

THE ROLE OF PSYCHOSOCIAL FACTORS IN DIABETIC FOOT ULCERS

Diabetic foot ulcers can lead to amputation and increased mortality, so it is always important to address all the risk factors involved. Two new reviews address how psychosocial factors, and interventions based on psychosocial factors, influence prevention and healing of foot ulcers. Their findings could help influence diabetic footcare ▶

PHOTO: ADOBE STOCK

Foot ulceration may affect up to 25% of those with diabetes during their lifetime, and approximately 1–4% of people with diabetes have a foot ulcer at any one time. A diabetic foot ulcer can be difficult to heal and may recur. Those with an unhealed foot ulcer have a poorer quality of life, increased risk of amputation and a higher mortality rate at five years. The burden of diabetic foot ulcers at both a personal and health service level is considerable. Depression commonly co-exists in a third of those with a foot ulcer, and this is associated with a threefold higher risk of mortality. And the cost of treatment of diabetic foot ulcers to the NHS in England was estimated at £837m to £962m in 2014–2015. Risk factors for developing a foot ulcer include increased age, male sex, longer duration of diabetes, loss of sensation in the foot, peripheral arterial disease and previous history of ulceration. Several of these factors are also involved in non-healing.

For prevention of foot ulcers, guidelines recommend identification of the at-risk foot, regular checks, wearing appropriate footwear and modification of risk factors. Interventions for active ulcers include pressure offloading and protection of the ulcer, ulcer debridement and removal of callus. Of course, people with diabetes themselves play a role in both prevention and management of foot ulcers. One study suggests that up to 75% of foot ulcers could be prevented with adequate adherence to interventions.

Two new reviews highlight the role of psychosocial and behavioural factors in diabetic foot ulcers. The first looks at psychosocial and behavioural prognostic factors for diabetic foot ulcer development and healing, while the second investigates the effectiveness of psychosocial interventions for the prevention and treatment of diabetic foot ulcers. The findings suggest this is an area worthy of further research, in

order to understand how best to target psychosocial factors to improve outcomes in this common diabetes complication

Review 1. Psychosocial factors in diabetic foot ulcers

Maggie Westby of the Division of Nursing, Midwifery and Social Work at the University of Manchester and her team have carried out an extensive review of the literature on how psychosocial and behavioural factors affecting people with diabetes predict adverse foot outcomes (ulceration, non-healing and amputation). Psychosocial factors can be emotional (eg depression), cognitive (eg coping style) or social (eg social support). Behavioural factors include foot self-care and adherence to interventions like offloading. The authors consider that these factors could be independent prognostic factors for ulceration and healing. Possible mechanisms could include the way these factors affect pathophysiological processes or how they impact the effectiveness of interventions. Psychosocial factors may, in themselves, influence behavioural factors.

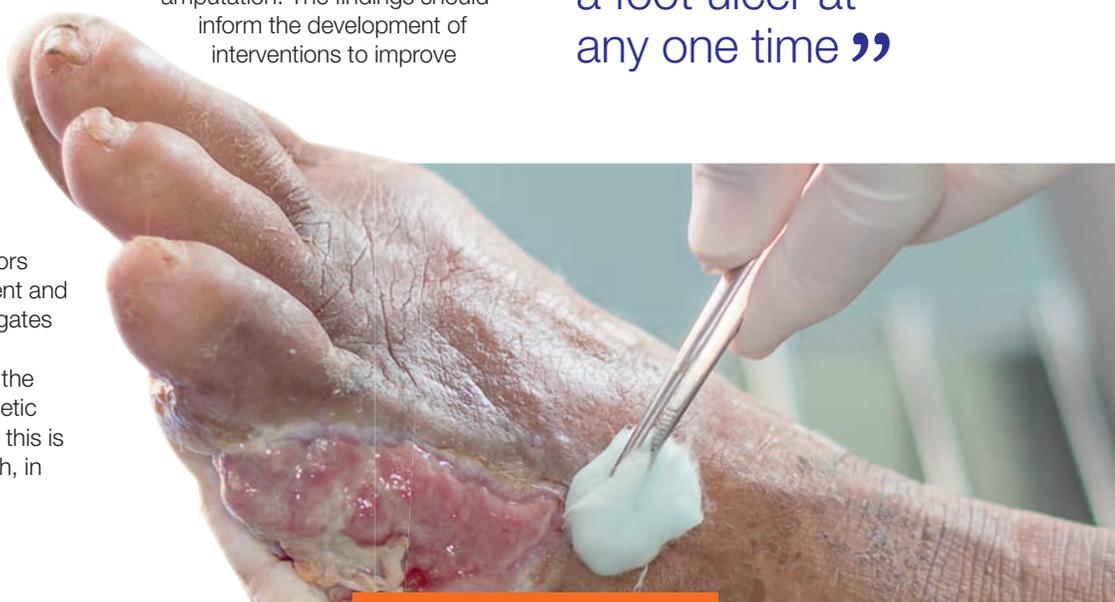
The authors believe this is the first systematic review of the evidence on the independent impact of psychosocial and behavioural prognostic factors on future ulceration, healing and amputation. The findings should inform the development of interventions to improve

