possible.

Dealing with missing data

It is common for data to be missing from trial reports. Excluding randomised participants from the analysis or ignoring those participants who are lost to follow-up compromises the randomisation, and potentially introduces bias into the trial. Where we thought data were missing we planned to contact the relevant study authors to request these data.

Where data were missing for the 'proportion of participants developing a new pressure ulcer' outcome for analysis, we intended to assume that if randomised participants were not included in an analysis, they did not have an incident ulcer (i.e. they would be considered in the denominator but not the numerator). We planned to explore this in a sensitivity analysis where the impact of no imputation (complete case analysis) was considered (see Sensitivity analysis).

In a time-to-pressure ulceration analysis using survival analysis methods, dropouts should be accounted for as censored data so we did not plan to take any action regarding missing data.

For all secondary outcomes, we intended to present available data from the study reports/study authors and did not plan to impute missing data. Where measures of variance were missing, we planned to calculate these where possible. If calculation was not possible, we planned to contact the study authors for further information. Where these measures of variance were not available, we aimed to exclude the study from any relevant meta-analyses that we conducted.

Assessment of heterogeneity

Assessment of heterogeneity can be a complex, multi-faceted process. 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. We aimed to supplement this assessment of clinical and methodological heterogeneity with information regarding statistical heterogeneity, assessed using the Chi^2 test (we would have considered a significance level of $P < 0.10$ to indicate statistically significant heterogeneity) in conjunction with the I^2 measure (Higgins 2003). The I^2 measure examines the percentage of total variation across RCTs that is due to heterogeneity rather than chance (Higgins 2003). In general, I^2 values of 25% or less may mean a low level of heterogeneity (Higgins 2003), and values of more than 75% indicate very high heterogeneity (Deeks 2021). However, these figures are only a guide, and it is recognised that statistical tests and metrics may miss important heterogeneity. Whilst we planned to assess these, the overall assessment of heterogeneity would have looked at these measures in combination with the methodological and clinical assessment of heterogeneity. Where there was evidence of high heterogeneity, we aimed to explore this further by checking for errors and subgroup analysis or meta-regression.

Assessment of reporting biases

Reporting biases arise when the dissemination of research findings is influenced by the nature and direction of results. Publication bias is one of a number of possible causes of 'small study effects', that is, a tendency for estimates of the intervention effect to be more beneficial in smaller RCTs. Funnel plots allow a visual assessment of whether small study effects may be present in a meta-analysis. A funnel plot is a simple scatter plot of the intervention effect estimates from individual RCTs against some measure of each trial's size or precision (Page 2021). We planned to present funnel plots for meta-analyses comprising 10 RCTs or more using Review Manager 5 (RevMan 5) (Review Manager 2020).

Data synthesis

We intended 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 by time period. We planned to consider clinical and methodological heterogeneity and to undertake pooling when studies appeared appropriately similar in terms of wound type, intervention type, duration of follow-up, and outcome type.

We could not pre-specify the amount of clinical, methodological, and statistical heterogeneity in the included studies, but it may have been extensive. Thus, we anticipated using a random-effects approach for meta-analysis. Conducting meta-analysis with a fixed-effect model in the presence of even minor heterogeneity may provide overly narrow CIs. We planned to only use a fixed-effect approach when clinical and methodological heterogeneity would be considered to be minimal, and the assumption that a single underlying treatment effect is being estimated holds. We planned to use Chi^2 and I^2 measures to quantify heterogeneity but did not intend to use these to guide choice of model for meta-analysis. We planned to exercise caution when meta-analysed data were at risk of small study effects, because a random-effects model may have been unsuitable. In this case, or where there were other reasons to question the selection of a fixed-effect or random-effects model, we planned to assess the impact of the approach using sensitivity analyses to compare results from alternate models. We aimed to report any evidence that suggested that the use of a particular model might not be robust. We planned to meta-analyse even when there was thought to be extensive heterogeneity. We planned to attempt to explore the causes behind this using meta-regression, if possible (Thompson 1999).

