



Cochrane Wounds Group Reviews and Review Updates

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Psychological interventions for treating foot ulcers, and preventing their recurrence, in people with diabetes

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Citation example: McGloin H, Devane D, McIntosh CD, Winkley K, Gethin G. Psychological interventions for treating foot ulcers, and preventing their recurrence, in people with diabetes. *Cochrane Database of Systematic Reviews 2021, Issue 2. Art. No.: CD012835.* DOI: 10.1002/14651858.CD012835.pub2.

ABSTRACT

Background: Diabetic foot ulceration (DFU) can be defined as a full-thickness wound below the ankle and is a major complication of diabetes mellitus. Despite best practice, many wounds fail to heal, and when they do, the risk of recurrence of DFU remains high. Beliefs about personal control, or influence, on ulceration are associated with better engagement with self-care in DFU. Psychological interventions aim to reduce levels of psychological distress and empower people to engage in self-care, and there is some evidence to suggest that they can impact positively on the rate of wound healing.

Objectives: To evaluate the effects of psychological interventions on healing and recurrence of DFU.

Search methods: In September 2019, we searched the Cochrane Wounds Specialised Register; the Cochrane Central Register of Controlled Trials (CENTRAL), Ovid MEDLINE (including In-Process & Other Non-Indexed Citations), Ovid Embase, Ovid PsycINFO and EBSCO CINAHL Plus. We also searched clinical trials registries for ongoing and unpublished studies, and reviewed refer-

ence lists of relevant included studies as well as reviews, meta-analyses and health technology reports to identify additional studies. There were no restrictions with respect to language, date of publication or study setting.

Selection criteria: We included randomised controlled trials (RCTs) and quasi-RCTs that evaluated psychological interventions compared with standard care, education or another psychological intervention. Our primary outcomes were the proportion of wounds completely healed; time to complete wound healing; time to recurrence and number of recurrences.

Data collection and analysis: Four review authors independently screened titles and abstracts of the studies identified by the search strategy for eligibility. Three authors independently screened all potentially relevant studies using the inclusion criteria and carried out data extraction, assessment of risk of bias and GRADE assessment of the certainty of the evidence.

Main results: We identified seven trials that met the inclusion criteria with a total of 290 participants: six RCTs and one quasi-RCT. The studies were conducted in Australia, the USA, the UK, Indonesia, Norway and South Africa. Three trials used a counselling-style intervention and one assessed an intervention designed to enhance an understanding of well-being. One RCT used a biofeedback relaxation training intervention and one used a psychosocial intervention based on cognitive behavioural therapy. A quasi-RCT assessed motivation and tailored the intervention accordingly.

Due to the heterogeneity of the trials identified, pooling of data was judged inappropriate, and we therefore present a narrative synthesis. Comparisons were (1) psychological intervention compared with standard care and (2) psychological intervention compared with another psychological intervention.

We are uncertain whether there is a difference between psychological intervention and standard care for people with diabetic foot ulceration in the proportion of

wounds completely healed (two trials, data not pooled, first trial RR 6.25, 95% CI 0.35 to 112.5; 16 participants, second trial RR 0.59, 95% CI 0.26 to 1.39; 60 participants), in foot ulcer recurrence after one year (two trials, data not pooled, first trial RR 0.67, 95% CI 0.32 to 1.41; 41 participants, second trial RR 0.63, 95% CI 0.05 to 7.90; 13 participants) or in health-related quality of life (one trial, MD 5.52, 95% CI -5.80 to 16.84; 56 participants). This is based on very low-certainty evidence which we downgraded for very serious study limitations, risk of bias and imprecision.

We are uncertain whether there is a difference in the proportion of wounds completely healed in people with diabetic foot ulceration depending on whether they receive a psychological intervention compared with another psychological intervention (one trial, RR 2.33, 95% CI 0.92 to 5.93; 16 participants). This is based on very low-certainty evidence from one study which we downgraded for very serious study limitations, risk of bias and imprecision.

Time to complete wound healing was reported in two studies but not in a way that was suitable for inclusion in this review. One trial reported self-efficacy and two trials reported quality of life, but only one reported quality of life in a manner that enabled us to extract data for this review. No studies explored the other primary outcome (time to recurrence) or secondary outcomes (amputations (major or distal) or cost).