adverse diabetic foot outcomes. And with the advent of virtual clinics in recent months, it should be remembered that seeing an at-risk foot is always a priority.

The psychosocial factor review details

The authors selected longitudinal studies investigating the prognostic value of psychosocial and behavioural factors in foot ulceration, healing or amputation. They included randomised controlled trials analysed as cohort studies where they took account of interventions in their analyses. Case-control studies were included where there were no cohort studies for a particular prognostic factor-outcome combination. Cross-sectional studies and qualitative studies were not considered, and no minimum follow-up period was specified. Studies in people living with any type of diabetes and a foot ulcer were included for investigation of healing and amputation and among those without a current foot ulcer for studying the development of new ulcers.

“Approximately 1–4% of people with diabetes have a foot ulcer at any one time”



Foot facts

25%

of people with diabetes will be affected by foot ulceration in their lifetime

£837M

estimated cost to NHS for diabetic foot ulcers 2014–2015

The following types of prognostic factor were studied:

- emotional (depression, anxiety, stress, mood, guilt, blame)
- cognitive (coping, illness beliefs, self-efficacy)
- social (social support, social isolation)
- behaviour related to feet (inspecting feet, reporting changes in foot health, using recommended footwear, adherence to offloading, taking physical activity)

Lifestyle factors directly unrelated to feet, like smoking and alcohol consumption, were excluded, along with education and knowledge and non-modifiable social factors like socioeconomic status.

The following primary outcome measures were recorded:

- for development of foot ulceration – foot ulceration, changes in foot risk, ulcer-free time
- for healing – complete healing with rate of reduction of ulcer area as a secondary outcome
- for amputation – major (above the ankle) and minor amputation

After the literature search from the main medical databases to 29 March 2019, the researchers applied data analysis, quality assessment, data synthesis and analysis. A total of 4,090 records were retrieved from their search, and they ended up with 15 studies that fitted their criteria.

Results

The 15 studies selected included 12,312 participants. Eleven of them had a cohort design, 10 were prospective and one retrospective. Four of them analysed data from randomised controlled trials. Most of the participants had type 2 diabetes, and nine of them had over 70% male participants.

Results were grouped under the subheadings of: emotional, cognitive, foot self-care behaviour, adherence behaviour and physical activity. Nine of the studies reported ulceration, with a follow-up time ranging from 12 months

“This is the first systematic review of the evidence on the independent impact of psychosocial and behavioural prognostic factors on future ulceration”

to a median of 5.4 years. Five studies reported ulcer healing and another reported reduction in ulcer size at six weeks. Three reported amputation at 12 months and 18 months in those with an ulcer at the start of the study.

High clinical and/or methodological heterogeneity precluded meta-analysis. The researchers judged the evidence in the review to be generally of low or very low quality, because of high to moderate risk of bias, inconsistency in the direction of association and imprecision. Bias arose from lack of full adjustment for what the authors consider to be key confounding factors, such as age, sex, education and ethnicity, ulcer area and longstanding illness. However, the review does record various useful snapshots from the studies considered.