We intended to present data using forest plots where possible. For dichotomous outcomes we planned to present the summary estimate as an RR with 95% CI. Where continuous outcomes were measured in the same way across studies, we planned to present a pooled MD with 95% CI; we planned to pool SMD estimates where studies measured the same outcome using different methods. For time-to-event data, we planned to plot (and, if appropriate, pool) estimates of HRs and 95% CIs as presented in the study reports using the generic inverse variance method in RevMan 5 (Review Manager 2020).

Where time to pressure ulceration was analysed as a continuous measure but it was not clear if all pressure ulcers developed, we planned to document use of the outcome in the study but not to summarise data or use them in any meta-analysis.

We aimed to obtain pooled estimates of treatment effect using RevMan 5 (Review Manager 2020).

Subgroup analysis and investigation of heterogeneity

Whilst we anticipated conducting an analysis of pressure redistributing chairs compared with standard chairs, we planned to assess potential heterogeneity with specific reference to the type of pressure redistribution chair being used. Where there was

evidence of between-trial heterogeneity, we envisaged conducting a subgroup analysis by chair type.

Where possible, we planned to also present a subgroup analysis of trials which would include incidence of all grades of ulcers compared with trials which only measured ulcers of grade II and above.

Where possible, we planned to perform subgroup analyses of the overall risk of bias category of a study (a binary comparison of studies at low or unclear risk of bias compared with studies classed at high risk of bias).

Sensitivity analysis

Where possible, we planned to perform sensitivity analyses to explore the effect of the following criteria:

- use of a fixed-effect versus a random-effects model;
- the impact of missing data: our base case analysis would have assumed that participants with missing data did not develop new pressure ulcers. In this sensitivity analysis we aimed to explore the impact of this assumption by undertaking the analysis with complete-case data only.

Summary of findings and assessment of the certainty of the evidence

We planned to present the main results of the review in summary of findings tables. These tables present key information concerning the certainty of the evidence, the magnitude of the effects of the interventions examined, and the sum of the available data for the main outcomes (Schünemann 2021). The summary of findings tables also include an overall grading of the evidence related to each of the main outcomes using the GRADE approach. The GRADE approach defines the certainty of a body of evidence as the extent to which one can be confident that an estimate of effect or association is close to the true quantity of specific interest. The certainty of a body of evidence involves consideration of within-trial risk of bias (methodological quality), directness of evidence, heterogeneity, precision of effect estimates, and risk of publication bias. We planned to present the following outcomes in the summary of findings tables:

- proportion of participants developing a new pressure ulcer;
- time to complete ulcer development, where analysed using an appropriate survival analysis method;
- participant health-related quality of life/health status;
- participant comfort;
- cost effectiveness.

For review outcomes reported for comparisons not listed above, we aimed to present a GRADE assessment without a summary of findings table.

When evaluating the risk of bias domain, we planned to downgrade the GRADE assessment only when we classified a study as being at high risk of bias for one or more domains, or when the risk of bias assessment for selection bias was unclear (i.e. classified as unclear for either the generation of the randomisation sequence or the allocation concealment domain). We did not plan to downgrade for unclear risk of bias assessments in other domains.

We planned to select an informal optimal information size of 300 for binary outcomes, following the GRADE default value (Guyatt 2011). We aimed to follow GRADE guidance and downgrade twice for imprecision when there were very few events and CIs around effects included both appreciable benefit and appreciable harm (considered GRADE 'default' of below 0.75 and above 1.25).

For calculating absolute risk differences for dichotomous and time-to-event outcomes, we planned to use the median of the risks in the control groups at particular time points.

We have based elements of this Methods section on the standard Cochrane Wounds protocol template.

