Research Proposal for Ethical Approval

Title

Neuropathic Manifestations and Nutritional Correlates of Burning Feet Syndrome among Adults in Ombada Locality, Omdurman, Sudan, during the Ongoing Armed Conflict 2024

Principal Investigator

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Study Site

The study will be conducted in **Ombada locality, Omdurman, Khartoum State, Sudan**, among adult residents affected by the ongoing armed conflict.

Background

Burning Feet Syndrome is a clinical condition characterized by burning pain, heat sensation, tingling, numbness, or discomfort in the feet. It may reflect peripheral neuropathy, nutritional deficiencies, metabolic disorders, or other systemic causes. In resource-limited and conflict-affected settings, such symptoms may be under-recognized despite their impact on quality of life, mobility, sleep, and daily functioning.

Sudan's ongoing armed conflict has disrupted food security, healthcare access, medication availability, diagnostic services, and continuity of care for chronic

diseases. Ombada locality in Omdurman has been heavily affected by displacement, insecurity, economic hardship, and interruption of essential health services. These conditions may increase vulnerability to nutritional deficiencies and untreated neurological symptoms.

Burning feet symptoms may be linked to deficiencies in B vitamins, poor dietary diversity, chronic illness, psychological stress, and limited access to healthcare. However, there is limited local evidence describing the clinical pattern, severity, associated nutritional factors, and health-seeking behavior of affected individuals in Sudan during the war.

This study aims to generate context-specific evidence on Burning Feet Syndrome among adults in Ombada locality. The findings may help guide clinical screening, nutritional interventions, community awareness, and referral pathways for people affected by neuropathic symptoms during humanitarian crises.

Problem Statement

During the ongoing conflict in Sudan, many communities have experienced food insecurity, displacement, reduced access to healthcare, and deterioration of living conditions. In Ombada locality, adults have reported symptoms suggestive of Burning Feet Syndrome, including burning pain, numbness, tingling, night discomfort, and temperature-sensitive pain.

Despite these complaints, there is limited local research documenting the severity of symptoms, possible nutritional and systemic associations, and patterns of healthcare access among affected individuals. Without proper documentation, Burning Feet Syndrome may remain neglected, leading to unnecessary suffering, functional limitation, sleep disturbance, and delayed diagnosis of treatable conditions.

Justification of the Study

This study is important because it addresses a neglected clinical problem in a conflict-affected population. The findings may:

- Provide local evidence on the clinical burden of burning feet symptoms.
- Identify possible nutritional and systemic risk factors.
- Support early recognition and referral of patients with neuropathic symptoms.
- Inform community-based health education and nutritional support.
- Contribute to conflict-health research in Sudan.

- Help healthcare providers and humanitarian actors understand hidden neurological morbidity during war.

Research Question

What are the clinical characteristics, severity patterns, and associated nutritional and systemic factors of Burning Feet Syndrome among adults in Ombada locality, Omdurman, Sudan, during the ongoing armed conflict?

General Objective

To assess the clinical manifestations, severity, and associated nutritional and systemic factors of Burning Feet Syndrome among adults in Ombada locality, Omdurman, Sudan, during the ongoing armed conflict.

Specific Objectives

1. To describe the socio-demographic characteristics of adults reporting burning feet symptoms in Ombada locality.
2. To assess the clinical characteristics of Burning Feet Syndrome, including duration, severity, timing, and associated neuropathic symptoms.
3. To evaluate the presence of nutritional stress indicators among participants.
4. To assess systemic symptoms and possible associated health conditions among participants.
5. To identify factors associated with severe burning feet pain.
6. To describe health-seeking behavior and access to medical care among affected individuals.

Methodology

Study Design

This will be a **descriptive cross-sectional community-based study**.

Study Area

The study will be conducted in Ombada locality, Omdurman, Khartoum State, Sudan. Ombada is a densely populated locality that has been affected by the ongoing armed conflict, displacement, economic hardship, and disruption of healthcare services.

Study Population

The study population will include adult residents of Ombada locality who report burning feet symptoms or related neuropathic complaints during the study period.

Inclusion Criteria

Participants will be included if they:

1. Are aged 18 years or above.
2. Are residents of Ombada locality during the study period.
3. Report burning sensation, heat, tingling, numbness, or neuropathic discomfort in the feet.
4. Are willing to participate voluntarily.
5. Provide informed consent.

