Wound-care teams for preventing and treating pressure ulcers.

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Moore ZEH, Webster J, Samuriwo R

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[Intervention Review]

Wound-care teams for preventing and treating pressure ulcers

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ABSTRACT

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. The cost implications of pressure ulcer treatment are considerable, compounding the challenges in providing cost effective, efficient health service delivery. International guidelines suggest that to prevent and manage pressure ulcers successfully a team approach is required. Therefore, this review has been conducted to clarify the role of wound-care teams in the prevention and management of pressure ulcers.

Objectives

To assess the impact of wound-care teams in preventing and treating pressure ulcers in people of any age, nursed in any healthcare setting.

Search methods

In April 2015 we searched: The Cochrane Wounds Group Specialised Register; The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*); Ovid MEDLINE; Ovid MEDLINE (In-Process & Other Non-Indexed Citations); Ovid EMBASE and EBSCO CINAHL. There were no restrictions with respect to language, date of publication or study setting.

Selection criteria

We considered RCTs that evaluated the effect of any configuration of wound-care teams in the treatment or prevention of pressure ulcers.

Data collection and analysis

Two review authors independently assessed titles and, where available, abstracts of the studies identified by the search strategy for their eligibility. We obtained full versions of potentially relevant studies and two review authors independently screened these against the inclusion criteria.

Main results

We identified no studies that met the inclusion criteria.

Authors' conclusions

We set out to evaluate the RCT evidence pertaining to the impact of wound-care teams on the prevention and management of pressure ulcers. However, no studies met the inclusion criteria. There is a lack of evidence concerning whether wound-care teams make a difference to the incidence or healing of pressure ulcers. Well-designed trials addressing important clinical, quality of life and economic outcomes are justified, based on the incidence of the problem and the high costs associated with pressure ulcer management.

PLAIN LANGUAGE SUMMARY

Wound-care teams for preventing and treating pressure ulcers (bed sores)

Background

Pressure ulcers (bed sores) are wounds that occur on the skin or underlying tissues. These wounds commonly occur in people who cannot move themselves. The wounds are difficult to heal. Therefore, it is important to try to prevent them from occurring in the first place. However, when they occur, it is also important to manage the wounds properly. A wound-care team is expected to deliver better outcomes for people with these wounds. This is when care is compared to the person being managed by only one health professional alone.

Review question

We wanted to discover the impact that a wound-care team has on the prevention or healing of pressure ulcers. We were interested in studies that included a team that focused on pressure ulcer prevention. We were also interested in studies that focused on treatment of pressure ulcers. The study could include people of any age. The setting where the care was provided could include any type of hospital or nursing home or the person's own home. The study could include people with pressure ulcers or at risk of developing pressure ulcers.

What we found

We searched for studies on 7 April 2015 and found no studies. Because we found no studies to include in this review, we cannot say whether wound-care teams improve the prevention or management of pressure ulcers. Therefore, the impact of wound-care teams on the prevention and management of pressure ulcers needs to be studied.

The evidence of this review is up-to-date as of 7 April 2015.

BACKGROUND

Description of the condition

A pressure ulcer is defined as a localised injury to the skin or underlying tissue, or both, 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 significance of which have yet to be elucidated (NPUAP/EPUAP/PPPIA 2014). Pressure ulcers are commonly classified according to the depth of tissue damage, ranging from non-blanching erythema of intact skin (tissue redness that does not turn white when pressed) to full-scale tissue destruction (NPUAP/EPUAP/PPPIA 2014).

A large number of risk factors may contribute to pressure ulcer development (Moore 2008), and in keeping with the NPUAP/EPUAP/PPPIA 2014 guidance, Coleman 2013 argued that a complex interplay of these factors increases the probability of pressure ulcer development. There are three primary risk factors of particular significance: mobility and activity, impaired perfusion (circulation problems, possibly due to diabetes) and fragile skin or existing or previous pressure ulcers (Coleman 2013). These risk factors mean that certain populations, such as the very old and people with an inability to reposition themselves freely, are at greater risk of developing pressure ulcers (Moore 2012).