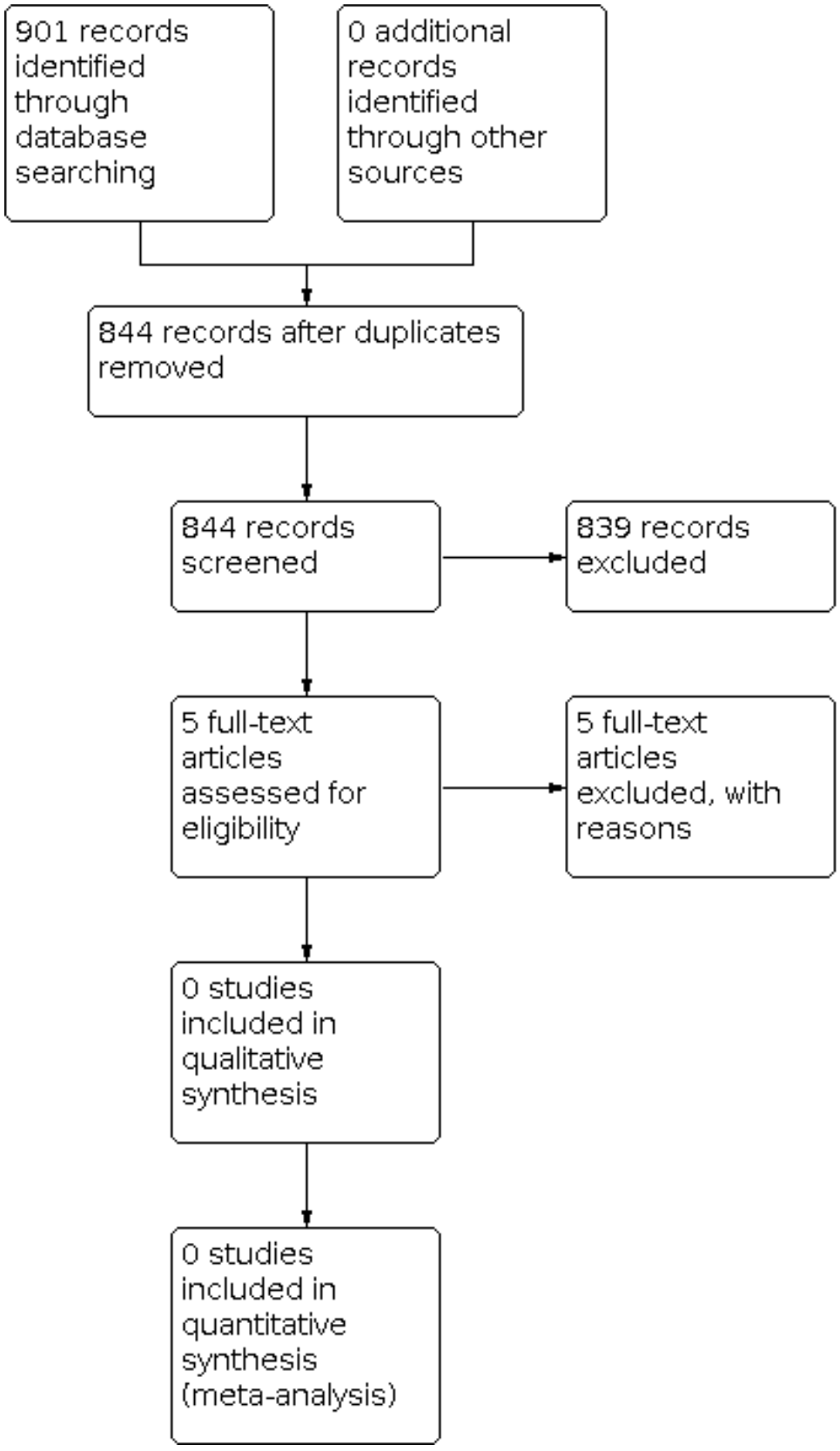
RESULTS

Description of studies

Results of the search

The search retrieved 901 unique records, of which 844 remained after duplicates were removed. We screened 844 records and obtained five full texts for further screening. We took a comprehensive approach to checking other reviews and guidelines in the field of pressure redistributing static chairs, as well as trial registers, and did not identify any additional records. No studies met the inclusion criteria for this review (Figure 1).

Figure 1. Study flow diagram



Included studies

We did not include any studies for analysis in this review, and there were no pending studies awaiting assessment. We did not locate any relevant ongoing studies.

Excluded studies

We excluded five studies (Characteristics of excluded studies). Of these, we excluded two studies because they were systematic reviews. The other three studies did not assess the pressure redistributing properties of static chairs and were not randomised controlled trials.

