University of Dongola

Faculty of Medicine and Health Science

Department of Community Medicine

Research Proposal

Title

Prevalence and Associated Factors of Diabetic Foot Ulcers Among Diabetic Patients Attending Al-Jemaih Diabetic Center, Dongola, Northern State, Sudan, 2026

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1. Introduction

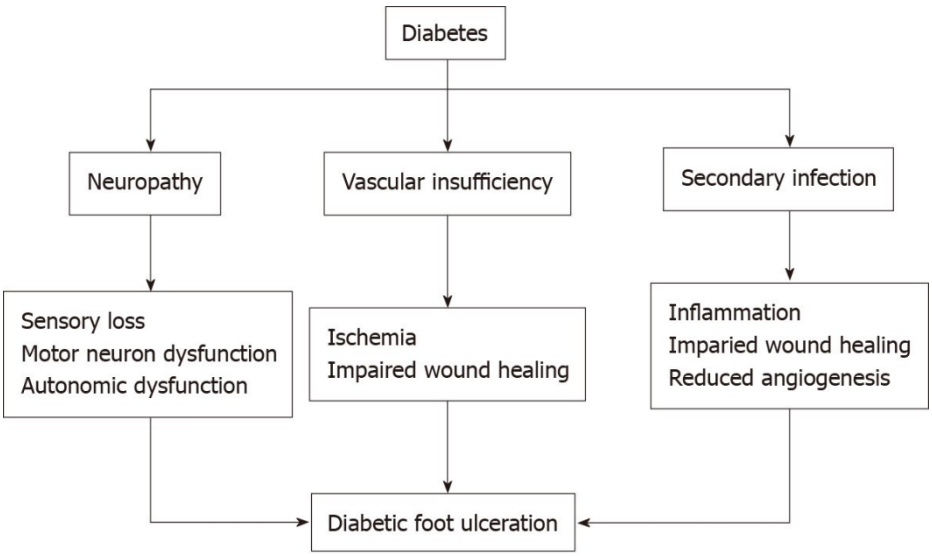
1.1 Background Information

Diabetes mellitus is a chronic metabolic disorder characterized by high blood glucose because the body cannot produce insulin or cannot use it effectively [1]. It affects roughly 422 million people worldwide [2], and its burden in Sudan is substantial: Sudan is among the countries with the highest diabetes burden in the Eastern Mediterranean region, and a prevalence of 10.4% was reported in Dongola as early as 1998 [3].

A diabetic foot ulcer (DFU) is a wound, infection or destruction of deep tissue of the lower limb below the ankle, usually affecting a weight-bearing or exposed area of the foot in a person with diabetes [2,4]. Its development involves three main pathological factors: peripheral neuropathy, vascular insufficiency and secondary infection following foot trauma [2]. Chronic hyperglycemia increases sorbitol and fructose production and depletes myo-inositol in nerve cells, which impairs nerve conduction and reduces protective sensation, so that minor injuries go unnoticed [2]. Autonomic neuropathy reduces sweating and leaves the skin dry and prone to fissures [2,5], motor neuropathy produces deformities such as claw toes that increase localized pressure from footwear [6], and diabetes-related atherosclerosis causes ischemia, particularly below the knee [5]. Ulcers are therefore classified as neuropathic, ischemic or mixed; neuropathic ulcers are the most prevalent, whereas ischemic ulcers are generally more severe and have poorer outcomes [5,7]. Several systems, including SINBAD, Wagner and Texas, are used to grade severity [7].

Globally, DFU affects an estimated 6.3% of people with diabetes, with a reported range of 1.5% to 16.6% across countries [1,4,8], and the lifetime risk of developing a DFU among people with diabetes is estimated at 34% [7]. In Africa the pooled prevalence is about 13% [5,7]. DFU is a leading cause of lower-limb amputation: an ulcer precedes about 85% of diabetes-related amputations [5], and 14%–24% of patients with ulcers eventually need amputation of the affected limb [2]. Patients experience long hospital stays, high treatment costs, poor quality of life and higher cardiovascular and all-cause mortality [1,4,7]. Because many ulcers are painless, prevention through regular foot screening, daily self-inspection, proper footwear and patient education is the cornerstone of management [2,9].

Figure 1: Pathophysiology of diabetic foot ulceration showing the interaction of neuropathy, vascular insufficiency, and secondary infection [2].



