



STUDY PROTOCOL

REVISED

Psychological factors and diabetic foot ulceration: a scoping review of the bi-directional relationship between diabetic foot ulcer healing and mental health factors [version 2; peer review: 1 approved with reservations, 1 not approved]

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Abstract

Introduction

Diabetic foot ulceration (DFU) is a major complication of diabetes and is associated with high morbidity and mortality rates. Psychological factors are believed to play a role in wound healing, but it remains uncertain if psychological interventions can help individuals with an active DFU, or a history of DFUs, to achieve complete or improved wound healing or prevent recurrence.

Objective

Open Peer Review

Approval Status ? X

1

2

version 2

(revision)

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version 1

18 Apr 2024

?

view

X

view

1. **Raquel Marques**^{id}, Universidade Católica Portuguesa, Institute of Health Sciences, Porto, Portugal

The objective of the proposed scoping review is to investigate the emotional consequences/burden of living with DFU and to examine how psychosocial factors may impact progression and management of ulcerations.

Methods

This review will be conducted in accordance with the Joanna Briggs Institute methodology for scoping reviews and the Preferred Reporting Items for Systematic reviews and Meta-Analysis extension for Scoping Reviews (PRISMA-ScR) will guide the reporting of results.

Discussion

While factors such as stress, depression, social support, and adherence to treatment have been identified as variables that may negatively affect DFU healing, there is a need for a greater understanding of how psychological and behavioural variables such as these may influence ulcer incidence, healing and recurrence in people with diabetes. This review will comprise of a broad and systematically mapped synthesis of the identified data. Findings will be used to provide a better understanding of the bi-directional relationship between DFU and psychological variables and will provide direction for the development or adaptation of a tailored psychological intervention that will aim to optimise wellbeing and improve outcomes for individuals with DFU.

Keywords

Diabetic foot ulcer; wound healing; emotions; psychology; psychosocial impact; psychological intervention; scoping review

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Any reports and responses or comments on the article can be found at the end of the article.



This article is included in the [Public and Patient Involvement](#) collection.

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Author roles: **Hanlon M:** Conceptualization, Formal Analysis, Investigation, Methodology, Project Administration, Validation, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing; **McGuire B:** Conceptualization, Funding Acquisition, Investigation, Methodology, Supervision, Validation, Visualization, Writing – Review & Editing; **MacGilchrist C:** Conceptualization, Investigation, Methodology, Supervision, Validation, Visualization, Writing – Review & Editing; **Dunne R:** Methodology, Validation, Visualization, Writing – Review & Editing; **Kirwan E:** Methodology, Validation, Writing – Review & Editing; **Ní Neachtain D:** Validation, Visualization, Writing – Review & Editing; **Dhatariya K:** Methodology, Validation, Visualization, Writing – Review & Editing; **Blanchette V:** Methodology, Validation, Visualization, Writing – Review & Editing; **Durand H:** Methodology, Validation, Writing – Review & Editing; **Dragomir A:** Methodology, Validation, Writing – Review & Editing; **McIntosh C:** Conceptualization, Funding Acquisition, Investigation, Methodology, Supervision, Validation, Visualization, Writing – Review & Editing

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REVISED Amendments from Version 1

This article has been updated following feedback from reviewers. The introduction now focuses on complex wounds and the many challenges associated with them, rather than providing a background on diabetes, and the discussion now contains a more comprehensive overview of previous research that has been conducted in the area.

Any further responses from the reviewers can be found at the end of the article

Introduction

Living with a complex wound presents numerous multifaceted challenges that significantly impact an individual's physical, psychological, and socio-economic well-being (Gouin & Kiecolt-Glaser, 2011). Characterized by their prolonged healing process, susceptibility to infection, and need for specialized care, complex wounds demand continuous medical attention and meticulous self-management (Harlin *et al.*, 2009). As they can cause significant pain, restricted mobility, and a diminished ability to perform daily activities, a decline in overall physical and mental health is common (Upton, 2014). Individuals may also withdraw from activities they previously enjoyed due to mobility issues or the stigma associated with visible wounds, so social isolation may occur. Furthermore, the financial strain caused by potential loss of employment and the cost of continuous medical care can add to the overall burden of managing a complex wound, intensifying the distress experienced by patients and their families. When diabetes is present all of these challenges are further exacerbated as the individual is then also predisposed to prolonged wound healing due to a complex pathophysiology involving vascular, neuropathic, immune, and biochemical components (Spampinato *et al.*, 2020).