Risk of bias in included studies

It was not possible to undertake a risk of bias assessment because no studies met the inclusion criteria.

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

Meta-analysis or a narrative synthesis was not possible in this review as no studies met the inclusion criteria.

DISCUSSION

Summary of main results

Although we conducted a wide-ranging search of numerous electronic databases, reviews, guidelines, and clinical trial registers, we did not identify any studies that met the inclusion criteria for this review. We excluded studies because they were not RCTs, or because they did not evaluate the pressure redistributing properties of static chairs on the prevention of pressure ulcers in health, rehabilitation, social care settings, and places of residence in which people may spend their day. We did not identify any relevant randomised controlled trials in progress.

Overall completeness and applicability of evidence

There is no randomised controlled trial evidence regarding the effects pressure redistributing properties of static chairs on the prevention of pressure ulcers in health, rehabilitation, social care settings, and places of residence in which people may spend their day. This field is lacking a robust evidence base.

Quality of the evidence

No assessment was possible as no studies met the inclusion criteria.

Potential biases in the review process

We used a thorough search strategy for this review to discover as much relevant evidence as possible pertinent to the objectives of this review. We sourced all potentially relevant papers. There were no limitations on the language of the studies assessed, however, none required translation. We also searched trial registers and did not find any relevant ongoing or previously conducted but unpublished studies. It is conceivable, however, that there may be other unpublished data that we have not been able to access.

Agreements and disagreements with other studies or reviews

There is a lack of rigorous evidence regarding the benefits and harms of pressure redistributing properties of static chairs on the prevention of pressure ulcers (Stephens 2017). For the prevention and management of pressure ulcers, NICE 2014 recommends health professionals to "Consider the seating needs of people at risk of developing a pressure ulcer who are sitting for prolonged periods" but, as we have shown for pressure redistributing static chairs, there are no trials available to guide this decision making. EPUAP 2014; NPIAP 2016 and NPIAP 2019 pressure ulcer prevention and management guidelines similarly advocate the use of appropriate seating: again recommendations are based on either good practice statements or moderate- and low-quality evidence.

AUTHORS' CONCLUSIONS

Implications for practice

We found no randomised controlled trial evidence on the relative effectiveness of pressure redistributing properties of static chairs on the prevention of pressure ulcers. Despite this lack of evidence, these types of chairs are widely used in multiple health and social care settings. In view of the uncertainty on the clinical and cost effectiveness of pressure redistributing properties of static chairs, current decisions on the use of them to prevent or manage pressure ulcers when seated are likely to be based on local guidelines, local seating and tissue viability expertise, the preferences of both people with pressure ulcers and health and social care professionals, and cost.

Implications for research

Pressure redistributing static chairs are currently used as part of the 24-hour prevention and management of pressure ulcers. Research in the form of randomised controlled trials of the pressure redistributing properties of static chairs should be assessed for feasibility, ensuring focus on high priority treatment options. A rigorous randomised controlled trial evaluating clinical effectiveness, cost effectiveness and patient-reported experiences would likely be in the interests of both people affected by pressure ulcers and the health and social care staff managing their care. Determining the effectiveness of pressure redistributing static chairs was emphasised by the Tissue Viability Society in their seating guidelines (Stephens 2017).

More work is required to engage those who deliver care to those who remain seated for extended periods of time, including

health and social care professionals who assess and prescribe pressure redistributing static chairs. Primary feasibility work will be essential to assess the acceptability of a trial to potential participants as well as health and social care staff. This would include anticipated recruitment rates and other methodological and logistical considerations. A trial in this area could have significant influence on future decision making. The potential benefits for those who remain seated for extended periods of time include possible mitigation of the development of pressure ulcers, improved quality of life, comfort and posture.

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To retain the independence of the editorial process Nuala Livingstone, Network Associate Editor, signed this review off for publication.