'Prevalence' refers to the number of people with a pressure ulcer at a point in time, or during a specific time period, while 'incidence' concerns the rate at which new pressure ulcers develop in a defined

population in a specific time period (Beaglehole 1993). Prevalence and incidence studies indicate that pressure ulcers are common. Indeed, prevalence rates range from 0.38% to 53.2% (Lahmann 2006; Capon 2007; Vanderwee 2007; Keelaghan 2008; Tubaishat 2010; Kwong 2011; Moore 2012; Igarashi 2013; Stevenson 2013; Moore 2013a), and incidence rates vary from 1.9% to 71.6% across Europe, Japan, China, the Middle East, the USA, Australia and Canada (Jolley 2004; Defloor 2005; Scott 2006; Kwong 2011; Moore 2011; Igarashi 2013; Moore 2013a). Mean prevalence was reported as 20.9% within the acute-care setting, and 11.7% within the long-stay setting; among people in hospice the mean figure was 35.7%, but dropped to 0.04% to 4% for people nursed in the community (Moore 2013a). Incidence figures among the different care settings are similar to prevalence figures. For example, mean incidence of pressure ulcers in the acute-care setting was 18% and for the long-stay setting was 6.6%. There is little information available about pressure ulcer incidence within the community-care setting (Moore 2013a).

The impact of pressure ulcers on the individual is profound, spanning the physical, emotional and social domains of life (Gorecki 2009). This impact is largely influenced by factors related to the individual themselves, the healthcare professional and the environment of care delivery (Gorecki 2012). Fundamentally, people living with pressure ulcers experience significant anxieties that relate to their experiences of the ulcer, for example, the presence of unrelieved intractable pain, in addition to challenges to their ability to cope with the demands that treatments impose upon them (Gorecki 2012).

From a European perspective, pressure ulcer management absorbs between 4% and 5% of the annual healthcare budget, with nurse or healthcare-assistant time accounting for up to 90% of the overall costs (Posnett 2009). In the USA, pressure ulcers cost between USD 9.1 billion to USD 11.6 billion per year (EUR 6.7 billion to EUR 8.5 billion), with estimates in 2007 that each pressure ulcer adds USD 43,180 (EUR 31,580) in costs to a hospital stay (Agency for Healthcare Research and Quality 2011). Within the acute-care setting in Australia in 2005, median opportunity costs for pressure ulcers were estimated at AUD 285 million (EUR 202 million) (Graves 2005). The human and economic drain on healthcare systems is compounded by the fact that healthcare professionals and clinicians are often not trained in prevention and treatment of pressure ulcers or remain in systems where multidisciplinary and integrated care processes are not in place, or both (Moore 2013b). Indeed, a higher incidence and prevalence of pressure ulcers has been noted in settings where there are poor organisational strategies for preventing and managing pressure ulcers (Igarashi 2013).

Description of the intervention

Since the late 1990s there have been reports of the impact that multidisciplinary wound-care teams can have on pressure ulcer prevention and management in clinical practice (Doan-Johnson 1998; Granick 1998; Dolynchuk 2000). During this era, it was noted that there was an increasing number of formal and informal multidisciplinary wound-care teams that adhered to specific care protocols (Doan-Johnson 1998).

Once the best available evidence on the most appropriate way to improve wound-related outcomes had been synthesised and integrated with expert opinion, multidisciplinary wound-care teams were created in many settings through the consensus of healthcare professionals with an interest in wound care (Dolynchuk 2000; Gottrup 2003; Haworth 2009). The aim of these teams was to focus on delivering high-quality, holistic and patient-specific skin care to improve wound-related outcomes and to prevent the deterioration of the integrity of people's tissues (Dolynchuk 2000; Gottrup 2003; Haworth 2009).

The exact composition of the multidisciplinary wound-care team is mainly determined by the person's needs, thus, potentially, any healthcare professional can be a member if it is in the person's best interest (Gottrup 2004; Clark 2007; Zulkowski 2007; Haworth 2009). Therefore, it is evident that multidisciplinary wound-care teams can consist of different healthcare professionals. Teams' key roles include overseeing the pressure ulcer-related education of staff, people with or at risk of pressure ulcers and carers; undertaking pressure ulcer-related research; and supervising the person's pressure ulcer prevention and management strategies (Dolynchuk 2000; Ryan 2003; Gottrup 2004; Woo 2008).