Diabetic foot ulcers are a type of complex wound that are notoriously difficult to heal and necessitate rigorous daily wound care that places a substantial burden on the medical system, patients and caregivers (Frykberg & Banks, 2015; Greenhalgh, 2003). Defined as a full-thickness wound (a wound that penetrates dermal tissues) below the ankle in a person with currently or previously diagnosed diabetes mellitus, diabetic foot ulceration (DFU) is usually accompanied by neuropathy and/or peripheral artery disease in the lower extremity (Hoogveen *et al.*, 2015; IWGDF, 2023; van Netten *et al.*, 2016). The progression and outcomes from DFU are worsened by a number of complications associated with living with diabetes and there is a high risk of recurrence. Chronic ulceration can lead to adverse patient outcomes and complications, including sepsis and amputation above or below the knee (Armstrong *et al.*, 2017). Irish data has shown that the lifetime risk of an individual with diabetes mellitus undergoing an amputation was 22.3 times that of an individual without diabetes mellitus and it has been suggested that up to 85% of such amputations are preceded by a non-healing DFU (Buckley *et al.*, 2012). There is also significant mortality associated with DFUs, with up to 50% of patients not surviving five years post amputation. In people

with diabetes mellitus who have a 'high risk' foot or an active foot ulcer, the risk of premature death is up to nine times the risk of amputation due to the underlying co-morbid diabetes and the risk of premature cardiovascular disease (Vadiveloo *et al.*, 2018).

Rationale for this study

Early intervention for DFU is listed as a key priority in both national and international guidelines and strategies (HSE: Model of Care for the Diabetic Foot, 2021; International Working Group of the Diabetic Foot (IWGDF, 2023); NHS: National DiabetesFoot Care Audit, 2022). However, despite this international consensus on care delivery based on risk, a systematic review of prevention strategies concluded that the evidence base for interventions to prevent first foot ulcers is 'practically non-existent' (van Netten *et al.*, 2016). This same review of interventions to prevent recurrent ulcers found there is strong evidence for self-management and footwear interventions but weak evidence for other interventions. A recent Cochrane systematic review (McGloin *et al.*, 2021) also highlighted the limited psychological interventions that currently exist for patients with DFU and the need for more robust studies in this area. The review recognised the potential impact psychological wellbeing has on wound healing in DFU but also demonstrated that there is a dearth of RCTs in this area, which could be due to the fact that there are very few specialist psychologists working in this field. As a result of the limited number of RCTs available, there is a high risk of bias so conclusions cannot be drawn. A scoping review was thus selected for this study as this methodology will allow synthesis and appraisal of the wider evidence-base, including non-RCT designed studies. A scoping review is also considered the most appropriate methodology to broadly map the key sources and types of evidence available on the area of interest, and identify gaps for further research, when the extent and nature of the research is largely unknown (Arksey & O'Malley, 2005; Pham *et al.*, 2014).

Methods

This review is being conducted to (a) investigate the emotional and psychosocial burden of living with DFU and (b) identify psychological variables that may lead to poor outcomes in DFU. The aim of this review will thus be to understand how psychological factors may impact behaviour, progression of the disease, and management of the condition, in order to make sure that psychological interventions will target the most important factors. The review will be conducted in accordance with the Joanna Briggs Institute methodology for scoping reviews (Peters *et al.*, 2020) and the Preferred Reporting Items for Systematic reviews and Meta-Analysis extension for Scoping Reviews (PRISMA-ScR) will guide the reporting of results (Tricco *et al.*, 2018).

Principal terminology definitions

Complex wound: In recent years, chronic wounds have been described as "complex wounds," in order to represent the multifactorial dynamic tissue healing process that is involved (Hall *et al.*, 2014; Labib & Winters, 2024). For a wound to be classified as a complex wound, it must show one of the following features (Ferreira *et al.*, 2006): 1) Persistent for

more than three months; 2) Compromised vascularity or necrosis; 3) Presence of infection; 4) Associated comorbidities impair healing potential.

Diabetic Foot Ulcer (DFU). DFU is defined as an infection, ulceration, or destruction of tissues of the foot of a person with currently or previously diagnosed diabetes mellitus, usually accompanied by neuropathy and/or peripheral artery disease in the lower extremity (IWGDF, 2023).