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CHARACTERISTICS OF STUDIES

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

Study	Reason for exclusion
Collins 1999	Not an RCT of the effectiveness of pressure redistributing properties of static chairs on the prevention of pressure ulcers

Study	Reason for exclusion
Daly 2012	Not a RCT of the effectiveness of pressure redistributing properties of static chairs on the prevention of pressure ulcers
Groah 2015	A systematic review, not an RCT of the effectiveness of pressure redistributing properties of static chairs on the prevention of pressure ulcers
Regan 2009	A systematic review, not an RCT of the effectiveness of pressure redistributing properties of static chairs on the prevention of pressure ulcers
Rosenthal 2003	Not an RCT of the effectiveness of pressure redistributing properties of static chairs on the prevention of pressure ulcers

RCT: randomised controlled trial

APPENDICES

Appendix 1. Search strategies

Cochrane Wounds Specialised Register

1 MESH DESCRIPTOR Pressure Ulcer EXPLODE ALL AND INREGISTER

2 (pressure next (ulcer* or sore* or injur*)) AND INREGISTER

3 (decubitus next (ulcer* or sore*)) AND INREGISTER

4 (bedsore* or bed sore*) AND INREGISTER

5 #1 OR #2 OR #3 OR #4

6 MESH DESCRIPTOR wheelchairs EXPLODE ALL AND INREGISTER

7 MESH DESCRIPTOR Posture EXPLODE ALL AND INREGISTER

8 MESH DESCRIPTOR Ergonomics EXPLODE ALL AND INREGISTER

9 (wheelchair* or wheel-chair* or chair* or armchair* or arm-chair* or seat or seats or seated or seating or sit or sitting) AND INREGISTER

10 (riser-recline* or (riser recline*)) AND INREGISTER

11 (tilt-in-space) AND INREGISTER

12 (backrest* or back-rest* or armrest* or arm-rest* or legrest* or leg-rest*) AND INREGISTER

13 #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12

14 #5 AND #13

The Cochrane Central Register of Controlled Clinical Trials (CENTRAL)

#1 MeSH descriptor: [Pressure Ulcer] explode all trees

#2 (pressure next (ulcer* or sore* or injur*)):ti,ab,kw

#3 (decubitus next (ulcer* or sore*)):ti,ab,kw

#4 (bedsore* or bed sore*):ti,ab,kw

#5 #1 or #2 or #3 or #4

#6 MeSH descriptor: [Wheelchairs] explode all trees

#7 MeSH descriptor: [Posture] explode all trees

#8 MeSH descriptor: [Ergonomics] explode all trees

#9 (wheelchair* or wheel-chair* or chair* or armchair* or arm-chair* or seat or seats or seated or seating or sit or sitting):ti,ab,kw

#10 (riser-recline* or (riser recline*)):ti,ab,kw

#11 tilt-in-space:ti,ab,kw

#12 (backrest* or back-rest* or armrest* or arm-rest* or legrest* or leg-rest*):ti,ab,kw

#13 #6 or #7 or #8 or #9 or #10 or #11 or #12

#14 #5 and #13 in Trials

The Cochrane Central Register of Controlled Clinical Trials (CENTRAL) search via Cochrane Register of Studies

1 MESH DESCRIPTOR Pressure Ulcer EXPLODE ALL AND CENTRAL:TARGET

2 (pressure next (ulcer* or sore* or injur*)) AND CENTRAL:TARGET

3 (decubitus next (ulcer* or sore*)) AND CENTRAL:TARGET

4 (bedsore* or bed sore*) AND CENTRAL:TARGET

5 #1 OR #2 OR #3 OR #4 AND CENTRAL:TARGET

6 MESH DESCRIPTOR wheelchairs EXPLODE ALL AND CENTRAL:TARGET

7 MESH DESCRIPTOR Posture EXPLODE ALL AND CENTRAL:TARGET

8 MESH DESCRIPTOR Ergonomics EXPLODE ALL AND CENTRAL:TARGET

9 (wheelchair* or wheel-chair* or chair* or armchair* or arm-chair* or seat or seats or seated or seating or sit or sitting) AND CENTRAL:TARGET

10 (riser-recline* or (riser recline*)) AND CENTRAL:TARGET

11 (tilt-in-space) AND CENTRAL:TARGET

12 (backrest* or back-rest* or armrest* or arm-rest* or legrest* or leg-rest*) AND CENTRAL:TARGET