Authors' conclusions: We are unable to determine whether psychological interventions are of any benefit to people with an active diabetic foot ulcer or a history of diabetic foot ulcers to achieve complete wound healing or prevent recurrence. This is because there are few trials of psychological interventions in this area. Of the trials we included, few measured all of our outcomes of interest and, where they did so, we judged the evidence, using GRADE criteria, to be of very low certainty.

Plain language summary

Do psychological therapies help diabetic foot ulcers to heal and prevent their recurrence?

Background: Diabetes is a condition that causes high levels of sugar in the blood. Blood sugar levels are controlled by insulin, a hormone made by the pancreas. Insulin instructs the liver, muscles and fat cells to remove sugar from the blood and store it. When the pancreas does not make enough insulin, or the body does not respond to insulin, too much sugar stays in the blood.

High blood sugar can damage the nerves in the body's extremities (such as the hands or feet) and cause numbness. This means that if someone with diabetes cuts their foot by stepping on a sharp object, or develops blisters on their feet, they might not be aware of it. Blisters may develop into open wounds or sores, known as diabetic

foot ulcers (DFU). These can be slow to heal, because diabetes damages blood vessels and this restricts blood supply – and the oxygen and nutrients blood carries, which are necessary for healing. If left untreated, ulcers can become infected. In severe cases, amputation of a toe, foot, or more, may be necessary.

People with DFU may feel distressed about their wounds and the impact these have on their life. This can reduce chances of ulcers healing, and make them more likely to reappear. Psychological therapies might improve ulcer healing and prevent reappearance, by helping people to feel that they can manage their diabetes and overcome DFU.

What did we want to find out? We wanted to find out if psychological therapies improve DFU healing and prevent their reappearance. We also wanted to know if they affect the number of amputations, quality of life, cost of treatment and people's belief that they can manage the condition, in addition to comparing the effects of different psychological therapies.

Our methods: We searched for relevant randomised controlled trials, in which the treatment each person receives is chosen at random. These studies give the most reliable evidence about the effects of a treatment. We then compared the results, and summarised the evidence from all the studies. We assessed how certain the evidence was by considering factors such as the way studies were conducted, study sizes, and consistency of findings across studies. Based on our assessments, we categorised the evidence as being of very low, low, moderate or high certainty.

What we found: We found seven studies that involved 290 people with diabetes who were followed up for between six weeks and six months. The studies were conducted in Australia, the USA, Norway, Indonesia, South Africa and the UK. The psychological therapies investigated were:

- counselling (three studies);
- muscle relaxation (one study);
- individually-tailored motivation (one study);
- a therapy that aims to develop a person's understanding of well-being (one study);
- group-based cognitive behavioural therapy (one study).

Psychological therapies compared to usual care: We do not know if psychological therapies improve healing of DFU, or prevent ulcer reappearance, because the evidence is of very low certainty.

Different psychological therapies compared to each other

We do not know if some psychological therapies have more of an effect than others on healing of DFU or preventing ulcer reappearance. This is because either no studies investigated this, or the evidence is of very low certainty.

We do not know if psychological therapies have an effect on the time it takes for ulcers to reappear, amputation, quality of life or a person's belief in their ability to manage their condition, because there were either no or too few studies investigating this. No studies reported information about the cost of psychological therapies.

What does this mean? There is no robust evidence about the effects of psychological therapies on DFU healing and recurrence.

There is a need for high-quality studies that include enough people to detect a potential effect of psychological therapies on ulcer healing or reappearance. It would be helpful to agree on a set of clear measures to include in all future studies, so that results from different studies could be compared and analysed together.

How-up-to date is this review? The evidence in this Cochrane Review is current to September 2019.

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Patient and lay carer education for preventing pressure ulceration in at-risk populations

Tom O'Connor, Zena EH Moore, Declan Patton

Citation example: O'Connor T, Moore ZEH, Patton D. Patient and lay carer education for preventing pressure ulceration in at-risk populations.