Emotional wellbeing. Emotional wellbeing refers to a person's overall mental and emotional state of being, characterized by the ability to manage and regulate emotions, cope with stress and adversity, and experience a sense of life satisfaction and overall psychological functioning (Huppert & So, 2013).

Psychosocial wellbeing. Psychosocial wellbeing refers to the combination of psychological and social factors that contribute to an individual's overall sense of well-being (Eisenberg *et al.*, 2007). Encompassing an individual's mental, emotional, social, and spiritual well-being, psychosocial wellbeing can be impacted by a variety of internal and external factors such as cultural and societal norms, physical health, economic status, personal relationships, and life experiences.

Behavioural factors. Behaviour refers to observable actions and processes that are initiated in response to external or internal stimuli that are received (Furr, 2009). Factors that may influence or affect human behaviour include individual characteristics (*i.e.*, the individual's personal disposition, ideology and belief systems, general knowledge, and personality characteristics), interpersonal factors (*i.e.*, the individual's relationships, social support network, and spiritual or religious relations), institutional factors (*i.e.*, the individual may behave differently due to the rules, regulations, and informal structures that exist within the community that they reside in or the organization that they work in) and community factors (*i.e.*, an individual's behaviour may be directly or indirectly influenced by the available resources which they have access to in their community and the associated societal norms).

Wound healing. A healed wound or complete wound closure can be defined as 100% re-epithelialization of the wound without drainage (Armstrong *et al.*, 2017). However, wound healing in diabetic foot ulcers is a complex process. In diabetes, several biological elements can adversely affect ulcer healing including persistent and impaired inflammation, loss of protective sensation, motor neuropathy causing abnormal biomechanics, peripheral arterial disease, and infection (Rayman *et al.*, 2020). The management of diabetic foot ulcers (DFUs) remains a challenge, thus proper wound care is critical to facilitate healing in diabetic foot ulcers. This includes cleaning the wound, keeping it moist, and protecting it from further injury or infection. Other treatment options may include debridement (removal of dead tissue), off-loading (reducing pressure on the ulcer), and various types of wound dressings or advanced therapies such as hyperbaric oxygen therapy or negative

pressure wound therapy. Systemic factors such as age, gender or sex, stress levels, medication (steroids, NSAIDs), alcohol use, smoking and diet may also impact wound healing (Chhabra *et al.*, 2017). The management of lifestyle factors, blood sugar levels, infection, and other underlying medical conditions is essential for successful healing of diabetic foot ulcers (Alexiadou & Doupis, 2012).

DFU Recurrence. A new foot ulcer in a person who has a history of foot ulceration, irrespective of location and time since previous foot ulcer (IWGDF, 2023)

Protocol

This protocol is structured according to the steps suggested by Arksey and O'Malley (2005). Any deviations from the protocol will be tracked on the review's Open Science Framework project page. The protocol was registered with the Open Science Framework on 17 November 2022 (DOI: [10.17605/OSF.IO/U5JDW](https://doi.org/10.17605/OSF.IO/U5JDW)).

Stage 1: Identifying the research question

As recommended by the Joanna Briggs Institute (2015), the PCC (Population/ participants, Concept and Context) framework was used to cultivate the research questions for this scoping review. This framework acts as a guide to facilitate the construction of a clear and meaningful title and the development of subsequent question(s) for a scoping review. For the current review, the authors are interested in individuals with diabetic foot ulceration (P) and exploring how living with this condition impacts their emotional and social wellbeing (C) in order to investigate if psychosocial factors influence the progression or reoccurrence of ulceration (C).

Research Questions

1. What are the psychological and emotional consequences of living with diabetic foot ulceration?
2. Do psychosocial factors influence progression or reoccurrence of ulceration in patients who have diabetic foot ulceration?

Stage 2: Identifying relevant studies

Eligibility criteria. The PCC framework that was used for developing the research questions will inform inclusion and exclusion criteria, and consequently the literature search strategy (Peters *et al.*, 2020). A justification will be provided for all exclusion criteria and any given limitations that are required (Pollock *et al.*, 2021; Tricco *et al.*, 2018). The review will consider both qualitative and quantitative primary research in the English language and between the years 2002 and 2022, to ensure currency of content. Unpublished (grey literature) will also be included. See Table 1 for full inclusion and exclusion criteria.

Search strategy

An expert university librarian has been part of the research team from the start of this scoping review. They have assisted with designing and refining the search strategy and provided

Table 1. Inclusion and exclusion criteria.

