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# Prevalence and incidence of mental health issues amongst adults with diabetes at risk of foot complications in the European Union: a systematic review protocol

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## ABSTRACT

**Objective:** The objective of this systematic review is to evaluate and synthesize the evidence to establish the prevalence and incidence of mental health issues in people at risk of diabetic foot ulceration living within the European Union.

**Introduction:** Due to the large health and financial burden of diabetic foot ulceration, prevention is a key focus for clinicians and researchers. Current foot ulcer prevention strategies are directed at the assessment and management of physical pathologies and risk factors for diabetic foot ulceration. Psychological burden and risk factors are often overlooked. This review will determine the prevalence and incidence of mental health issues among adults with diabetes mellitus who are at risk of foot ulceration. The review will focus on European Union countries.

**Inclusion criteria:** Studies considered for inclusion will report on adults with a formal diagnosis of either type 1 or type 2 diabetes mellitus, who are at risk of foot ulceration and mental health issues. Studies will have been completed in the European Union.

**Methods:** A search of MEDLINE, CINAHL, AMED, Embase, Cochrane CENTRAL, and PsycINFO will be conducted for studies published in or translatable into English. Unpublished and gray literature will be searched. Studies will be selected against the review inclusion/exclusion criteria, and selected studies will be critically appraised, with data extraction and synthesis completed using the relevant JBI systematic review tools.

**Systematic review registration:** PROSPERO CRD42021260815

**Keywords:** at-risk foot; diabetes; mental health; psychological; ulceration

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## Introduction

In 2014, the World Health Organization reported that, globally, there were 422 million people diagnosed with diabetes mellitus.<sup>1</sup> Within the United Kingdom (UK), diabetes affects 3.8 million people, and this figure is predicted to increase to 5 million by 2025.<sup>2</sup> As with many long-term conditions, diabetes can affect an individual's physical and psychological

health, affecting well-being and quality of life.<sup>3</sup> Diabetes can cause complications in the feet, such as loss of protective sensation, also known as neuropathy, or peripheral arterial disease (PAD), resulting in reduced circulation in the feet.<sup>4</sup> Neuropathy and PAD are risk factors for diabetic foot ulceration, defined as “a break in the skin of the foot in a person with diabetes, which does not promptly heal.”<sup>5(p.2)</sup> This serious complication precedes 80% of diabetes-related lower-extremity amputations.<sup>6</sup> Globally, the prevalence of ulceration differs between geographical regions. Zhang *et al.*<sup>7</sup> estimate the global prevalence to be 6.3%, with the United States having the highest prevalence (13%), Europe being midrange

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(5.1%), and Oceania having the lowest (3%). Such differences are attributed to lifestyle and the presence of risk factors, such as smoking and obesity. However, health care provision, affordability and accessibility, specialist professional training, preventative management provision, and education differences are also known to create inequalities in patient outcomes between countries, especially developed and developing countries.<sup>8</sup> European Union (EU) countries are working together toward an agreed EU health policy, providing a platform for financial, technical, legislative, and research support, reducing inequality in health care across the EU.<sup>9</sup> The UK was an EU member until January 31, 2020, when it officially withdrew.<sup>10</sup> For the purposes of this review, it will be treated as part of the EU.

In the UK, the National Health Service (NHS) provides free treatment at the point of care. In 2014–2015, NHS England spent an estimated £972 million to £1.13 billion on diabetes-related foot ulceration and amputation, with the majority allocated to severe, prolonged ulceration.<sup>11</sup> While these costs reflect the financial burden, the human cost is higher in terms of psychosocial, physical, functional, and financial implications.<sup>12</sup> Clinical outcomes report that the mortality rate for those who develop their first diabetic foot ulceration is 40% at five years.<sup>13</sup>

The International Working Group for the Diabetic Foot (IWGDF) advocates identifying the “at-risk” diabetic foot, based on the presence of one or both primary physiological risk factors: neuropathy or PAD.<sup>14</sup> Following “at-risk” foot status determination, other physiological, social, and behavioral factors are considered to allow risk stratification and management planning (see Table 1).<sup>4</sup>