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1.2 Problem Statement

Diabetic foot ulcers are common, costly and largely preventable, yet their reported frequency in Sudan varies widely between settings: 12.7% among 2,048 adults with diabetes in River Nile State [10], 33% among 400 patients in Wad Madani [11], 10.6% in Gadarif, Eastern Sudan [5], and 18.1% in Khartoum, where 30% – 40% of cases are reported to recur within the first year [9]. The Sudanese studies identify older age, longer diabetes duration, type 2 diabetes, hypertension, obesity, family history and smoking as factors associated with ulceration [8,10,11]; studies elsewhere add male sex, poor glycemic control, previous ulceration, rural residence and socioeconomic barriers [1,4,9].

The situation of people with diabetes in Sudan has been made worse by the ongoing war, which has placed a heavy economic strain on patients through inflation and electricity shortages that hinder access to insulin, and has led about one-third of people with diabetes to change their dietary habits [5]. Delays in seeking care in socioeconomically disadvantaged patients lead to worse outcomes [4].

1.3 Rationale

Findings from other states cannot simply be transferred to Dongola because populations differ in lifestyle, occupation, footwear habits, access to health services and rural–urban distribution. A facility-based study at Al-Jemaih Diabetic Center is feasible, quick and inexpensive and will generate the first local estimate of DFU prevalence together with its associated factors. The results will help the center and the State Ministry of Health to prioritise foot screening, plan patient education and referral for high-risk patients, and will serve as a baseline for future prospective studies. Since most DFU risk factors are modifiable (glycemic control, smoking, footwear, foot care), identifying them locally offers a direct opportunity to prevent ulceration and amputation.

Despite this, the Northern State has received little attention: to the best of our knowledge, no published study has estimated the prevalence of DFU or its risk factors among patients in Dongola, even though the town hosts a dedicated diabetic center that serves patients from the whole state, including rural areas. Without local data, screening and prevention programmes cannot be targeted and health planners cannot estimate the burden of this complication.

1.4 Objectives

General objective: To determine the prevalence and associated factors of diabetic foot ulcers among diabetic patients attending Al-Jemaih Diabetic Center, Dongola, Northern State, Sudan, during the study period (October – January 2027).

Specific objectives:

1. To estimate the prevalence of current diabetic foot ulcers among the study participants.
2. To describe the sociodemographic characteristics (age, sex, residence, education, occupation, income) and the clinical characteristics (type and duration of diabetes, treatment, hypertension, family history, previous foot ulcer, glycemic control, BMI and blood pressure) of the participants.
3. To assess the foot-care practices (daily foot inspection, washing and drying, walking barefoot, footwear type and previous foot-care education) of the participants.
4. To identify the sociodemographic, clinical and behavioral factors (including smoking, physical activity and foot-care practices) associated with diabetic foot ulcers.

1.5 Research Questions

1. What is the prevalence of diabetic foot ulcers among diabetic patients attending Al-Jemaih Diabetic Center, Dongola?
2. What are the sociodemographic and clinical characteristics of these patients?
3. What are the foot-care practices and footwear habits of these patients?
4. Which sociodemographic, clinical and behavioral factors (e.g., age, sex, residence, duration of diabetes, type of diabetes, hypertension, BMI, smoking, foot-care practices, physical activity) are associated with diabetic foot ulcers?

1.6 Research Hypotheses

Null hypothesis (H0): There is no statistically significant association between the presence of diabetic foot ulcers and the sociodemographic, clinical or behavioral characteristics of diabetic patients attending Al-Jemaih Diabetic Center.

Alternative hypothesis (H1): There is a statistically significant association between the presence of diabetic foot ulcers and one or more of these characteristics. Specifically, we hypothesise that DFU is

more frequent among patients who are older, have a longer duration of diabetes (more than 10 years), have hypertension or obesity, are smoke, live in rural areas, and do not practice regular foot care.

The prevalence objective is descriptive and does not need a hypothesis; the hypotheses above will be tested with the chi-square test and logistic regression at a significance level of 0.05 (see Data Analysis).

1.7 Summaries of Three Very Similar Published Studies

Paper 1 – Abdelbagi et al. (2021) [10]

Prevalence of diabetic foot amongst adults with diabetes mellitus in northern Sudan: a cross-sectional study. International Journal of Clinical Practice, 75(12):e14892.

This cross-sectional study aimed to determine the prevalence of diabetic foot and its associated factors among adults with diabetes in River Nile State, northern Sudan. It enrolled 2,048 adults with diabetes. The prevalence of diabetic foot was 12.7%. Older age, longer diabetes duration, type 2 diabetes, a family history of diabetes, hypertension and obesity were associated with diabetic foot, whereas gender and overweight status were not significantly associated. Geographically and culturally this is the closest study to our setting; its prevalence is used to calculate our sample size and its risk factors guided our questionnaire.