Category	Inclusion criteria	Exclusion criteria
The condition	Publications that report on the: <ul style="list-style-type: none"> • epidemiology of diabetic foot ulcers. • associated mortality and/or morbidity of diabetic foot ulcers. • cost to the health service of diabetic foot ulcers • natural history or pathophysiology of diabetic foot ulcers. 	<ul style="list-style-type: none"> • Any publication about diabetes that does not relate to the diabetic foot.
Emotional implications	Publications that report on: <ul style="list-style-type: none"> • emotional responses experienced as a result of living with diabetic foot ulcer 	<ul style="list-style-type: none"> • Any publication that explores the emotional implications of living with diabetes but does not explore diabetic foot specifically.
Psychosocial impact	Publications that report on: <ul style="list-style-type: none"> • psychosocial impacts experienced as a result of living with diabetic foot ulcer 	<ul style="list-style-type: none"> • Any publication that explores the psychosocial impacts of living with diabetes as a condition but does not look at the diabetic foot.
Wound healing	Publications that report on: <ul style="list-style-type: none"> • emotional and psychosocial factors and their impact on wound healing in diabetic foot ulcer 	<ul style="list-style-type: none"> • Any publication that looks at the role that emotional and psychosocial factors have on wound healing but does not explore this in relation to the diabetic foot specifically.

guidance on how best to adapt these terms for individual databases. This input is crucial to ensure the search strategy and results are transparent and auditable.

A three-step search strategy will be utilised for the scoping review. First, an initial search of two databases, PubMed and PsycINFO, will be undertaken, followed by an analysis of the text words contained in the title and abstract of retrieved papers. Using the PCC framework, ideas will be expanded using search terms and appropriate thesaurus terms and synonyms. A second search using all identified keywords and index terms will then be undertaken across all included databases. Databases to be searched include the Cochrane Database of Systematic Reviews, OVID (Medline), EMBASE (Elsevier), CINAHL (EBSCO), PsycINFO (EBSCO), SCOPUS and Web of Science Core Collection. Thirdly, the reference lists of identified reports and articles will be searched for additional sources. A search for grey material will also be carried out within ProQuest E-Thesis Portal, and Lenus. See [Table 2](#) for search strategy development.

Stage 3: Study selection

Screening for this review will be conducted within Covidence, a systematic review data management system <https://www.covidence.org/> (Covidence, 2019). Covidence is a core component of the Cochrane review production toolkit and has also been endorsed by the Joanna Briggs Institute. An open access alternative such as Rayyan (<https://www.rayyan.ai/>) could also be used.

Pilot testing will be conducted prior to embarking on source selection. This will involve the research team selecting a sample of 25 titles and abstracts at random and two members (MH and EK) independently screening them using the

pre-defined eligibility criteria and definitions. The team will then meet and if any discrepancies have been identified these will be discussed and modifications will be made to the eligibility criteria and definitions if required. Screening will start once an agreement rate of 75% (or greater) is achieved. Using the pre-specified inclusion and exclusion criteria, two reviewers will independently screen each title and abstract. A third independent reviewer will be consulted and make the final decision regarding inclusion if consensus is not reached between the two reviewers.

The process of study selection will be reported using a PRISMA flow diagram (Tricco *et al.*, 2018), which will then be updated once the review is completed.

Stage 4: Charting the data

The research team will design a data charting tool, as set out by the PRISMA-ScR Checklist (Tricco *et al.*, 2018), to which the following information will be extracted by two members of the research team:

- Author(s)
- Year of publication
- Study title
- Origin/country of origin/origins (where the source was published or conducted)
- Aims/purpose
- Context
- Population
- Sample size

Table 2. Search strategy development.