Following risk identification, preventative management (eg, callus debridement; risky behavior avoidance, including barefoot walking<sup>15</sup>; and patient education for foot self-care at home) plays a role in preventing diabetic foot ulceration.<sup>12,16</sup> When ulceration has been identified by a medical professional, the National Institute of Health and Care Excellence<sup>17</sup> recommends management by a specialist multidisciplinary team, comprising podiatrists and vascular, diabetes, and orthopedic consultants, as well as psychological support.<sup>17</sup>

The IWGDF<sup>4</sup> recommends an annual risk assessment by a trained health professional. At the assessment, decision-making is informed by the presence of physical manifestations linked to physical pathologies within the foot. Only when physical risk factor presence is confirmed are social and behavioral risk factors considered. Furthermore, mental health issues, such as stress, anxiety, and depression—although reportedly associated with diabetic foot ulceration—are not considered when assessing ulceration development risk, even when physical risk factors are present.<sup>4</sup> A study by Hoban *et al.*<sup>18</sup> compared self-reported mental health issues for participants with diabetes in the presence and absence of foot complications. The study reported that mental health issues were associated with diabetic foot ulceration presence, with symptoms of increased pain, depressive symptoms, suicidal behavior, and decreased quality of life. A previous prospective cohort study in the UK determined that one-third of those with their first diabetic foot ulceration were clinically depressed and that this was associated with an increased mortality rate.<sup>19</sup> Individuals with diabetes are twice as likely as the general population to experience depression, with an estimated

**Table 1: Additional risk factors for consideration following identification of the “at-risk” diabetic foot to allow risk stratification<sup>4</sup>**

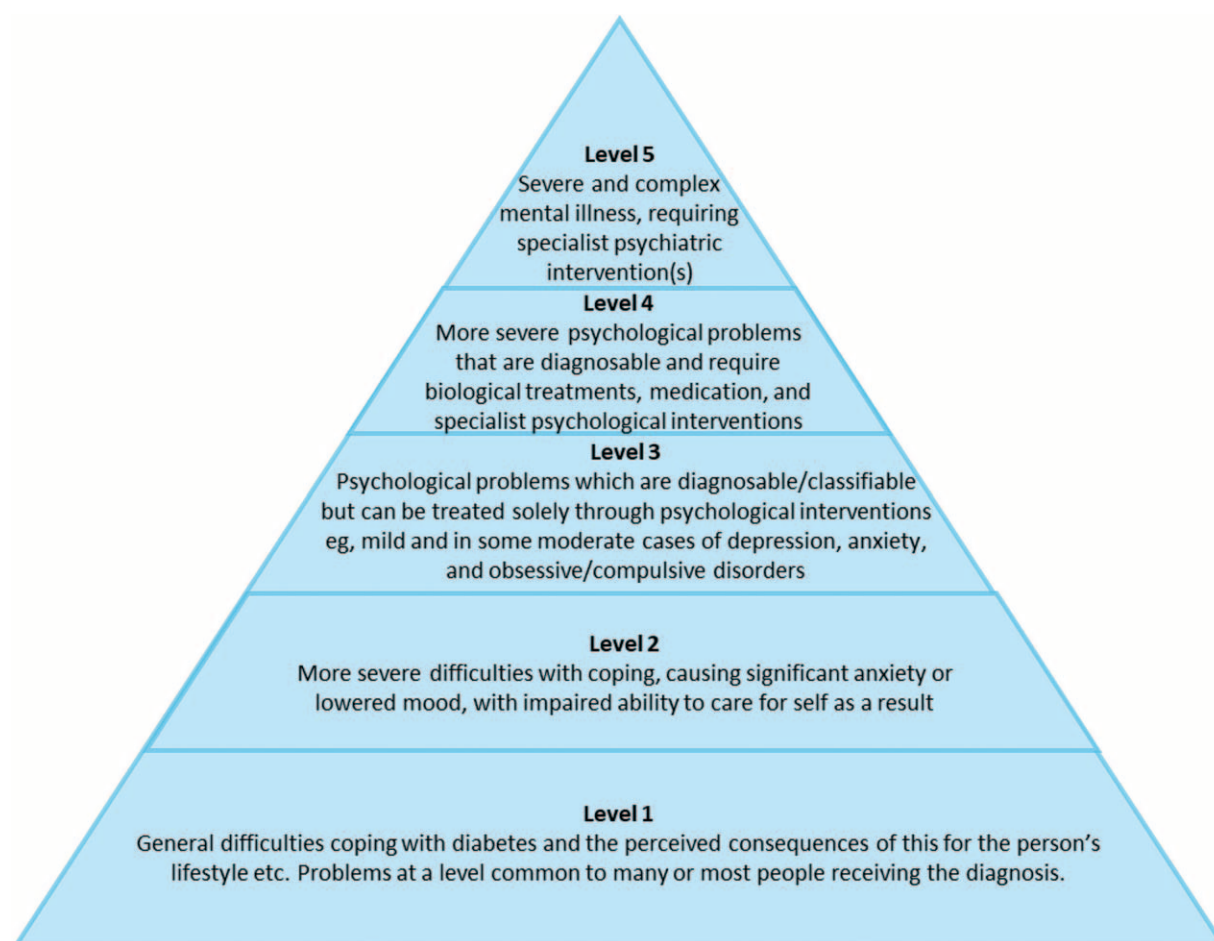
	Foot deformity	Abnormal joint mobility
Physiological	History of ulceration	Amputation
	Pain or numbness in the feet	Claudication
	Abnormal skin color or temperature	Presence of edema
	Presence of calluses	End-stage renal failure
Social	Poor access to health care	Inadequate, ill-fitting footwear
	Financial constraints	Social isolation
Behavioral	Poor foot hygiene	Physical disabilities limiting care (ie, poor eyesight, obesity)
	Previous foot education	