Overall, the researchers found that three studies consistently suggested that depression may be associated with increased ulceration in people with diabetes without prior ulcers. But it is unclear whether this applies to those who did have prior ulcers. There was evidence from one study that depression may be associated with amputation, but the findings for healing were inconsistent in three studies. There was only limited evidence for the influence of anxiety and coping, and this was restricted to associations with ulcer healing. A small ▶

We've got lots of resources to help you deliver quality footcare to your patients

Our footcare pathway helps healthcare professionals to identify the level of risk of a foot problem in people with diabetes and escalate their care appropriately. It includes a detailed checklist for carrying out an annual foot check, as well as how to advise people with diabetes to take care of their feet. You access this resource at www.diabetes.org.uk/up-foot-pathway.

If you need printed information, we've got leaflets that you can order for free or download from our shop. You can find all of these leaflets at www.diabetes.org.uk/up-foot-leaflets.



Ten simple steps outlines some key lifestyle changes that anyone with diabetes can make to keep their feet in good health.

What to expect at your annual foot check is to support people before and during their foot check, detailing what to expect and what information they should have before they leave.



Reduce your risk of a serious foot problem explains what it means to be at high risk of a foot problem and what signs to look out for, so

that they can seek emergency help as quickly as possible.

75%

of foot ulcers could be prevented with adequate adherence to interventions



study suggested that confrontation coping was associated with less healing, with uncertainty about the role of anxiety. One large study that suggested that scores on the EQ-5D anxiety-depression subscale show little or no association with healing, while its impact on amputation is uncertain.

Evidence from three studies on foot self-care behaviours suggests that people with diabetes, but without prior ulcers, who examine their feet and check their shoes are less likely to develop foot ulcers. For those with prior ulcers, there is no clear association. Three small studies looked at different adherence behaviours. They found that adherence to footwear may not be associated with ulceration in people with diabetes and prior ulcers, adherence to offloading may be associated with increased healing, while poorer adherence to clinic appointments may be associated with greater risk of amputation. Finally, evidence from two studies suggests that physical activity may be linked to less ulceration for those with and without prior ulcers. But it is not clear whether physical activity is associated with healing.

Evidence suggests that ulcer history could affect the magnitude and direction of influence of the various prognostic factors. In those without previous ulcers, depression and poor foot self-care behaviour independently predict ulceration. But among those with a previous ulcer, there may be a general

lack of association of psychosocial and behavioural factors with ulceration. However, this evidence was of low or very low quality, and there might be alternative explanations for differences between ulcer history populations, such as treatment of previous ulcers and contact with healthcare professionals. Very few studies explored possible mechanisms for the effect of psychosocial and behavioural factors. Those that did were limited to looking at the role of foot self-care as a mediator of the association between depression and ulcer incidence.

Conclusions

This systematic review summarises the best available evidence for the impact of psychosocial and behavioural factors on adverse foot outcomes. Risk of bias and the quality of evidence were assessed. The investigation was, however, limited by the analytical approaches adopted by the primary studies and the disparate methods of measurement of the prognostic factors.

In conclusion, the evidence does suggest that psychosocial and behavioural factors could well determine outcomes, such as occurrence of first ulceration, healing and amputation. There was moderate-quality evidence for a link between depression and increased ulceration risk among those with no previous ulcer. And there was

“There is a need for clinicians and clinical guidelines to take psychosocial and behavioural factors into account, alongside pathophysiology”

also low-quality evidence in this group for an association between better foot self-care and decreased ulceration risk. However, the authors say that more research is needed to determine whether these prognostic factors affect outcomes in those who have a history of ulceration.

Another fruitful area for investigation would be the underlying mechanisms by which these factors affect foot outcomes in people who are living with diabetes. Meanwhile, the authors argue that there is a need for clinicians and clinical guidelines to take psychosocial and behavioural factors into account, alongside pathophysiology, when caring for people with, or at risk of, diabetic foot ulcers.