	Concept 1	Concept 2	Concept 3	Concept 4
Key concepts	The Condition (Diabetic Foot Ulcer)	Emotional implications (Living with Diabetic Foot Ulcer)	Psychosocial impact (Managing/living with Diabetic Foot Ulcer)	Wound Healing (Effect emotional and psychosocial factors- & associated behaviours-have on wound healing in Diabetic Foot Ulcer)
Free text terms / natural language terms	Related Terms & Synonyms: Diabetic foot ulcer Diabetic foot disease Diabetic foot Diabetic foot syndrome	Related Terms & Synonyms: Emotions Feelings Emotional Reactions Emotional Responses Emotional Status Emotional Factors	Related Terms & Synonyms: Psychological factors Psychological behaviours Psychosocial stressors Social aspects Social Behaviours Psychosocial	Related Terms & Synonyms: Ulcer healing Wound: Injury Healing: Recovery Rehabilitation
Controlled vocabulary terms / Subject terms (MeSH terms, Emtree terms)	Diabetic foot diabetic foot feet, diabetic foot, diabetic foot ulcer, diabetic diabetes-kw *Diabetes Mellitus *Diabetes Complications Foot ulcer* plantar ulcer* venous ulcer*.tw. neuropathic ulcer*.tw	*Emotional adjustment emotional adaptation* psychological adjustment emotional intelligence* social intelligence* emotional regulation emotion self-regulation emotional-mp *Anxiety angst anxieties, social nervousness mood, depression distress, stress	*Psychology psychological factor psychological side effect psychology* psychosocial factor* *Clinical psychology Positive psychology *Quality of life HRQL Health related quality of quality sleep quality	Wound healing/ Wound infection/ Debridement/ exp "Wounds and Injuries"/ neuropathic ulcer*.tw. neuropathic wound.tw. foot wound.tw. diabetic wound.tw. chronic wound.tw. (nonhealing* adj3 ulcer*).tw. ("hard to heal" adj3 wound*).tw.

- Study design/intervention type
- Risk of bias
- Key findings that relate to the scoping review question/s.

To ensure that the coding framework is consistently applied, two team members will pilot test the charting table by using a sample (10%) of the complete list of retrieved studies that are to be included. If necessary, modifications to the categories and revisions to the charting table may occur at this stage. Any discrepancies or queries that emerge from the pilot will be discussed by the full team before going ahead with the data extraction process. During this iterative process, the authors are aware that the charting tool may also need to be adjusted to ensure accurate representation of all data sources.

Stage 5: Collating, summarising, and reporting of results

A PRISMA flow diagram will be used to visually represent study selection and reasons for exclusion at full text review. Presentation of the results will be in a visual and aggregate form (e.g., using charts and tables), as well as a descriptive format aligning to the objectives and scope of this review.

Step 6: Consultation with stakeholders

In order to identify any further references and studies that should be included and to gather feedback regarding the scoping review findings, the Arksey and O’Malley framework proposes an optional sixth step that involves consulting with

key stakeholders. The authors of this paper believe this to be a very worthwhile and valuable exercise as it will ensure that the search strategy includes all relevant and appropriate terms and will enhance the relevance of the research overall by gathering feedback on the content. A stakeholder group that included multidisciplinary team members and external collaborators were thus consulted in advance of beginning this review. The group consisted of an independent patient representative (DNN), a clinical psychologist (AD), a podiatrist (VB), a health researcher (HD), and an endocrinologist (KD).

Patient and Public Involvement

Patient and public involvement (PPI) is an important and meaningful part of research. Accordingly, the authors have begun the process of recruiting a panel of patient representatives to this research project. Understanding the complexity of how emotional and psychosocial factors impact DFU development and reoccurrence is key to informing the content of interventions and the research team believe that any intervention that aims to improve outcomes should be designed with the voice of the user in mind. To ensure PPI practice is based on the best evidence, the GRIPP2-SF checklist tool (Staniszewska *et al.*, 2017) will guide reporting of PPI involvement in this study.

Discussion

DFUs impose a major medical, psychological, social, and financial burden upon patients. In addition to the demands associated with the need to frequently attend healthcare

services, effective management of a DFU requires affected individuals to engage in complex, continual, and demanding self-care behaviours. This burden can have a significant impact on quality of life, treatment adherence, and well-being, particularly as the chronic nature of DFUs often leads to prolonged periods of pain, limited mobility, and a constant fear of severe complications such as infection and amputation (Ahmad *et al.*, 2018; Price *et al.*, 2014). From previous research, we know that DFUs also exert a heavy psychological burden on patients and their families (Vileikyte *et al.*, 2020). This has been attributed to reasons such as practical restrictions in daily life, lower social functioning, dependency on others, social deprivation, risk of amputation, increased health care needs, and loss of mobility associated with ulceration severity; which in turn has been associated with feelings of stress, fear, helplessness, and frustration (Hurst *et al.*, 2020; Iversen *et al.*, 2015; Winkley, 2012). A number of studies (Ahmad *et al.*, 2018; Kuang *et al.*, 2021; Margolis *et al.*, 2015; Murphy *et al.*, 2021) have also explored how risk factors such as depression, anxiety, low self-efficacy, and poor health literacy skills may effect DFU development and have examined the effectiveness of psychosocial interventions for the prevention