41% having poor psychological well-being.<sup>20</sup> The pyramid of psychological problems illustrates the level of severity and intervention requirements for individuals with diabetes (see Figure 1). The model predicts that self-management activities become inhibited at four out of five levels and the risk of moving through the levels increases with disease progression.<sup>21</sup> The detrimental impact of poor emotional well-being on diabetes self-management reduces the individuals' capacity to complete self-management tasks, such as glycemic monitoring and control, which, in turn, increases the risk of developing the physical complications of diabetes.<sup>22</sup>

Despite this apparent acknowledgment that psychological burden plays a role in both the overall management of diabetes and diabetic foot ulceration, mental health issues are not considered by clinicians

when assessing the risk of developing foot ulceration.<sup>4,17</sup> Evaluating the prevalence and incidence of mental health issues, both during and as a precursor to diabetic foot ulceration, will provide further understanding for the holistic assessment of the individual, ultimately reducing foot ulceration incidence.

A preliminary search of PROSPERO, MEDLINE, the Cochrane Library, and *JBI Evidence Synthesis* revealed no in-progress systematic reviews on the topic. Two systematic reviews on the presence of mental health issues and foot concerns were found. First, Jiang *et al.*<sup>23</sup> indicated the presence of depression, as reported by validated assessment processes, in 47% of individuals presenting with foot ulceration and diabetes. However, this review did not consider other mental health issues or those without foot ulceration and other diabetes-related foot complications,



**Figure 1: Pyramid of psychological problems for individuals with diabetes mellitus<sup>21</sup>**

such as charcot arthropathy. More recently, Westby *et al.*<sup>24</sup> published a systematic review evaluating the evidence on psychosocial and behavioral factors as prognostic indicators of diabetic foot ulceration. Overall, the review determined that individuals with diabetes and depression had an increased risk of first-time foot ulceration, whereas engagement in self-care activities reduced ulceration risk. However, the risk of re-ulceration in those with previous foot ulceration, depression, and diabetes was not significant. A wide range of psychosocial and behavioral factors was evaluated against the presence of ulceration, amputation, or a change to a foot care behavior, such as drying the feet. However, evaluation of the literature regarding the presence of other diabetes-related foot complications was not completed.

This review aims to enrich the knowledge base by determining the prevalence and incidence of professionally diagnosed and self-reported mental health issues in relation to the risk of foot ulceration from risk factors such as PAD and neuropathy.

### Review objective

The objective of the review is to evaluate and synthesize the evidence in the literature to determine the prevalence and incidence of mental health issues in people with the following indicators, as described by IWGDF:<sup>14</sup>

- overall risk of developing diabetic foot ulceration: ulcerated, high, moderate, or low risk;
- presence of individual foot-related complications recognized as ulceration risk factors (eg, neuropathy, PAD, musculoskeletal changes [deformity/limited joint movement], history of foot ulceration, amputation);
- patient physiological risk factors for foot ulceration (eg, end-stage chronic kidney disease).