“ During the period 2014–2015, £1 in every £140 spent by the NHS in England was consumed by the costs of managing the diabetic foot, and this is rising ”

Review 2. Psychosocial interventions for diabetic foot ulcers

Gill Norman, also from the school of Nursing, Midwifery and Social Work at the University of Manchester, and her team have carried out a literature review of the evidence for the effectiveness of psychosocial interventions to promote the prevention, or healing, of diabetic foot ulcers. As has been stated above, adverse psychosocial factors may lead to poorer foot outcomes. So, one might expect effective interventions to lead to an improvement in these outcomes.

The psychosocial intervention review details

The researchers included randomised controlled trials involving participants with type 1 or type 2 diabetes, with or without active foot ulceration, where they assessed any individual or group psychological, behavioural or social intervention alone, or in combination. Examples included cognitive behavioural therapy, motivational interviewing, counselling, psychological therapy, social support and mindfulness. They included cluster-randomised trials but excluded quasi-randomised studies. They also included studies involving exercise or educational interventions, if they had a psychosocial component and involved more than printed materials. Any comparator was eligible, including alternative interventions, usual care and no treatment.

Primary outcomes were ulceration and complete healing. Secondary foot-related outcomes were rate of wound healing, amputation, standardised diabetes foot ulcerations risk assessment, footcare knowledge or behaviours and foot-related adverse events. Studies had to report a foot-related outcome to be included.

The researchers also assessed:

- mortality
- non-foot-ulcer-related adverse events
- general and diabetes-related health behaviour and indicators
- social activity/participation
- psychological outcomes (depression, anxiety and stress)
- health-related quality of life.

Medical databases were searched to March 2019, and 31 studies were found, enrolling 4,511 people. Of these, 24 assessed interventions for preventing ulceration and seven assessed interventions for treating ulceration in those with existing ulcers. Sample sizes ranged from 13 to 530, and most participants had type 2 diabetes.

The psychosocial interventions were diverse but with some common approaches. Many involved some element of footcare education, particularly when it came to prevention.

Results and discussion

The researchers note that the quality of methods and reporting were suboptimal in all the intervention studies. Many were affected by bias. Thus, all evidence considered was of low or very-low quality. Assessment also found severe limitations in the level of detail reported for the interventions, with more recent studies demonstrating better reporting. Many studies did not report a robust theoretical basis for the intervention, and only five reported information on adherence.

The review gives a number of brief descriptive snapshots of the various studies. Overall, the researchers conclude that the focus in intervention studies has remained upon educational interventions. The researchers point out that during the period 2014–2015, £1 in every £140 spent by the NHS in England was consumed by the costs of managing the diabetic foot, and these

Psychological approaches were more common in treatment studies. All the interventions involved face-to-face sessions, evenly divided between small group and one-on-one delivery. Most were delivered by healthcare practitioners – usually nurses – in outpatient clinics, inpatient clinics or participants' homes. Follow-up time ranged from 30 days to 10 years.

Many of the studies focused on behavioural, knowledge and psychological outcomes. Only nine of 24 prevention studies reported ulceration rates and only two of seven treatment studies reported complete healing. Seven reported amputation and three reported mortality.

costs are rising. If there are to be improvements in foot ulcer outcomes for patients and healthcare providers alike, then robust trial evidence of psychosocial interventions with a strong theoretical basis that examine the impact on clinical outcomes is urgently needed. These trials need to be appropriately powered, with adequate follow-up to assess effectiveness and, ultimately, amputation. Trials in people with active ulceration should ideally assess time to healing and re-ulceration. Finally, future trials should refer to the ongoing COMET initiative, which will provide a core outcome set for management of foot ulceration in people with diabetes. A new focus on research into the role of psychosocial factors and interventions could inform healthcare professionals and people living with diabetes alike how best to meet the challenge of the diabetic foot.

i This is a digested version of Westby M, Norman G, Vedhara K et al (2020). Psychosocial and behavioural prognostic factors for diabetic foot ulcer development and healing: a systematic review. *Diabetic Medicine* 37, 1244–1255 and Norman G, Westby M, Vedhara K

et al (2020). Effectiveness of psychosocial interventions for the prevention and treatment of foot ulcers in people with diabetes: a systematic review. *Diabetic Medicine* 37, 1256–1265. To download the articles, go to: <https://doi.org/dme.14310> and <https://doi.org/dme.14326>