and treatment of foot ulcers in people with diabetes (Norman *et al.*, 2020). However, more extensive research is required to better understand how psychosocial and emotional factors affect people with a history of ulceration, so that we can explore the mechanisms by which psychosocial and behavioural factors may influence foot outcomes, and develop more appropriate interventions (Vileikyte *et al.*, 2020; Westby *et al.*, 2020). Psychological interventions have the potential to improve quality of life and patient outcomes, as they can provide behavioural techniques and strategies that will help people to manage low mood and stress levels, adhere to treatment recommendations, adjust to living with long-term conditions, and feel more in control of managing their overall health and well-being. Thus, it is important to examine the role that psychological factors may have on wound healing in patients with DFU and to identify psychological interventions that may have a positive impact on psychosocial functioning and reoccurrence of foot ulcerations.

Data availability

No data are associated with this article.

References

- Ahmad A, Abujbara M, Jaddou H, *et al.*: **Anxiety and Depression Among Adult Patients With Diabetic Foot: Prevalence and Associated Factors.** *J Clin Med Res.* 2018; **10**(5): 411–418.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Alexiadou K, Doupis J: **Management of diabetic foot ulcers.** *Diabetes Ther.* 2012; **3**(1): 4.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Arksey H, O'Malley L: **Scoping studies: towards a methodological framework.** *Int J Soc Res Methodol.* 2005; **8**(1): 19–32.
[Publisher Full Text](#)
- Armstrong DG, Boulton AJ, Bus SA: **Diabetic foot ulcers and their recurrence.** *N Engl J Med.* 2017; **376**(24): 2367–2375.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Buckley CM, O'Farrell A, Canavan RJ, *et al.*: **Trends in the incidence of Lower Extremity Amputations in people with and without diabetes over a five-year period in the Republic of Ireland.** *PLoS One.* 2012; **7**(7): e41492.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Chhabra S, Chhabra N, Kaur A, *et al.*: **Wound healing concepts in clinical practice of OMFS.** *J Maxillofac Oral Surg.* 2017; **16**(4): 403–423.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Covidence: Veritas Health Innovation: **Better Systematic Review Management.** 2019.
[Reference Source](#)
- Eisenberg D, Golberstein E, Gollust SE: **Help-seeking and access to mental health care in a university student population.** *Med Care.* 2007; **45**(7): 594–601.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Ferreira MC, Tuma P Jr, Carvalho VF, *et al.*: **Complex wounds.** *Clinics (Sao Paulo).* 2006; **61**(6): 571–578.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Frykberg RG, Banks J: **Challenges in the Treatment of chronic wounds.** *Adv Wound Care (New Rochelle).* 2015; **4**(9): 560–582.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Furr RM: **Personality psychology as a truly behavioural science.** *Eur J Pers.* 2009; **23**(5): 369–401.
[Publisher Full Text](#)
- Gouin JP, Kiecolt-Glaser JK: **The impact of psychological stress on wound healing: methods and mechanisms.** *Immunol Allergy Clin North Am.* 2011; **31**(1): 81–93.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Greenhalgh DG: **Wound healing and diabetes mellitus.** *Clin Plast Surg.* 2003; **30**(1): 37–45.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Hall J, Buckley HL, Lamb KA, *et al.*: **Point prevalence of complex wounds in a defined United Kingdom population.** *Wound Repair Regen.* 2014; **22**(6): 694–700.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Harlin SL, Harlin RD, Sherman TI, *et al.*: **Using a structured, computer-administered questionnaire for evaluating health-related QOL with chronic lower extremity wounds.** *Ostomy Wound Manage.* 2009; **55**(9): 30–39.
[PubMed Abstract](#)
- Hoogveen RC, Dorresteijn JAN, Kriegsman DMW, *et al.*: **Complex interventions for preventing diabetic foot ulceration.** *Cochrane Database Syst Rev.* 2015; **2015**(8): CD007610.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- HSE: **Model of care for the diabetic foot.** 2021.
[Reference Source](#)
- Huppert FA, So TTC: **Flourishing across Europe: application of a new conceptual framework for defining well-being.** *Soc Indic Res* 2013; **110**(3): 837–861.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Hurst JE, Barn R, Gibson L, *et al.*: **Geospatial mapping and data linkage uncovers variability in outcomes of foot disease according to multiple deprivation: a population cohort study of people with diabetes.** *Diabetologia.* 2020; **63**(3): 659–667.
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Iversen MM, Tell GS, Espehaug B, *et al.*: **Is depression a risk factor for diabetic foot ulcers? 11-years follow-up of the Nord-Trøndelag Health Study (HUNT).** *J Diabetes Complications.* 2015; **29**(1): 20–5.
[PubMed Abstract](#) | [Publisher Full Text](#)
- IWGDF Editorial Board: **IWGDF definitions and criteria.** 2023.
[Reference Source](#)
- Kuang D, Gu DF, Cao H, *et al.*: **Impacts of psychological resilience on self-efficacy and quality of life in patients with diabetic foot ulcers: a prospective cross-sectional study.** *Ann Palliat Med.* 2018; **10**(5): 5610–5618.
[PubMed Abstract](#) | [Publisher Full Text](#)
- Labib A, Winters R: **Complex wound management.** [Updated 2023 Jul 4]. In: *StatPearls.* Treasure Island (FL): StatPearls Publishing; 2024.
[Reference Source](#)