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ABSTRACT

Background: Pressure ulcers (PUs) are injuries to the skin and underlying tissues that occur most commonly over bony prominences, such as the hips and heels as a result of pressure and shear forces. PUs cause pain, discomfort, longer hospital stays, and decreased quality of life. They are also very costly to treat and consume substantial parts of healthcare budgets. PUs are largely preventable, and education targeted at patients and their carers is considered important.

Objectives: To assess the effects of patient and/or lay carer education on preventing pressure ulceration in at-risk people, in any care setting.

Search methods: In June 2019 we searched the Cochrane Wounds Specialised Register; the Cochrane Central Register of Controlled Trials (CENTRAL); Ovid MEDLINE (including In-Process & Other Non-Indexed Citations); Ovid Embase; Ovid PsycINFO and EBSCO CINAHL Plus. We also searched clinical trials registries for ongoing and unpublished studies. There were no restrictions with respect to language, date of publication or study setting.

Selection criteria: We included randomised controlled trials (RCTs) that recruited people of any age at risk of pressure ulceration, and RCTs that recruited people who informally care for someone at risk of pressure ulceration.

Data collection and analysis: Two review authors independently performed study selection, data extraction, 'Risk of bias' assessment, and GRADE assessment of the certainty of the evidence.

Main results: We included 10 studies with 11 publications (2261 participants analysed). Seven targeted their intervention at people at risk of ulceration and measured outcomes on these at risk people; two targeted those at risk and their family carers and measured outcomes on the at risk people cared for by their families; and one targeted lay carers only and measured outcomes on the at risk people they cared for. There were two main types of interventions: the provision of information on prevention of pressure ulcers, and the use of different types of education programmes.

Provision of information on the prevention of pressure ulcers: Three studies (237 participants) reported data for this comparison: two provided information directly to those at risk and their carers, and the third provided information to lay carers. As data could not be pooled we present individual study data. The evidence for primary outcomes is of very low certainty (downgraded twice for study limitations and twice for imprecision).

We are uncertain whether the combined use of a self-instruction manual and one-to-one patient training and counselling versus a self-instruction manual alone reduces the proportion of at risk people developing a new PU (risk ratio (RR) 0.40, 95% confidence interval (CI) 0.14 to 1.18), or whether carer self-instruction and one-to-one counselling versus self-instruction alone reduces the proportion of at risk people developing a new PU (RR 2.05, 95% CI 0.19 to 21.70).

We are uncertain whether the use of home-based training, compared with routine ward-based training, reduces

the proportion of at risk people developing a new PU (RR 0.53, 95% CI 0.27 to 1.02).

One study explored the secondary outcome patient knowledge of pressure ulcer prevention; however, as usable data were not provided, we were unable to carry out further analysis, and no effect estimate could be calculated.

Educational programmes on the prevention of pressure ulcers: Seven studies (2024 participants analysed) provided data for this comparison. In all studies the intervention was aimed at people at risk of ulceration.

Risk of pressure ulceration: One secondary report of an included study reported the primary outcome as time to PU development or occurrence and three studies and one secondary report of an included study reported this as the proportion of at risk people developing a new PU. One study reported the secondary outcome grade of PU and five studies and one secondary report of an included study reported on patient knowledge.

There is low certainty evidence of there being no clear difference in the proportion of participants developing a new PU between use of a pressure ulcer prevention care bundle (PUPCB) and standard care: HR 0.58, 95% CI 0.25 to 1.33 (downgraded twice for imprecision).

One secondary report of an included study explored whether individualised PU education and monthly structured telephone follow-up changes the mean time to PU occurrence. Not all participants in this study developed a pressure ulcer, therefore the mean time to pressure ulcer occurrence could not be calculated from the data.

We are uncertain whether the following three interventions reduce the proportion of at risk people developing a new PU as we assessed the certainty of evidence as very low: individualised PU education and monthly structured telephone follow-up (RR 0.55, 95% CI 0.23 to 1.30), education delivery (RR 3.57, 95% CI 0.78 to 16.38), (downgraded twice for risk of bias and twice for imprecision); and computerised feedback and one-to-one consultations (no clear data provided), (downgraded twice for risk of bias and once for indirectness).

Grade of pressure ulcer: There is low certainty evidence that use of a PU prevention care bundle may make no difference to the severity of new PU development when compared with standard care.