### Inclusion criteria

#### Participants

The review will consider studies that include adults, 18 years of age and over, formally diagnosed with type 1 or type 2 diabetes mellitus. Outcome measures or descriptors will report on diabetic foot ulcer risk status and/or diabetic foot risk factors.

The following exclusion criteria will apply: data from individuals under 18 years of age, from other types of diabetes, only discussing mental health issues and/or diabetes without outcomes/descriptors for foot status or risk factors for foot ulceration, or

mental health issues not being concurrent with the assessment/report of foot status or risk factors.

#### Condition

The literature contains numerous definitions and tools for assessing mental health. The World Health Organization<sup>25</sup> describes good mental health as “a state of well-being in which an individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and is able to make a contribution to his or her community.”<sup>(para 2)</sup> It is recognized that many individuals diagnosed with diabetes also experience some form of mental health issue.<sup>21</sup> This review will consider studies that report on participants who have either a clinical diagnosis of a mental health disorder or a mental health issue identified via an assessment tool recognized in the literature, such as the Hospital Anxiety and Depression Scale<sup>26</sup> or the Warwick-Edinburgh Mental Well-being Scale.<sup>27</sup> Mental health issues of all severity and type will be considered for inclusion in the review.

#### Context

Currently, international and national guidelines for the management of diabetic foot complications do not differentiate between the needs of individuals diagnosed with either type 1 or type 2 diabetes mellitus. The same absence of distinction is present in position papers, such as “Too often missing,”<sup>28</sup> describing the management and presence of mental health issues and emotional well-being for those with diabetes. To reflect this, papers reporting on either type 1, type 2, or a combination will be considered.

Globally, there are numerous tools to assess and classify diabetic foot risk status and contributors. This review will consider descriptors of any recognized complication of diabetes or physiological risk factors increasing ulceration risk, as described by Bus *et al.*<sup>14</sup> This includes PAD, loss of protective sensation/neuropathy, plus additional physiological, social, and behavioral factors, as per Table 1. Subgroup analysis for individual physical risk factors and mental health conditions will enrich the knowledge base for “at risk” foot status assessment and management to prevent foot ulceration.

The review will include studies completed in EU countries listed on the EU member state list, as published on December 31, 2019.<sup>10</sup> The ulceration prevalence rate,<sup>7</sup> and health care service provision within these countries are similar and guided by

agreed policy. This comparability will allow any results obtained to be transferable between the populations and exclude those countries and populations where diverse classification and access to mental health treatment may bias our results.

### *Types of studies*

This review will consider analytical epidemiological observational studies, including longitudinal, prospective, and retrospective cohort studies, case-control studies, and analytical cross-sectional studies. Experimental study designs will also be considered, including intervention trials that report on the prevalence and incidence of mental health issues in relation to both diabetes and foot complications within baseline data. Prevalence data from intervention studies, collected or solely detailed post-intervention, as well as case studies, will be excluded.

### **Methods**

The proposed systematic review will be conducted in accordance with the JBI methodology for systematic reviews of prevalence and incidence.<sup>29</sup>

### *Search strategy*

A three-step search strategy will be followed. An initial limited search of MEDLINE (PubMed) was undertaken to identify articles on the topic (see Appendix I). The text words contained in the titles and abstracts of relevant articles, and the index terms used to describe the articles will be used to develop a full search strategy. A second comprehensive search of all databases, locating both published and unpublished studies, will be conducted. The search strategy, including keywords and index terms, will be adapted for each information source. The reference lists of all studies selected for critical appraisal will be screened for additional studies.

Studies published in English or studies with translations that are freely available will be considered. Where translations are unavailable, authors will be contacted to determine availability. Studies published from database inception to the present will be included.

The databases to be searched include MEDLINE (PubMed), CINAHL (EBSCO), AMED (EBSCO), Embase (Ovid), Cochrane Central Register of Controlled Trials (CENTRAL), and PsycINFO (EBSCO). Pre-prints, unpublished studies, and gray literature will be searched via sources such as Google Scholar and preprints.org.