While a number of different approaches to the formation of multidisciplinary wound-care teams have been reported in clinical practice, they are all said to have had a positive impact on the wound prevention and management care that people receive (Gottrup 2003; Gottrup 2004; Haworth 2009). Indeed, in one hospital, the multidisciplinary wound-care team was found to have reduced the prevalence of pressure ulcers by 18% over three years, and in a different hospital the team reduced the pressure ulcer prevalence by 15% in one year (Granick 1998). In another setting, the multidisciplinary wound-care team achieved a high rate of wound healing as 68% of 103 people with chronic wounds achieved complete or almost complete wound healing, and only 2% of the people had the recurrence of an old wound (Donnelly 2000). However, the studies referred to here lack the rigor required to determine the impact of the introduction of the multidisciplinary wound-care team clearly, because they use a pre-post test design with significant time gaps between the pre and post test, and outcome data were collected using an audit methodology.

How the intervention might work

The intervention in this review was the wound-care team: this review considered the impact that these teams had on pressure ulcer prevention and management. We defined the wound-care team as a formally constituted team of healthcare professionals who worked closely to supervise the pressure ulcer prevention and management care of people in hospitals or community-care set-

ting, or both. The team may have been multidisciplinary (e.g. any combination of dietician, nurse, medical doctor, physiotherapist, occupational therapist) or uni-disciplinary (e.g. team composed entirely of nurses). The team may have focus on a simple strategy (e.g. a turning-only regimen) or a complex strategy (e.g. dietary, mobilisation, education).

The World Health Organization (WHO) argued that collaborative practice strengthens healthcare systems and improves health outcomes (WHO 2010). Furthermore, the WHO suggested that such an approach to care delivery is key to optimising outcomes of individual people with or at risk of pressure ulcers (WHO 2010), thereby enhancing overall health and social gain. A lack of integrated care systems and functioning multidisciplinary teams compounds the suffering of people with or at risk of pressure ulcers and increases demands on already overstretched health budgets (Moore 2005). Conversely, structured multidisciplinary interventions, such as interdisciplinary collaboration and education, improve outcomes of people with or at risk of pressure ulcers and overall health service delivery (Apelqvist 2000).

The multidisciplinary wound-care team is expected to deliver better outcomes compared to the alternative, where a person's pressure ulcer prevention and management-related care is delivered by one group of healthcare professionals (e.g. just nurses alone), without the insight, expertise and active participation of fellow healthcare professionals (e.g. physiotherapists, occupational therapists, pharmacists and doctors). There are a number of factors that can contribute to the formation of pressure ulcers, or can affect the healing of pressure ulcers, which are perhaps best addressed by pooling the expertise of different healthcare professionals in order to enhance the prevention and management-related outcomes of people with or at risk of pressure ulcers. Thus, the multidisciplinary wound-care team may have a positive impact on these outcomes because it brings together a range of healthcare professionals with different expertise in order to plan and deliver care to prevent and manage pressure ulcers in a holistic way that is designed to suit the person's individual needs.

Why it is important to do this review

International guidelines suggest that to prevent and manage pressure ulcers successfully a team approach is required (Agency for Healthcare Research and Quality 2011; NPUAP/EPUAP/PPPIA 2014). Furthermore, a team approach to care delivery is advocated by the WHO (WHO 2010). Although there have been many reports about the positive impact that wound-care teams have had on pressure ulcer prevention and management, many of these reports appear to have been underpinned by anecdotal evidence, or have been subjected to little critical scrutiny, so, overall, the precise impact of wound-care teams is unclear. Therefore, it was important to search and appraise the literature systematically in order to determine the impact of teams on the prevention and management of pressure ulcers.

OBJECTIVES

To assess the impact of wound-care teams on preventing and treating pressure ulcers in people of any age, nursed in any healthcare setting.

METHODS

Criteria for considering studies for this review

Types of studies

We planned to include randomised controlled trials (RCTs) that evaluated the effect of any configuration of wound-care teams in the treatment or prevention of pressure ulcers. For this intervention, there was a high probability that hospitals, or wards within hospitals, rather than individuals, would be randomised. Consequently, we planned to also include cluster-RCTs if the cluster design had been properly accounted for in the trial's analysis. We planned to include cluster-RCTs if information was available in the paper, or from the investigator, that would have allowed us to conduct an appropriate analysis. We planned to exclude trials that did not use a validated instrument (such as the NPUAP/EPUAP/PPPIA 2014 definitions) to assess pressure ulcers. We also planned to exclude studies using quasi-randomisation, controlled before-and-after studies and interrupted-time-series studies. We would have considered cross-over studies eligible if data from the first period, before cross-over, were reported separately.