Patient knowledge: We are uncertain whether the following interventions improve patient knowledge: enhanced educational intervention and structured follow-up (mean difference (MD) 9.86, 95% CI 1.55 to 18.17); multi component motivational interviewing/self-management with a multi component education intervention (no clear data provided); Spinal Cord Injury Navigator pro-

gramme (no clear data provided); individualised PU education and monthly structured telephone follow-up (no clear data provided); computerised feedback (no clear data provided), structured, patient-centric PU prevention education event (MD 30.15, 95% CI 23.56 to 36.74). We assessed the certainty of the evidence for this outcome as low or very low (downgraded for risk of bias, imprecision, or indirectness).

Authors' conclusions: We are uncertain whether educational interventions make any difference to the number of new PUs that develop, or to patient knowledge based on evidence from the 10 included studies, which we assessed as of low or very low certainty due to problems with risk of bias, serious imprecision and indirectness. The low certainty of evidence means that additional research is required to confirm these results.

Plain language summary

Patient and lay carer education for preventing pressure ulceration in at-risk populations

What is the aim of this review? The aim of this review was to find out whether education programmes aimed at people at risk of developing pressure ulcers (also known as bedsores or decubitus ulcers) and their carers are effective in the prevention of pressure ulcers. We collected and analysed all relevant studies (randomised controlled trials) to answer this question, and found 10 studies with 11 publications for inclusion. Randomised controlled trials are medical studies where the treatment or care that people receive is chosen at random. This type of trial provides the most reliable health evidence.

Key messages: In all studies, it is uncertain whether educational interventions make any difference to the proportion of at risk people developing a new ulcer, or to patient or lay carer knowledge.

What was studied in the review? Pressure ulcers are wounds that occur on the skin or underlying tissues. People who cannot move and change position (such as those using wheelchairs, or in long-term nursing and hospital care) are at most risk of developing pressure ulcers. These wounds can cause pain, discomfort, and distress and have a negative effect on quality of life. Preventing pressure ulcers is therefore very important. Educating people about the risks of pressure ulcers and how to prevent them is considered to be an important part of preventative care.

What are the main results of the review? We found 10 relevant studies, with 11 publications, (2261 participants analysed) dating from 2002 to 2018 comparing interventions aimed at educating people at risk of developing pressure ulcers or their carers. Four studies (five publications) included people with spinal cord injuries, mainly males, with a mean age of less than 60 years. The remaining studies included both males and females of

varying ages, some who had disorders of the central nervous system, and others who were other types of at risk people cared for in hospital or in the community. Seven studies focused on people at risk of pressure ulcers; two focused on at risk people and carers; and one focused on lay carers. The interventions tested aimed to prevent pressure ulcers either by providing people with written information or by involving them in a variety of educational programmes. The studies explored the impact of the interventions on at risk people, either 1) the number of new pressure ulcers developed, 2) the severity of pressure ulcers developed, or 3) patient knowledge. None of the studies explored patient or lay carer satisfaction with the interventions.

Two studies (three publications) were funded by the Department of Veterans Affairs (USA). Two studies were funded by the National Institute for Disability and Rehabilitation Research (USA). One study was funded by the Department of Health Policy Research Programme (UK); one study by the Post Graduate Institute of Medical Education and Research (Chandigarh, India); one study by the Indian Council of Medical Research (New Delhi, India); and one study by the National Health and Medical Research Council (Australia). Two studies did not outline any source of funding.

The results of the trials do not allow us to draw any firm conclusions regarding the effectiveness of educational interventions in preventing pressure ulcers, or in increasing patient knowledge about pressure ulcer prevention. The certainty of the evidence in these trials is low or very low.

How up-to-date is this review? We searched for studies that had been published up to June 2019.