13 #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 AND CENTRAL:TARGET

14 #5 AND #13 AND CENTRAL:TARGET

15 (NCT0* or ACTRN* or ChiCTR* or DRKS* or EUCTR* or eudract* or IRCT* or ISRCTN* or JapicCTI* or JPRN* or NTR0* or NTR1* or NTR2* or NTR3* or NTR4* or NTR5* or NTR6* or NTR7* or NTR8* or NTR9* or SRCTN* or UMIN0*):AU AND CENTRAL:TARGET

16 http*:SO AND CENTRAL:TARGET

17 #15 OR #16

18 #15 OR #16 AND CENTRAL:TARGET

19 #14 AND #18

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 exp Wheelchairs/

7 exp Posture/

8 exp Ergonomics/

9 (wheelchair* or wheel-chair* or chair* or armchair* or arm-chair* or seat or seats or seated or seating or sit or sitting).tw.

10 (riser-recline* or riser recline*).tw.

11 tilt-in-space.tw.

12 (backrest* or back-rest* or armrest* or arm-rest* or legrest* or leg-rest*).tw.

13 or/6-12

14 5 and 13

15 randomized controlled trial.pt.

16 controlled clinical trial.pt.

17 randomized.ab.

18 placebo.ab.

19 drug therapy.fs.

20 randomly.ab.

21 trial.ab.

22 groups.ab.

23 or/15-22

24 exp animals/ not humans.sh.

25 23 not 24

26 14 and 25

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 exp body position/

8 exp Ergonomics/

9 (wheelchair* or wheel-chair* or chair* or armchair* or arm-chair* or seat or seats or seated or seating or sit or sitting).tw.

10 (riser-recline* or riser recline*).tw.

11 tilt-in-space.tw.

12 (backrest* or back-rest* or armrest* or arm-rest* or legrest* or leg-rest*).tw.

13 or/6-12

14 5 and 13

15 Randomized controlled trial/

16 Controlled clinical study/

17 Random$.ti,ab.

18 randomization/

19 intermethod comparison/

20 placebo.ti,ab.

21 (compare or compared or comparison).ti.

22 ((evaluated or evaluate or evaluating or assessed or assess) and (compare or compared or comparing or comparison)).ab.

23 (open adj label).ti,ab.

24 ((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab.

25 double blind procedure/

26 parallel group$1.ti,ab.

27 (crossover or cross over).ti,ab.

28 ((assign$ or match or matched or allocation) adj5 (alternate or group$1 orintervention$1 or patient$1 or subject$1 or participant $1)).ti,ab.

29 (assigned or allocated).ti,ab.

30 (controlled adj7 (study or design or trial)).ti,ab.

31 (volunteer or volunteers).ti,ab.

32 trial.ti.

33 or/15-32

34 (exp animal/ or animal.hw. or nonhuman/) not (exp human/ or human cell/ or (human or humans).ti.)

35 33 not 34

36 14 and 35

EBSCO CINAHL Plus

S38 S14 AND S37

S37 S36 NOT S35

S36 S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29

S35 S33 NOT S34

S34 MH (human)

S33 S30 OR S31 OR S32

S32 TI (animal model*)

S31 MH (animal studies)

S30 MH animals+

S29 AB (cluster W3 RCT)

S28 MH (crossover design) OR MH (comparative studies)

S27 AB (control W5 group)

S26 PT (randomized controlled trial)

S25 MH (placebos)

S24 MH (sample size) AND AB (assigned OR allocated OR control)

S23 TI (trial)

S22 AB (random*)

S21 TI (randomised OR randomized)

S20 MH cluster sample

S19 MH pretest-posttest design

S18 MH random assignment

S17 MH single-blind studies

S16 MH double-blind studies

S15 MH randomized controlled trials

S14 S5 AND S13

S13 S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12

S12 TI ((backrest* or back-rest* or armrest* or arm-rest* or legrest* or leg-rest*)) OR AB ((backrest* or back-rest* or armrest* or arm-rest* or legrest* or leg-rest*))

S11 TI (tilt-in-space) OR AB (tilt-in-space)

S10 TI ((riser-recline* or (riser recline*))) OR AB ((riser-recline* or (riser recline*)))