Paper 2 – AbdElrahman Elnour Eltilib (2021) [11]

Association between smoking and foot ulcer among patients with diabetes mellitus, Wad Madani, Sudan. Sudan Journal of Medical Sciences, 16:450–463.

This study aimed to assess the association between smoking and foot ulcers among patients with diabetes in Wad Madani, central Sudan. It included 400 patients with diabetes. About 33% of them had diabetic foot ulcers, and smoking was significantly associated with the presence of ulcers. The study shows that a considerably higher burden can be found in a facility-based sample, and it confirms smoking as a modifiable risk factor that we will measure in our study.

Paper 3 – Imamaldin et al. (2026) [5]

Prevalence and associated factors of diabetic foot ulcer among patients with diabetes mellitus in Eastern Sudan: a cross-sectional study. Scientific Reports, 16(1):24600.

This cross-sectional study estimated the prevalence of diabetic foot ulcer and identified its associated factors among patients with diabetes in Eastern Sudan. The prevalence of DFU in Gadarif was 10.6%. The authors place DFU within the wider burden of diabetic limb complications: about 13.3% of adults with diabetes in Africa have a DFU, an ulcer precedes 85% of diabetes-related amputations, about 50% of ulcers become infected and 20% of moderate-to-severe cases end in amputation. They also highlight the economic strain of the war on people with diabetes. It is a very recent Sudanese study with the same objective and design as ours, conducted in the context of the current war, and it supports our design and the choice of risk factors.

Summary of the comparison: the three studies used cross-sectional designs among Sudanese adults with diabetes and reported prevalence between 10.6% and 33%, depending on setting and sample. Consistently reported factors were older age, longer diabetes duration, hypertension, obesity and smoking. No comparable data exist for the Northern State, which this study addresses.

2. Materials and Methods

2.1 Study Design

A descriptive, analytical, facility-based cross-sectional study.

2.2 Study Area

The study will be conducted at Al-Jemaih Diabetic Center in Dongola, the capital of the Northern State of Sudan. The Northern State lies in the north of the country along the River Nile, with Dongola as its administrative and commercial center, and its population is mostly settled in agricultural communities along the Nile. The center provides outpatient care for patients with diabetes, including follow-up visits, treatment and education, and receives patients from both urban Dongola and surrounding rural areas.

2.3 Study Population

Patients with diabetes attending Al-Jemaih Diabetic Center during the data-collection period.

Inclusion criteria:

- Adults aged 18 years or more with a documented diagnosis of type 1 or type 2 diabetes mellitus.
- Attending the center during the study period.
- Willing to participate and give the informed consent.

Exclusion criteria:

- Gestational diabetes.
- Patients with bilateral lower-limb amputation (no foot available for examination).
- Critically ill patients or those unable to give consent or answer the questions.

2.4 Sampling

Sample size. The sample size is calculated using the formula for estimating a single proportion in a descriptive study:

$$\mathbf{n = Z^2 \times p \times q / d^2}$$

Where n is the sample size; Z is the standard normal value for the confidence level (1.96 for 95%); p is the expected prevalence, taken as 12.7% (0.127) from the River Nile State study [10], the nearest comparable population; q = 1 – p = 0.873; and d is the margin of error (0.05).

$$n = (1.96)^2 \times 0.127 \times 0.873 / (0.05)^2 = 170.4 \approx 171$$

Design effect. Because the study is facility-based and patients are sampled over several clinic days, the sample size obtained above (171) is multiplied by a design effect of 2, giving 342. This doubling keeps the prevalence estimate precise, makes the sample representative of the center's attendees, and provides enough participants with ulcers for a reliable analysis of the associated factors. A 5% non-response allowance is then added (342 × 1.05 = 359), and the final sample size is rounded to 360 patients. At the expected prevalence of 12.7%, about 46 patients with ulcers are anticipated, so the multivariable model will include a limited number of variables (about one for every 10 cases).

Sampling technique. Systematic random sampling will be used. The sampling frame is the daily list of registered attendees. The sampling interval k = N/n (expected number of attendees during the data-collection period divided by 180) will be calculated, a random starting point will be chosen between 1 and k, and every kth patient will be invited. Patients who decline or are ineligible will be replaced by the next patient on the list.