Types of participants

People of any age, in any setting (hospitals, nursing homes, residential care, rehabilitation centres) who were at risk of developing a pressure ulcer (as identified through either a structured or unstructured risk assessment, or by clinical judgement alone), or who had an existing pressure ulcer (of any stage), were eligible for inclusion.

Types of interventions

The intervention of interest was a team that focused on pressure ulcer prevention or treatment, or both. The team may have been multidisciplinary (e.g. any combination of dietician, nurse, medical doctor, physiotherapist, occupational therapist) or uni-disciplinary (e.g. team composed entirely of nurses). The team may have focused on a simple strategy (e.g. a turning-only regimen) or a complex strategy (e.g. dietary, mobilisation, education).

We planned to compare the impact of the wound-care team on pressure ulcer prevention and management against the delivery of

care to prevent or manage pressure ulcers by an individual health-care professional.

Types of outcome measures

We planned to consider primary and secondary outcomes under two categories, prevention and treatment.

Primary outcomes

Prevention studies

- Pressure ulcer incidence (the proportion of participants developing any new pressure ulcer(s) of any grade).

Treatment studies

The primary outcome for treatment studies was complete healing, but this may have been measured and reported in several ways by trial authors. Therefore, we planned to include RCTs that reported any of the following:

- an objective measure of pressure ulcer healing such as absolute or percentage change in pressure ulcer area or volume over time; proportion of individuals with pressure ulcers healed at the completion of the trial period; or healing rate (we planned to accept trials with any length of follow-up, we also planned to adjust for any differences in our analyses);
- time to complete wound healing (using methods of survival analysis and expressing the intervention effect as a hazard ratio (HR)).

Secondary outcomes

Prevention studies

- Resource use (including costs associated with the team and those costs associated with dressings and other additional interventions where reported).
- Length of hospital stay.
- Satisfaction (using any validated scale).
- Morbidity (e.g. infection).

Treatment studies

- Pain (measured at any time with any validated instrument e.g. visual analogue scale).
- All-cause mortality.
- Health-related quality of life (using any validated measure such World Health Organization Quality of Life (WHOQOL)-BREF, 36-item Short Form (SF-36), 12-item Short Form (SF-12)).
- Resource use (including costs associated with the team and those associated with dressings and other additional interventions where reported).
- Morbidity (e.g. infection, proportion requiring surgical repair).
- Mortality (pressure ulcer-related or infection-related mortality).

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 Group Specialised Register (searched 7 April 2015);
- The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2015, Issue 3);
- Ovid MEDLINE (1946 to 6 April 2015);
- Ovid MEDLINE (In-Process & Other Non-Indexed Citations) (6 April 2015);
- Ovid EMBASE (1974 to 6 April 2015);
- EBSCO CINAHL (1982 to 7 April 2015).

We used the following search strategy in The Cochrane Central Register of Controlled Trials (CENTRAL):

#1 MeSH descriptor: [Patient Care Team] explode all trees
#2 ((care or health or healthcare or medical or nursing or interdisciplinary or multidisciplinary or wound* or turn*) next team*):ti,ab,kw
#3 ("team nursing" or nurse-led or nurse-centred or team-based):ti,ab,kw
#4 {or #1-#3}
#5 MeSH descriptor: [Pressure Ulcer] explode all trees
#6 (pressure next (ulcer* or sore* or injur*)):ti,ab,kw
#7 (decubitus next (ulcer* or sore*)):ti,ab,kw
#8 ((bed next sore*) or bedsore):ti,ab,kw
#9 {or #5-#8}
#10 #4 and #9

The search strategies for the Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL can be found in Appendix 2. 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 2013). There were no restrictions with respect to language, date of publication or study setting.

We also searched the following clinical trials registries:

- ClinicalTrials.gov (https://clinicaltrials.gov/) (searched 7 April 2015);
- WHO International Clinical Trials Registry (ICTR) (http://apps.who.int/trialsearch/default.aspx) (searched 7 April 2015);
- The EU Clinical Trials Register (www.clinicaltrialsregister.eu/) (searched 7 April 2015).

Searching other resources

We planned to search reference lists of all included studies and other relevant publications, such as systematic reviews and guidelines. We contacted experts in the field to identify any completed or ongoing trials. We planned to contact the authors of relevant publications to identify any completed or ongoing trials. We also performed manual searches of conference proceedings to identify authors and papers related primarily to wound-care teams for the prevention or treatment, or both, of pressure ulcers.