Margolis DJ, Hampton M, Hoffstad O, *et al.*: **Health literacy and diabetic foot ulcer healing.** *Wound Repair Regen.* 2015; **23**(3): 299–301.

[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)

McGloin H, Devane D, McIntosh CD, *et al.*: **Psychological interventions for treating foot ulcers, and preventing their recurrence, in people with diabetes.** *Cochrane Database Syst Rev.* 2021; **2**(2): CD012835.

[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)

Murphy PT, Liew A, McGuire BE, *et al.*: **Do personality and mood difficulties predict foot self-care in diabetes?** *J Wound Manag Off J Eur Wound Manag Assoc.* 2021; **22**: 43–54.

[Publisher Full Text](#)

NHS: **National diabetes footcare audit.** 2022.

[Reference Source](#)

Norman G, Westby MJ, Vedhara K, *et al.*: **Effectiveness of psychosocial interventions for the prevention and treatment of foot ulcers in people with diabetes: a systematic review.** *Diabet Med.* 2020; **37**(8): 1256–1265.

[PubMed Abstract](#) | [Publisher Full Text](#)

Peters MDJ, Godfrey CM, McInerney P, *et al.*: **Chapter 11: scoping reviews (2020 version).** In: Aromataris E, Munn Z (Editors). *JBIManual for Evidence Synthesis.* JBI, 2020.

[Publisher Full Text](#)

Pham MT, Rajić A, Greig JD, *et al.*: **A scoping review of scoping reviews: advancing the approach and enhancing the consistency.** *Res Synth Methods.* 2014; **5**(4): 371–385.

[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)

Pollock D, Davies EL, Peters MDJ, *et al.*: **Undertaking a scoping review: a practical guide for nursing and midwifery students, clinicians, researchers, and academics.** *J Adv Nurs.* 2021; **77**(4): 2102–2113.

[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)

Price P, Harding K, van Acker K: **The impact of diabetic foot complications on health-related quality of life.** *Diabet Med.* 2014; **31**(1): 39–45.

Rayman G, Vas P, Dhatariya K, *et al.*: **Guidelines on use of interventions to enhance healing of chronic foot ulcers in diabetes (IWGDF 2019 update).** *Diabetes Metab Res Rev.* 2020; **36** Suppl 1: e3283.

[PubMed Abstract](#) | [Publisher Full Text](#)

Spampinato SF, Caruso GI, De Pasquale R, *et al.*: **The treatment of impaired**

wound healing in diabetes: looking among old drugs. *Pharmaceuticals (Basel).* 2020; **13**(4): 60.

[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)

Stanišzewska S, Brett J, Simera I, *et al.*: **GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research.** *BMJ.* 2017; **358**: j3453.

[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)

The Joanna Briggs Institute: **The Joanna Briggs Institute reviewers' manual 2015 edition.** *Chapter 1: Methodology for JBI Scoping Reviews.* Publisher: the Joanna Briggs Institute. Editors: Edoardo Aromataris, 2015.