2.5 Methods of Data Collection

Data will be collected by two trained final-year medical students, over approximately 14 working days. Three tools will be used:

1. Structured interview questionnaire. A structured, pre-tested questionnaire in Arabic covering sociodemographic characteristics, diabetes history and treatment, comorbidities, smoking and physical activity, and foot-care and footwear practices.

2. Measurements. Anthropometric measurements (weight and height) and blood pressure will be taken by trained final-year medical students to ensure accuracy and adherence to standardized measurement protocols. The presence of an active diabetic foot ulcer will initially be assessed by asking the participant. However, to avoid missing painless or unnoticed ulcers, the data collectors will perform a direct visual inspection of the participants' feet to confirm the presence or absence of an active wound, particularly for those who report not having one. While this visual inspection ensures an accurate estimation of the prevalence, detailed clinical examinations of the ulcer such as grading, classification, or specific sensory and vascular tests will not be perform

3. Record review. The most recent fasting blood glucose and/or HbA1c, treatment regimen and diagnosed comorbidities will be extracted from the patient's file.

Pre-test. The questionnaire and examination procedure will be pre-tested on about 10% of the sample these patients will not be included in the final analysis. The tool will be modified accordingly.

2.6 Study Variables

Type	Variable	Definition / measurement
Dependent variable	Diabetic foot ulcer	Presence of an active foot ulcer at the time of data collection, as answered by the patient to a single yes / no question (item 24).
Independent – sociodemographic	Age, sex, residence, education, occupation, monthly income	Self-reported; age in years (grouped); residence urban / rural.
Independent – clinical	Type of diabetes, duration (<5, 5–10, >10 years), treatment type, hypertension, family history of diabetes, previous foot ulcer, glycaemic control, BMI, blood pressure	Interview, record review and nurse measurements. Hypertension = known diagnosis or BP ≥ 140/90 mmHg; BMI by WHO categories; glycaemic control from the latest fasting glucose / HbA1c.
Independent – behavioural	Smoking, physical activity, foot-care practices, daily foot inspection, footwear type, walking barefoot, previous foot-care education	Self-reported by questionnaire.

2.7 Data Analysis

Data will be coded, entered and cleaned in SPSS (version 27), which will also be used for analysis. Continuous variables will be summarized as mean ± standard deviation (or median and interquartile range if not normally distributed) and categorical variables as frequencies and percentages. The prevalence of DFU will be reported with its 95% confidence interval. Associations between DFU and each independent variable will be tested with the chi-square test (or Fisher's exact test when expected counts are small) and the independent t-test. Variables with $p < 0.25$ in the bivariate analysis will enter a multivariable binary logistic regression model, and results will be presented as adjusted odds ratios with 95% confidence intervals. A p-value of less than 0.05 will be considered statistically significant. Results will be presented in tables and figures.

2.8 Ethical Clearance

Ethical approval will be obtained from the research the Ethical Committee of the Northern State Ministry of Health, together with administrative permission from the management of Al-Jemaih Diabetic Center before data collection begins. The principles of respect for persons, beneficence and justice will be followed:

- Verbal informed consent will be obtained from every participant after explaining the purpose, procedures, duration, and the fact that participation is voluntary and that refusal will not affect the care the patient receives. Participants may withdraw at any time.

- No names or identifying data will be recorded on the questionnaires; participants will be identified by code only, and completed forms will be kept in a locked place accessible only to the research team.
- The only procedures are the interview and the measurement of weight, height and blood pressure, which are non-invasive and carry minimal risk; they will be performed by trained staff in privacy and with respect for cultural norms (same-sex nurse where possible).
- Participants who report an active foot ulcer will be advised immediately and referred to the physician at the centre for care. All participants will receive brief advice on foot care.
- Data will be used only for the purpose of this research, and the results will be shared with the center and the State Ministry of Health.

3. Research Plan

3.1 Time-line

Task	Oct 2026	Nov	Dec	Jan 2027
Proposal writing and approval				
Pre-test of questioner				
Data collection				
Data analysis				
Draft report				
Final report and dissemination				

3.2 Budget Breakdown

No	Item / activity	Justification (calculation)	Amount (US $)
1	Equipment	Digital BP apparatus (2 × 300.000), weighing scale and stadiometer (2×200)	1,000,000
2	Local transportation	Team members × 20 days × 20.000	400,000
3	Data cleaning and statistical analysis	Lump sum for statistical support	250,000
4	Dissemination of results	Printing of final report 4 copies	320,000
5	Other costs / unforeseen	≈ 5% of the total	98,500
	Total		1,970,098,5

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5. Annexes

Annex 1: Informed Consent Form

Study title: Prevalence and associated risk factors of diabetic foot ulcers among diabetic patients attending Al-Jemaih Diabetic Center, Dongola, Northern State, Sudan, 2026.