Data collection and analysis

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

Selection of studies

Two review authors (ZM and RS) independently screened all titles and abstracts retrieved by the searches, and excluded those that clearly did not meet the inclusion criteria. We obtained the full text of one remaining paper, which three review authors (ZM, JW and RS) assessed for eligibility (Stern 2014). We subsequently excluded this study.

Data extraction and management

We planned to extract data from eligible studies using a data extraction sheet developed for this purpose. Specifically, we planned to extract the following information:

- author, title, source;
- date of study, country of origin;
- care setting;
- inclusion and exclusion criteria;
- baseline participant characteristics;
- sample size calculation;
- number of participants randomised to each arm;
- study design details;
- trial quality (method of randomisation; allocation concealment; blinding of the participant and outcome assessor; completeness of reporting);
- intervention details (specifically team composition and focus of the intervention), concurrent intervention(s);
- primary and secondary outcomes (with definitions);
- length of follow-up;
- loss to follow-up;
- outcomes data for primary and secondary outcomes (by group);
- intention-to-treat (ITT) analysis;
- funding source;
- conflicts of interest.

Two review authors were to extract data independently; we would have resolved any differences in opinion by discussion and, where necessary, reference to the Wounds Group editorial base. If data were missing from reports, we intended to make attempts to contact study authors to obtain the missing information. We planned to enter data into Review Manager 5 software (RevMan 2011).

Assessment of risk of bias in included studies

We planned to assess included studies using The Cochrane Collaboration tool for assessing risk of bias (Higgins 2011a). This tool addresses six specific domains: sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other issues (e.g. extreme baseline imbalance). We planned to present our assessment of risk of bias using a 'Risk of bias' summary figure, which shows a summary of all of the risk of bias items. We planned to assess the comparability of individually randomised trials however, no studies met the inclusion criteria (Higgins 2011b).

Measures of treatment effect

For dichotomous outcomes (e.g. number of wounds healed), we planned to calculate the risk ratio (RR) with 95% confidence intervals (CI). For continuously distributed outcome data (e.g. health-related quality of life), we planned to use the mean difference (MD) with 95% CIs.

We planned to report time-to-event data (e.g. time to complete wound healing) as 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 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 was unlikely that the mean is 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

We planned to check unit of analysis issues if we included cluster-RCTs. If required, and if sufficient data were available, we planned to recalculate results using the appropriate unit of analysis (Higgins 2011b). We also planned to note whether participants, or ulcers, had been randomised. Where there was evidence that multiple ulcers on a single person had been analysed incorrectly (i.e. by considering outcomes for multiple ulcers as independent), we planned seek further information from the trialist.

For cluster-RCTs that used analysis methods to account for the clustering, we planned to extract effect sizes and standard errors (SE) from the appropriate analysis.

Dealing with missing data

Where possible, we planned to perform all analyses using the ITT principle, that is, participants were to be 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 would have assumed that those missing from the analysis of dichotomous data had a negative outcome (e.g. developed a pressure ulcer or did not completely heal).

For continuous data, where SDs were missing, we planned to compute them from SE using the formula SD = SE x $\sqrt{N}$ (Higgins 2011c). If this was not possible, we planned to impute SDs from similar continuous outcome data and use sensitivity analyses to assess the impact of the assumptions we made (i.e. using small or large SDs) (Higgins 2011b). 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

We planned to assess clinical heterogeneity in terms of how comparable trials were according to their inclusion criteria, intervention and outcome measures. We planned to assess statistical heterogeneity by visual inspection of forest plots, using the Chi^2 test with significance set at 0.10, and using the I^2 statistic, which examines the percentage of total variation across studies that is due to heterogeneity rather than chance (Higgins 2003). Where I^2 values were 40% or less, we would have considered heterogeneity to be low, and where I^2 values exceeded 75%, we would have considered it to be high.

Assessment of reporting biases

We planned to assess reporting bias using guidelines in the *Cochrane Handbook for Systematic Reviews 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 would also have considered selective reporting (i.e. reporting some outcomes and not others) in our assessment of reporting bias.