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Wound cleansing for treating venous leg ulcers

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Citation example: McLain NEM, Moore ZEH, Avsar P. Wound cleansing for treating venous leg ulcers. *Cochrane Database of Systematic Reviews 2021, Issue 3. Art. No.: CD011675.*
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ABSTRACT

Background: Leg ulcers are open skin wounds that occur below the knee but above the foot. The majority of leg ulcers are venous in origin, occurring as a result of venous insufficiency, where the flow of blood through the veins is impaired; they commonly arise due to blood

clots and varicose veins. Compression therapy, using bandages or stockings, is the primary treatment for venous leg ulcers. Wound cleansing can be used to remove surface contaminants, bacteria, dead tissue and excess wound fluid from the wound bed and surrounding skin, however, there is uncertainty regarding the effectiveness of cleansing and the best method or solution to use.

Objectives: To assess the effects of wound cleansing, wound cleansing solutions and wound cleansing techniques for treating venous leg ulcers.

Search methods: In September 2019 we searched the Cochrane Wounds Specialised Register; the Cochrane Central Register of Controlled Trials (CENTRAL); Ovid MEDLINE (including In-Process & Other Non-Indexed Citations); Ovid Embase and EBSCO CINAHL Plus. We also searched clinical trials registries for ongoing and unpublished studies, and scanned reference lists of relevant included studies as well as reviews, meta-analyses and health technology reports to identify additional studies. There were no restrictions with respect to language, date of publication or study setting.

Selection criteria: We considered randomised controlled trials (RCTs) comparing wound cleansing with no wound cleansing, or RCTs comparing different wound cleansing solutions, or different wound cleansing techniques.

Data collection and analysis: We screened studies for their appropriateness for inclusion, assessed their risk of bias using the Cochrane 'Risk of bias' tool, and used GRADE methodology to determine the certainty of evidence. Two review authors undertook these tasks independently, using predetermined criteria. We contacted study authors for missing data where possible.

Main results: We included four studies with a total of 254 participants. All studies included comparisons between different types of cleansing solutions, and three of these reported our primary outcomes of complete wound healing or change in ulcer size over time, or both. Two studies reported the secondary outcome, pain. One study (27 participants), which compared polyhexamethylene biguanide (PHMB) solution with saline solution for cleansing venous leg ulcers, did not report any of the review's primary or secondary outcomes. We did not identify any studies that compared cleansing with no cleansing, or that explored comparisons between different cleansing techniques.

One study (61 participants) compared aqueous oxygen peroxide with sterile water. We are uncertain whether aqueous oxygen peroxide makes any difference to the number of wounds completely healed after 12 months of follow-up (risk ratio (RR) 1.88, 95% confidence interval (CI) 1.10 to 3.20). Similarly, we are uncertain whether

aqueous oxygen peroxide makes any difference to change in ulcer size after eight weeks of follow-up (mean difference (MD) -1.38 cm², 95% CI -4.35 to 1.59 cm²).

Finally, we are uncertain whether aqueous oxygen peroxide makes any difference to pain reduction, assessed after eight weeks of follow-up using a 0 to 100 pain rating, (MD 3.80, 95% CI -10.83 to 18.43). The evidence for these outcomes is of very low certainty (we downgraded for study limitations and imprecision; for the pain outcome we also downgraded for indirectness).

Another study (40 participants) compared propyl betaine and polihexanide with a saline solution. The authors did not present the raw data in the study report so we were unable to conduct independent statistical analysis of the data. We are uncertain whether propyl betaine and polihexanide make any difference to the number of wounds completely healed, change in ulcer size over time, or wound pain reduction. The evidence is of very low certainty (we downgraded for study limitations and imprecision).

The final study (126 participants) compared octenidine dihydrochloride/phenoxethanol (OHP) with Ringer's solution. We are uncertain whether OHP makes any difference to the number of wounds healed (RR 0.96, 95% CI 0.53 to 1.72) or to the change in ulcer size over time (we were unable to conduct independent statistical analysis of available data). The evidence is of very low certainty (we downgraded for study limitations and imprecision).

None of the studies reported patient preference, ease of use of the method of cleansing, cost or health-related quality of life. In one study comparing propyl betaine and polihexanide with saline solution the authors do not report any adverse events occurring. We are uncertain whether OHP makes any difference to the number of adverse events compared with Ringer's solution (RR 0.58, 95% CI 0.29 to 1.14). The evidence is of very low certainty (we downgraded for study limitations and imprecision).