We are medical students at the Faculty of Medicine, University of Dongola, conducting a research study under the supervision of Dr. Mohamed Ismail. The study aims to find out how common foot ulcers are among people with diabetes attending this centre and which factors are linked to them. If you agree to take part, we will ask you questions for about 15 minutes, examine your feet (look at the skin and test sensation with a thin nylon filament), measure your weight, height and blood pressure, and review your medical file.

Your participation is entirely voluntary. You may refuse or withdraw at any time without any effect on the care you receive. Your name will not be written on the questionnaire, and all information will be kept confidential and used for research only, and if we find a problem you will be referred to the doctor at the center.

نموذج الموافقة المستنيرة

عنوان الدراسة: انتشار قرحة القدم السكرية والعوامل المرتبطة بها بين مرضى السكري المترددين على مركز السكري بدنقلا (Al-Jemaih)، الولاية الشمالية، السودان، 2026.

نحن طلاب بكلية الطب جامعة دنقلا نجري دراسة بحثية تحت إشراف د. محمد إسماعيل، بهدف معرفة مدى انتشار قرحة القدم بين مرضى السكري بهذا المركز والعوامل المرتبطة بها. في حال موافقتك سنطرح عليك بعض الأسئلة (حوالي 15 دقيقة)، ونفحص قدميك فحصاً بسيطاً غير مؤلم، ونقيس وزنك وطولك وضغط الدم، ونراجع ملفك الطبي.

المشاركة طوعية تماماً، ويمكنك الرفض أو الانسحاب في أي وقت دون أن يؤثر ذلك على الرعاية التي تتلقاها. لن يُكتب اسمك في الاستبيان، وستظل جميع المعلومات سرية وتُستخدم لأغراض البحث فقط. لا توجد مخاطر تُذكر، وفي حال اكتشاف أي مشكلة سيتم تحويلك إلى الطبيب بالمركز.

أوافق على المشاركة في هذه الدراسة.

Annex 2: Data Collection Tool

Questionnaire No: _____ Date: _____ Collector: _____

Section A: Sociodemographic characteristics

No	Question	Response options
1	Age (years)	Age groups
2	Sex	1 Male 2 Female
3	Residence	1 Urban 2 Rural
4	Education level	1 Illiterate 2 Primary 3 Secondary 4 University
5	Occupation	1 Employee 2 Farmer 3 Business 4 Housewife 5 Retired 6 Other
6	Average monthly income	1 Low 2 Middle 3 High (per local categories)

Section B: Diabetes history, clinical data and measurements

No	Question	Response options
7	Type of diabetes	1 Type 1 2 Type 2
8	Duration of diabetes (years)	1 <5 2 5–10 3 >10
9	Current treatment	1 Diet only 2 Oral drugs 3 Insulin 4 Oral drugs + insulin
10	Hypertension (known diagnosis)	1 Yes 2 No
11	Family history of diabetes	1 Yes 2 No
12	Previous foot ulcer	1 Yes 2 No
13	Latest fasting blood glucose (mg/dL) / HbA1c (%) from file	_____ / _____
14	Attends regular follow-up	1 Yes 2 No
15	Weight (kg) / height (cm) / BMI (measured by nurse)	_____ / _____ / _____
16	Blood pressure (mmHg)	_____ / _____

Section C: Lifestyle

No	Question	Response options
17	Smoking status	1 Never 2 Ex-smoker 3 Current smoker
18	Physical activity (≥30 min, ≥3 days/week)	1 Yes 2 No

Section D: Foot-care practices

No	Question	Response options
19	Do you inspect your feet daily?	1 Yes 2 No
20	Do you wash and dry between the toes?	1 Yes 2 No
21	Do you walk barefoot (indoors or outdoors)?	1 Yes 2 No
22	Usual footwear	1 Closed shoes 2 Sandals 3 Slippers 4 Special diabetic shoes
23	Have you ever received foot-care education?	1 Yes 2 No

Section E: Active foot ulcer

No	Question	Response options
24	Do you have an active foot ulcer (an open wound or sore on the foot, below the ankle) now, during the data-collection period?	1 Yes 2 No