[Reference Source](#)

Tricco AC, Lillie E, Zarin W, *et al.*: **PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation.** *Ann Intern Med.* 2018; **169**(7): 467–73.

[PubMed Abstract](#) | [Publisher Full Text](#)

Upton D: **Psychological aspects of wound care: implications for clinical practice.** *J Community Nurs.* 2014; **28**(2): 52–57.

[Reference Source](#)

Vadiveloo T, Jeffcoate W, Donnan PT, *et al.*: **Amputation-free survival in 17,353 people at high risk for foot ulceration in diabetes: a national observational study.** *Diabetologia.* 2018; **61**(12): 2590–2597.

[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)

Vileikyte L, Pouwer F, Gonzalez JS: **Psychosocial research in the diabetic foot: are we making progress?** *Diabetes Metab Res Rev.* 2020; **36** Suppl 1: e3257.

[PubMed Abstract](#) | [Publisher Full Text](#)

van Netten JJ, Price PE, Lavery LA, *et al.*: **Prevention of foot ulcers in the at-risk patient with diabetes: a systematic review.** *Diabetes Metab Res Rev.* 2016; **32** Suppl 1: 84–98.

[PubMed Abstract](#) | [Publisher Full Text](#)

Westby M, Norman G, Vedhara K, *et al.*: **Psychosocial and behavioural prognostic factors for diabetic foot ulcer development and healing: a systematic review.** *Diabet Med.* 2020; **37**(8): 1244–1255.

[PubMed Abstract](#) | [Publisher Full Text](#)

Winkley K, Sallis H, Kariyawasam D, *et al.*: **Five-year follow-up of a cohort of people with their first diabetic foot ulcer: the persistent effect of depression on mortality.** *Diabetologia.* 2012; **55**(2): 303–10.

[PubMed Abstract](#) | [Publisher Full Text](#)

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Version 1

Reviewer Report 21 June 2024

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Hanlon and colleagues describe a protocol for a scoping review of the bi-directional relationship between diabetic foot ulcer healing and mental factors. Specifically, they aim to identify: 1) emotional and psychosocial burden of living with DFU and (b) psychological variables that may lead to poor outcomes in DFU.

I do not believe that a scoping review is the way to answer the bi-directionality question.

1. There are already more published reviews (systematic, scoping etc) than there are original, high-quality studies. An overview of systematic reviews in this area (*Crawford, F et al. Reliability of the evidence to guide decision-making in foot ulcer prevention in diabetes: an overview of systematic reviews. BMC Med Res Methodol* **22**, 274 (2022) identified 30 reviews that collectively assessed 26 largely poor-quality RCTs with substantial overlap. Most of these systematic reviews are at high risk of bias and fail to provide reliable evidence for decision-making.
2. To answer the research question regarding the bi-directional relationships between psychological/emotional factors and DFUs, the authors should conduct a longitudinal, adequately powered study of well-defined (DFU and psychological factors) population to determine: analysis 1: the incidence of DFUs and the associated risk with psychological factors (e.g., depression), and analysis 2: the incidence of e.g., depression and associated risk with DFUs. See [1]

References

1. Golden SH, Lazo M, Carnethon M, Bertoni AG, et al.: Examining a bidirectional association between depressive symptoms and diabetes. *JAMA*. 2008; **299** (23): 2751-9 [PubMed Abstract](#) | [Publisher Full Text](#)

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

No

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: The role of psychological/behavioral factors in patient adaptation to diabetic neuropathy and foot ulceration

I confirm that I have read this submission and believe that I have an appropriate level of expertise to state that I do not consider it to be of an acceptable scientific standard, for reasons outlined above.

Reviewer Report 15 May 2024

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Thank you for submitting this work. These types of studies are needed to contribute to the improvement of care provided to patients with wounds.

The protocol is well-written and easy to follow, with a logical structure.

I have a few comments for the authors:

- In the title add the word protocol
- I suggest choosing different keywords from the title, so your study has more scope, for example: wounds and injuries; Review the literature.
- The introduction of the protocol could explore the challenges of living with a complex wound, the process of healing such wounds, and some risk factors for delayed healing, instead of explaining what diabetes is.
- In the methodology, clearly define the PCC. Review the exclusion criteria, it is not enough to deny the inclusion criteria.
- The discussion can be enriched with what already exists in the literature on the topic.

- References, to mention as 2023 IWGDF Guidelines instead of 2019.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Wound care, complex wound, assessment wound.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.