Data synthesis

Initially we planned to present a structured narrative summary of the study reviewed. Quantitative data were to be entered into Review Manager for analysis (RevMan 2011). If included studies were sufficiently similar in terms of population, inclusion criteria, interventions and outcomes (including the times at which outcomes were assessed in both intervention and treatment trials), we planned to pool the data statistically, using meta-analysis. We planned to use a fixed-effect model if appropriate (i.e. when I^2 values were 40% or less), otherwise we planned to use a random-effects model. We planned not to pool data where the I^2 values were greater than 75%. A summary of results from the data synthesis and assessment of quality of evidence were to be included in a 'Summary of findings' table for the main comparisons. We planned to combine cluster-RCTs with individually randomised trials in the same meta-analysis, using subgroups to assess the effect of the randomisation method. We planned to explore the possibility of important differences in the effects being evaluated in the different types of trials before conducting a meta-analysis (Higgins 2011b). We planned to include trials that reported time-to-event data as continuous, using means or medians, but we planned to report results from these trials in the narrative and we planned not to include these results in any meta-analyses.

'Summary of findings' tables

To assess the overall body of evidence, we planned to develop a 'Summary of findings' table using GRADE profiler (GRADEpro). We planned to assess the quality of the body of evidence against five principle domains: limitations in design and implementation; indirectness of evidence or generalisability of findings; inconsistency of results - for example unexplained heterogeneity and inconsistent findings; imprecision of results where confidence intervals are wide; and other potential biases, for example publication bias or high manufacturer involvement (Schunemann 2011).

Subgroup analysis and investigation of heterogeneity

If substantial heterogeneity had existed between studies for the primary outcomes (i.e. when the I^2 statistic exceeds 50%), we planned to explore reasons for heterogeneity. We envisaged that the number of studies meeting our inclusion criteria may be low. Consequently, to avoid type 1 errors, we planned to conduct a minimal number of sub-analyses that would include the following, if possible:

- acute care versus residential care;
- type of wound-care team (e.g. single discipline versus multidisciplinary);
- type of intervention (single-factor versus multi-factorial).

Sensitivity analysis

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

RESULTS

Description of studies

Results of the search

The search yielded 198 citations. ZM and RS examined the abstracts of all papers, independently, to assess for potential relevance. Following this assessment, no papers met the inclusion criteria. RS contacted 28 experts in the field enquiring about further potential papers, and no further papers were identified. JW identified one paper on searching Clinicaltrials.com (Stern 2014), which we excluded (see Characteristics of excluded studies).

Included studies

No study met the inclusion criteria.

Excluded studies

We excluded one study from this review as this paper involved a cluster randomised step-wedge design and was analysed in such a way that we were unable to extract data for any of our outcomes (Stern 2014). We contacted the trial investigator but he was unable to provide us with further information (see Characteristics of excluded studies).

Risk of bias in included studies

Allocation

No study met the inclusion criteria.

Blinding

No study met the inclusion criteria.

Incomplete outcome data

No study met the inclusion criteria.

Selective reporting

No study met the inclusion criteria.

Other potential sources of bias

No study met the inclusion criteria.

Effects of interventions

No study met the inclusion criteria.

DISCUSSION

Pressure ulcers are common, costly and impact negatively on health-related quality of life. The incidence and prevalence of pressure ulcers are often used as measures of quality of care provided for people with or at risk of pressure ulcers and as such many healthcare providers are investing significantly in measures aimed at reducing the occurrence of these wounds. Recent developments in healthcare delivery have placed a greater emphasis on healthcare providers working together in teams with the aim of enhancing clinical outcomes. Within the field of pressure ulcer prevention and management, such teams have become more prevalent. One publication exploring the concept of a team approach to wound care noted, following an iterative review of the literature, that there were 24 pressure ulcer studies published in this field (Moore 2014). The majority of studies were descriptive and observational with the exception of one randomised intervention trial which was excluded from this review as this paper involved a cluster randomised step-wedge design and was analysed in such a way that we were unable to extract data for any of our outcomes. Team Interventions were multifaceted, lacked homogeneity and mainly described the impact of these interventions without the use of a control group. A reduction in pressure ulcer prevalence after team intervention was reported in all of the studies; however, there was a lack of clarity surrounding which elements, or group of elements, contributed most to the outcome so other concurrent factors may have influenced pressure ulcer reduction, for example, changes in clinical practice, electronic medical records and new technology or speciality beds (Moore 2014). The variety of methods employed within the studies included by Moore 2014 impact on bias, which reduces the ability to draw conclusions that would be useful to the reader. Therefore, as yet, the precise impact of teams has not be assessed from a rigorous systematic review perspective. Therefore, we set out to evaluate the RCT evidence pertaining to the impact of wound-care teams on the prevention and management

of pressure ulcers. No study met the inclusion criteria, therefore, it remains unclear whether wound-care teams make a difference to the incidence or healing of pressure ulcers. From a health policy perspective, this is important given the drive for increased inter-professional collaboration in education and practice, which is thought to be the key to providing the best care, enhancing clinical and health-related outcomes, and strengthening the healthcare system as a whole (WHO 2010).