Authors' conclusions: There is currently a lack of RCT evidence to guide decision making about the effectiveness of wound cleansing compared with no cleansing and the optimal approaches to cleansing of venous leg ulcers. From the four studies identified, there is insufficient evidence to demonstrate whether the use of PHMB solution compared with saline solution; aqueous oxygen peroxide compared with sterile water; propyl betaine and polihexanide compared with a saline solution; or OHP compared with Ringer's solution makes any difference in the treatment of venous leg ulcers. Evidence from three of the studies is of very low certainty, due to study limitations and imprecision. One study did not present data for the primary or secondary outcomes. Further well-designed studies that address important clinical, quality

of life and economic outcomes may be important, based on the clinical and patient priority of this uncertainty.

Plain language summary

Does cleaning venous leg ulcers help them to heal?

Background: Leg ulcers are open skin wounds that develop below the knee, usually because blood flow is poor in the lower leg. This can occur because of blockages, for example when small blood clots form in the veins. It can also happen when the valves (flaps) in the veins that prevent blood from flowing backwards stop working properly. Poor blood flow damages the skin and tissue, and creates venous leg ulcers.

Ulcers are unsightly and may become painful or infected. On average, ulcers take from six to nine months to heal. However, some ulcers can take years to heal, and a small number never do. Once ulcers have healed, they can reoccur.

The main treatment for venous leg ulcers is to use bandages or stockings that compress the leg (compression therapy), to increase blood flow in the veins. It is also thought to be important to clean the wound. Different types of cleaning solutions can be used, including: normal saline; water; antiseptics (solutions that stop or slow down the growth of micro-organisms such as bacteria); detergents (solutions that remove bacteria and dirt); or disinfectants (solutions such as bleach, that kill micro-organisms).

Cleaning solutions can be applied to the ulcer using a swab (similar to a cotton bud), a syringe with a needle, or a spray canister. Ulcers can also be bathed in the cleaning solution, using a basin or bucket, or during a shower. Cleaning can cause discomfort, and may be painful.

What did we want to find out?

We wanted to find out:

- whether cleaning venous leg ulcers helps them to become smaller and heal;
- whether some cleaning solutions, or methods of applying solutions, are more effective than others;
- which cleaning solution people prefer and find easiest to use;
- whether cleaning wounds has an impact on quality of life;
- how much cleaning wounds costs; and
- whether cleaning wounds is associated with adverse (unwanted) effects such as pain, infection or skin damage.

Our methods: First, we searched for randomised controlled studies (clinical studies where the treatment or care people receive is chosen at random). These studies provide the most reliable health evidence about the effects of a treatment. We then compared the results and summarised the evidence from all the studies. Finally, we rated our confidence in the evidence, based on factors such as study methods and sizes, and the consistency of findings across studies.

What we found: We found four studies that involved a total of 254 people with venous leg ulcers. There were 108 men and 144 women, all over 18 years old (information about gender was missing for two people).

The studies compared the effects of:

- a disinfectant and antiseptic agent (polyhexamethylene biguanide) applied using a syringe with a needle to flush (irrigate) the ulcer with fluid, against a salt (saline) solution;
- a gentle spray of a bleaching and antiseptic agent (aqueous oxygen peroxide, which is ozone dissolved in water), against sterile water;
- a detergent (propyl betaine combined with polyhexanide), against a saline solution – method of application not reported; and
- an antiseptic (octenidine dihydrochloride combined with phenoxylethanol) sprayed onto the wound, against a solution of several salts dissolved in water (Ringer's solution).

No studies compared cleaning with no cleaning, or compared different cleaning methods.

We cannot tell whether cleaning wounds is beneficial or associated with any unwanted effects. This is because we have too little confidence in the evidence available regarding healing, changes in ulcer size, pain and unwanted effects. No study reported on patient preference, ease of use, cost or impact on quality of life.

What does this mean? We do not know whether cleaning solutions are better than sterile water or saline solutions to help venous leg ulcers heal, or whether the choice of cleaning solution or method of application makes any difference to venous leg ulcer healing. Our confidence in the available evidence is very low. The results of our review are likely to change if more evidence becomes available.

How up-to-date is this review? The evidence in this Cochrane Review is current to September 2019. ■