S9 TI ((wheelchair* or wheel-chair* or chair* or armchair* or arm-chair* or seat or seats or seated or seating or sit or sitting)) OR AB ((wheelchair* or wheel-chair* or chair* or armchair* or arm-chair* or seat or seats or seated or seating or sit or sitting))

S8 (MH "Ergonomics+")

S7 (MH "Posture+")

S6 (MH "Wheelchairs+")

S5 S1 OR S2 OR S3 OR S4

S4 TI ((bedsore* or bed sore*)) OR AB ((bedsore* or bed sore*))

S3 TI ((decubitus N1 (ulcer* or sore*))) OR AB ((decubitus N1 (ulcer* or sore*)))

S2 TI ((pressure N1 (ulcer* or sore* or injur*))) OR AB ((pressure N1 (ulcer* or sore* or injur*)))

S1 (MH "Pressure Ulcer+")

US National Institutes of Health Ongoing Trials Register (ClinicalTrials.gov)

chair OR wheelchair OR armchair OR backrest OR armrest OR legrest OR sit OR seat OR sitting OR rise OR recline Or tilt | Pressure Ulcer

chair OR wheelchair OR armchair OR backrest OR armrest OR legrest OR sit OR seat OR sitting OR rise OR recline Or tilt | Pressure Injury

chair OR wheelchair OR armchair OR backrest OR armrest OR legrest OR sit OR seat OR sitting OR rise OR recline Or tilt | Pressure Ulcer, Buttock

World Health Organization International Clinical Trials Registry Platform

chair OR wheelchair OR armchair OR backrest OR armrest OR legrest OR sit OR seat OR sitting OR rise OR recline OR tilt | pressure ulcer,buttock

chair OR wheelchair OR armchair OR backrest OR armrest OR legrest OR sit OR seat OR sitting OR rise OR recline OR tilt | pressure ulcer

chair OR wheelchair OR armchair OR backrest OR armrest OR legrest OR sit OR seat OR sitting OR rise OR recline OR tilt | pressure injury

chair OR wheelchair OR armchair OR backrest OR armrest OR legrest OR sit OR seat OR sitting OR rise OR recline OR tilt | ulcer

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

1. Was the allocation sequence randomly generated?

Low risk of bias

The investigators describe a random component in the sequence generation process such as: referring to a random number table; using a computer random number generator; coin tossing; shuffling cards or envelopes; throwing dice; drawing of lots.

High risk of bias

The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: sequence generated by odd or even date of birth; sequence generated by some rule based on date (or day) of admission; sequence generated by some rule based on hospital or clinic record number.

Unclear

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

2. Was the treatment allocation adequately concealed?

Low risk of bias

Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone, internet-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. envelopes were unsealed, non-opaque, or not sequentially numbered); alternation or rotation; date of birth; case record number; any other explicitly unconcealed procedure.

Unclear

Insufficient information provided to permit a judgement of low or high risk of bias. This is usually the case if the method of concealment is not described, or not described in sufficient detail to allow a definite judgement, for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque, and sealed.

3. Blinding - was knowledge of the allocated interventions adequately prevented during the study?

Low risk of bias

Any one of the following:

- no blinding, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding;
- blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken;
- either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others 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

Either 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 are 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 the observed event risk is not enough to have a clinically relevant impact on the intervention effect estimate;
- for continuous outcome data, a plausible effect size (difference in means or standardised difference in means) among missing outcomes is not enough to have a clinically relevant impact on the 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 are likely to be related to the true outcome, with either an 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 the intervention effect estimate;
- for continuous outcome data, a plausible effect size (difference in means or standardised difference in means) among missing outcomes is enough to induce a clinically relevant bias in the observed effect size;
- 'as-treated' analysis done with a substantial departure of 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 prespecified (primary and secondary) outcomes that are of interest in the review have been reported in the prespecified way;
- the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were prespecified (convincing text of this nature may be uncommon).

High risk of bias

Any one of the following:

- not all of the study's prespecified primary outcomes have been reported;
- one or more primary outcomes is/are reported using measurements, analysis methods, or subsets of the data (e.g. subscales) that were not prespecified;
- one or more reported primary outcomes was/were not prespecified (unless clear justification for their reporting is provided, such as an unexpected adverse effect);
- one or more outcomes of interest in the review is/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 provided to permit a judgement of low or high risk of bias. It is likely that most 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.