Summary of main results

No study met the inclusion criteria.

Overall completeness and applicability of evidence

No study met the inclusion criteria.

Quality of the evidence

No study 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. None of the review authors has any conflict of interest. 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

There have been many systematic reviews addressing the impact of teams in health care in chronic diseases such as heart failure (Holland 2005) and mental illness (Simmonds 2001; Malone 2007), in people at risk of poor nutrition (Naylor 2004) and people with leg or foot ulcers (Nordheim 2014). None of these reviews have focused on pressure ulcer prevention and management. The fact that Nordheim 2014 identified only one RCT to include in their review, suggests that, in the field of wound care, there is a lack of RCT evidence exploring the impact of wound-care teams. Due to the lack of studies and reviews in this area, we are unable to conclude whether this review agrees or disagrees with other studies or reviews.

AUTHORS' CONCLUSIONS

Implications for practice

Pressure ulcers are a common, costly and debilitating condition. Use of teams to prevent and manage pressure ulcers is advocated; however, there is no evidence from independently funded clinical trials to support or refute the use of wound-care teams for this purpose. Despite this, international guidelines in the field of wound care recommend the use of a team approach for preventing and treating pressure ulcers (Moore 2014). Additional research is needed to demonstrate the effect of the team approach clearly.

Implications for research

The evidence base for use of wound-care teams to prevent and manage pressure ulcers is very limited, despite the wide use of these teams. Further trials are justified, based on the incidence of the problem and the high costs associated with pressure ulcer prevention and management. 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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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Study	Reason for exclusion
Stern 2014	Employed a cluster step-wedge design and data could not be extracted for any of our outcomes

DATA AND ANALYSES

This review has no analyses.

APPENDICES

Appendix 1. Risk of bias criteria

1. Was the allocation sequence randomly generated?

Low risk of bias

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

High risk of bias

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

Unclear

Insufficient information about the sequence generation process to permit 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: using an open random allocation schedule (e.g. a list of random numbers); assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or nonopaque or not sequentially numbered); alternation or rotation; date of birth; case record number; any other explicitly unconcealed procedure.

Unclear

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

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 judged that the outcome and the outcome measurement were not likely to be influenced by lack of blinding.
- Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others was unlikely to introduce bias.

High risk of bias

Any one of the following.

- No blinding or incomplete blinding, and the outcome or outcome measurement was likely to be influenced by lack of blinding.
- Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, and the non-blinding of others was likely to introduce bias.

Unclear

Either of the following.

- Insufficient information available to permit judgement of low or high risk of bias 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 were 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 was 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 was not enough to have a clinically relevant impact on observed effect size.
- Missing data were imputed using appropriate methods.

High risk of bias

Any one of the following.

- Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with the observed event risk was 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 was enough to induce clinically relevant bias in observed effect size.
- 'As-treated' analysis done with substantial departure in the intervention received from that assigned at randomisation.
- Potentially inappropriate application of simple imputation.

Unclear

Either of the following.

- Insufficient reporting of attrition/exclusions to permit judgement of low or high risk of bias (e.g. number randomised not stated, no reasons for missing data provided).
- The study did not address this outcome.

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

Low risk of bias

Either of the following.

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

High risk of bias

Any one of the following.

- Not all of the study's pre-specified primary outcomes were reported.
- One or more primary outcomes was 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 was provided, such as an unexpected adverse effect).
- One or more outcomes of interest in the review were reported incompletely so that they could not be entered in a meta-analysis.
- The study report did not include results for a key outcome that would be expected to have been reported for such a study.

Unclear

Insufficient information was 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 appeared to be free of other sources of bias.

High risk of bias

There was at least one important risk of bias. For example, the study:

- had a potential source of bias related to the specific study design used; or
- had extreme baseline imbalance; or
- was claimed to have been fraudulent; or
- had some other problem.