### *Study selection*

Following the search, all identified citations will be collated and uploaded into EndNote v.X9 (Clarivate Analytics, PA, USA) and duplicates removed. Titles and abstracts will then be screened by two independent reviewers against the inclusion criteria for the review. Potentially relevant studies will be retrieved in full and their citation details imported into the JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI; JBI, Adelaide, Australia).<sup>30</sup> The full text of the selected citations will be assessed in detail against the inclusion criteria by two independent reviewers. Reasons for exclusion of full-text studies that do not meet the inclusion criteria will be recorded and reported in the systematic review. Any disagreements that arise between the reviewers at each stage of the study selection process will be resolved through discussion or with a third reviewer. The results of the search will be reported in full in the final systematic review and presented in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram.<sup>31</sup>

### *Assessment of methodological quality*

Eligible studies will be critically appraised by two independent reviewers at the study level for methodological quality in the review using standardized critical appraisal instruments for prevalence studies developed by JBI.<sup>29</sup> Authors of papers will be contacted to request missing or additional data for clarification, where required. Any disagreements that arise will be resolved through discussion or with a third reviewer. The results of the critical appraisal will be reported in narrative format and in a table. All studies, regardless of the results of their methodological quality, will undergo data extraction and synthesis, where possible.

### *Data extraction*

Data will be extracted from papers included in the review by two independent reviewers using the standardized data extraction tools in JBI SUMARI.<sup>30</sup> The data extracted will include specific details of interest to the review question and objectives. These will include geographical location, treatment setting, recorded mental health issue, diagnosis method for mental health, prevalence or incidence of mental health issues, diabetes type, individual risk factors for developing foot ulceration, diabetic foot risk status, study methods, and population demographics

(age, gender, and sample size). Any disagreements that arise between the reviewers will be resolved through discussion or with a third reviewer. Authors of papers will be contacted to request missing or additional data where required.

### Data synthesis

Results from the included studies will be managed and analyzed using JBI SUMARI. Where statistical pooling is not possible, the findings will be presented in narrative format, including tables and figures to aid in data presentation, where appropriate. Where studies are sufficiently close to combine, data will be pooled and analyzed by statistical meta-analysis. Sub-group analysis for mental health conditions, diabetic foot risk status, individual risk factors, and patient risk factors will be completed where sufficient data is present.

Effect sizes will be expressed as a proportion with 95% CI around the summary estimate. Heterogeneity will be assessed statistically using the standard  $\chi^2$ ,  $\tau^2$ , and  $I^2$  tests. A random effects model using the double arcsine transformation approach will be used. Sensitivity analyses will be conducted to test decisions made regarding the meta-analysis model used.

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### Author contributions

JW is the guarantor and drafted the manuscript. JW, RC, and JP contributed to the development of the selection criteria, risk of bias assessment strategy, and data extraction criteria. JW developed the search strategy. BK provided expertise in the systematic review process. All authors read, provided feedback, and approved the final manuscript.

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## Appendix I: Search strategy

### MEDLINE (PubMed)

Search conducted on June 13, 2021

((TX (podiatry or podiatrist or podiatric) OR TX chiropodist OR TX chiropody OR TX ('foot care' or 'diabetic foot care') OR (foot or feet) AND (((MH "Foot Ulcer+") OR (MH "Foot+") OR (MH "Diabetic Foot"))) OR TX 'foot status' OR TX ('low risk foot' or 'moderate risk foot' or 'high risk foot' or 'active foot' or 'at risk foot') OR TX (reulceration or re-ulceration) OR TX (dfu or diabetic foot ulcer) OR TX (amputation or amputee or amputees or limb loss) OR TX diabetic foot OR TX (diabetic foot ulcer or diabetic foot sore or diabetic foot or diabetic foot wound) OR TX peripheral vascular disease OR TX (neuropathy or peripheral neuropathy or neuropathic pain) OR TX kidney disease OR foot deformity) AND (TX (mental health or mental illness or mental disorder or psychiatric illness) OR TX psychological OR TX (distress or anxiety or stress or psychological or depression) OR TX emotional OR TX (depression or depressive disorder or depressive symptoms or major depressive disorder) OR TX (cope or coping or coping strategies or coping mechanisms or coping skills) OR TX hopelessness) AND ((MH "Diabetes Mellitus+") OR TX diabetic OR TX (niddm or type 2 diabetes) OR TX IDDM)

1070 studies retrieved