Appendix 3. Risk of bias (cluster-randomised controlled trials)

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

- Recruitment bias can occur when individuals are recruited to the trial after the clusters have been randomised, as the knowledge of whether each cluster is an 'intervention' or 'control' cluster could affect the types of participants recruited.
- Cluster-randomised trials often randomise all clusters at once, so lack of concealment of an allocation sequence should not usually be an issue. However, because small numbers of clusters are randomised, there is a possibility of chance baseline imbalance between the randomised groups, in terms of either the clusters or the individuals. Although not a form of bias as such, the risk of baseline differences can be reduced by using stratified or pair-matched randomisation of clusters. Reporting of the baseline comparability of clusters, or statistical adjustment for baseline characteristics, can help reduce concern about the effects of baseline imbalance.
- Occasionally complete clusters are lost from a trial, and have to be omitted from the analysis. Just as for missing outcome data in individually randomised trials, this may lead to bias. In addition, missing outcomes for individuals within clusters may also lead to a risk of bias in cluster randomised trials.
- Many cluster randomised trials are analysed by incorrect statistical methods, not taking the clustering into account. Such analyses create a 'unit of analysis error' and produce over-precise results (the standard error of the estimated intervention effect is too small)

and P values that are too small. They do not lead to biased estimates of effect. However, if they remain uncorrected, they will receive too much weight in a meta-analysis.

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

HISTORY

Protocol first published: Issue 6, 2020

CONTRIBUTIONS OF AUTHORS

Melanie Stephens: conceived the review; designed the review; co-ordinated the review; extracted data; checked quality of data extraction; analysed or interpreted data; undertook quality assessment; checked quality assessment; produced the first draft of the review; contributed to writing and editing the review; performed previous work that was the foundation of the current review; approved the final review prior to publication; is a guarantor of the review.

Carol Bartley: conceived the review; designed the review; extracted data; checked quality of data extraction; analysed or interpreted data; undertook quality assessment; checked quality assessment; produced the first draft of the review; contributed to writing and editing the review; performed previous work that was the foundation of the current review; approved the final review prior to publication; is a guarantor of the review.

Jo Dumville: designed the review; extracted data; checked quality of data extraction; analysed or interpreted data; undertook quality assessment; checked quality assessment; produced the first draft of the review; contributed to writing and editing the review; advised on the review; secured funding; approved the final review prior to publication.

Contributions of the Editorial Base

Nicky Cullum (Joint Co-ordinating Editor): edited the protocol; advised on methodology, interpretation, and content; and approved the final version of the protocol prior to submission.

Gill Rizzello (Managing Editor): co-ordinated the editorial process; advised on content; and edited the protocol and review.

Sophie Bishop (Information Specialist): designed the search strategy, ran the search and edited the search methods section.

Tom Patterson (Editorial Assistant): edited the reference sections and wrote the Plain Language Summary.

DECLARATIONS OF INTEREST

Melanie Stephens: the University of Salford received funding from CareFlex to conduct a small pilot study to test the pressure redistributing properties of three chairs manufactured by this company. This also included funding to present the findings at the OT Show. I had no control over the use of these funds.

Carol Bartley: the University of Salford received funding from CareFlex to conduct a small pilot study to test the pressure redistributing properties of three chairs manufactured by this company. This also included funding to present the findings at the OT Show. I had no control over the use of these funds.

Jo Dumville: I received research funding from the National Institute for Health Research (NIHR) for the production of systematic reviews focusing on high-priority Cochrane Reviews in the prevention and treatment of wounds. This research was cofunded by the NIHR Manchester Biomedical Research Centre, and partly funded by the NIHR Applied Research Collaboration (ARC) Greater Manchester. I am a joint Co-ordinating Editor of Cochrane Wounds and was not involved in the editorial process for this review.

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- NIHR Manchester Biomedical Research Centre, UK

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- National Institute for Health Research (NIHR), UK

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

None.