Unclear

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

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

Appendix 2. Search strategies for Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL

Ovid MEDLINE

1 exp Patient Care Team/
2 ((care or health or healthcare or medical or nursing or interdisciplinary or multidisciplinary or multidimensional or wound* or turn*) adj team*).tw.
3 (team nursing or nurse-led or nurse-centred or team-based).tw.
4 or/1-3
5 exp Pressure Ulcer/
6 (pressure adj (ulcer* or sore* or injur*)).tw.
7 (decubitus adj (ulcer* or sore*)).tw.
8 (bedsore* or bed sore*).tw.
9 or/5-8
10 4 and 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 (animals not (humans and animals)).sh.
20 18 not 19
21 10 and 20

Ovid EMBASE

1 exp patient care/
2 ((care or health or healthcare or medical or nursing or interdisciplinary or multidisciplinary or multidimensional or wound* or turn*) adj team*).tw.
3 (team nursing or nurse-led or nurse-centred or team-based).tw.
4 or/1-3
5 exp decubitus/
6 (pressure adj (ulcer* or sore* or injur*)).tw.
7 (decubitus adj (ulcer* or sore*)).tw.
8 (bedsore* or bed sore*).tw.
9 or/5-8
10 4 and 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

S25 S12 AND S24
S24 S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23
S23 MH "Quantitative Studies"
S22 TI placebo* or AB placebo*
S21 MH "Placebos"
S20 TI random* allocat* or AB random* allocat*
S19 MH "Random Assignment"
S18 TI randomi?ed control* trial* or AB randomi?ed control* trial*
S17 AB (singl* or doubl* or trebl* or tripl*) and AB (blind* or mask*)
S16 TI (singl* or doubl* or trebl* or tripl*) and TI (blind* or mask*)
S15 TI clinic* N1 trial* or AB clinic* N1 trial*
S14 PT Clinical trial
S13 MH "Clinical Trials+"
S12 S6 AND S11
S11 S7 OR S8 OR S9 OR S10
S10 TI (bedsore or bed sore) or AB (bedsore or bed sore)
S9 TI (pressure N1 (ulcer* or sore* or injur*)) OR AB (pressure N1 (ulcer* or sore* or injur*))
S8 TI decubitus or AB decubitus
S7 (MH "Pressure Ulcer")
S6 S1 OR S2 OR S3 OR S4 OR S5
S5 TI ("team nursing" or nurse-led or nurse-centred or team-based) OR AB ("team nursing" or nurse-led or nurse-centred or team-based)

S4 TI (((care or health or healthcare or medical or nursing or interdisciplinary or multidisciplinary or multidimensional or wound* or turn*) N1 team*)) OR AB (((care or health or healthcare or medical or nursing or interdisciplinary or multidisciplinary or multidimensional or wound* or turn*) N1 team*))
S3 (MH "Total Patient Care Nursing")
S2 (MH "Team Nursing")
S1 (MH "Multidisciplinary Care Team+")

CONTRIBUTIONS OF AUTHORS

Zena Moore: conceived, designed and co-ordinated the review; extracted data, checked quality of data extraction, and analysed and interpreted data; undertook and checked quality assessment; wrote and edited the review; advised on the review; approved the final version of the review prior to submission and is a guarantor of the review.

Joan Webster: conceived and designed the review; checked quality of the data extraction and analysed and interpreted data; checked quality assessment; wrote and edited the review; advised on the review; approved the final version of the review prior to submission and is a guarantor of the review.

Ray Samuriwo: extracted data, checked quality of data extraction, and analysed and interpreted data; undertook and checked quality assessment; wrote and edited the review; advised on the review; wrote to study authors; approved the final version of the review prior to submission and is a guarantor of the review.

Contributions of the editorial base

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

Jo Dumville: edited the review; advised on methodology, interpretation and review content; approved the final review prior to submission.

Sally Bell-Syer: co-ordinated the editorial process; advised on methodology, interpretation and content; edited the review.

Amanda Briant: designed the search strategy, ran the searches and edited the search Methods section.

DECLARATIONS OF INTEREST

The author, Zena Moore, has received an honorarium for speaking at professional meetings for ConvaTec, Vancive and Covidien.

Joan Webster: nothing to declare.

Ray Samuriwo: nothing to declare.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

None.

INDEX TERMS

Medical Subject Headings (MeSH)

Patient Care Team [*organization & administration]; Pressure Ulcer [prevention & control; *therapy]

MeSH check words

Humans