Exclusion Criteria

Participants will be excluded if they:

1. Are younger than 18 years.
2. Are unable to provide informed consent.
3. Are too ill to participate in the interview.
4. Refuse participation or withdraw consent.
5. Provide incomplete essential responses that prevent analysis of the main outcome.

Sample Size

The study will include all eligible respondents reached during the data collection period. Based on the available dataset, the study includes **154 adult participants**.

Because this study is exploratory and conducted in a conflict-affected setting, a convenience/community-based sampling approach will be used. The sample is intended to describe the clinical and nutritional profile of symptomatic individuals rather than estimate true population prevalence.

Sampling Technique

A **non-probability convenience sampling technique** will be used due to the difficult field conditions, insecurity, population movement, and limited accessibility during the ongoing armed conflict. Eligible adults who meet the inclusion criteria and agree to participate will be enrolled.

Data Collection Tool

Data will be collected using a structured questionnaire developed for the study. The questionnaire will include the following domains:

1. Socio-demographic characteristics.
2. Displacement and conflict-related circumstances.
3. Burning feet symptoms and clinical characteristics.
4. Pain severity and duration.
5. Neuropathic symptoms such as numbness, tingling, night pain, and temperature sensitivity.
6. Nutritional stress indicators.
7. Systemic symptoms and comorbid conditions.
8. Health-seeking behavior and access to care.

The questionnaire will be administered through direct interview or self-completion where appropriate.

Study Variables

Dependent Variables

The main outcome variables will include:

1. Presence of burning feet symptoms.
2. Severity of burning feet pain.
3. Severe pain, defined as average pain score of 7 or more out of 10.
4. Neuropathic symptom burden score.

Independent Variables

Independent variables will include:

1. Age.
2. Sex.
3. Residence or displacement status.
4. Duration of symptoms.
5. Nutritional stress indicators.
6. Systemic symptoms.
7. Temperature sensitivity.
8. Night symptoms.

9. Numbness and tingling.
10. Access to healthcare.
11. Use of medications or treatment.

Operational Definitions

Burning Feet Syndrome

For this study, Burning Feet Syndrome refers to a self-reported burning, hot, painful, tingling, or neuropathic sensation affecting one or both feet.

Severe Pain

Severe pain will be defined as an average self-reported pain score of **7 or more out of 10**.

Nutritional Stress

Nutritional stress refers to indicators suggestive of poor food intake, reduced dietary diversity, food insecurity, weight loss, or conflict-related nutritional hardship.

Neuropathic Symptom Burden

Neuropathic symptom burden refers to a composite measure based on the presence of symptoms such as burning, tingling, numbness, night pain, and temperature-sensitive pain.

Data Management and Analysis Plan

Data will be entered, cleaned, coded, and analyzed using appropriate statistical software such as SPSS, R, Python, or equivalent tools.

Descriptive Analysis

Categorical variables will be summarized using frequencies and percentages. Continuous variables will be summarized using mean and standard deviation if normally distributed, or median and interquartile range if not normally distributed.

Inferential Analysis

Associations between categorical variables will be tested using Chi-square test or Fisher's exact test where appropriate. Continuous or ordinal variables will be compared using Mann–Whitney U test or Kruskal–Wallis test if normality assumptions are not met.

Advanced Analysis

Additional analyses may include:

1. Reliability testing using Cronbach's alpha for symptom domains.
2. Correlation analysis using Spearman correlation.
3. Multivariable logistic regression to identify factors associated with severe pain.
4. Composite score development for nutritional stress and systemic symptom burden.
5. Exploratory clustering or phenotype grouping to identify symptom patterns.
6. Sensitivity analysis where appropriate.

A p-value of less than 0.05 will be considered statistically significant. Results will be presented using tables, figures, odds ratios, confidence intervals, and relevant summary statistics.

Ethical Considerations

Ethical Approval

Ethical approval will be obtained from **Northern state Ministry of health** before conducting or formally reporting the study.

Informed Consent

Participation will be voluntary. Each participant will receive information about the study objectives, procedures, potential risks, benefits, confidentiality, and right to withdraw at any time without penalty. Written or verbal informed consent will be obtained depending on field feasibility and literacy level.

Confidentiality

All collected data will be kept confidential. No personal identifiers will be used in the final analysis or publication. Data will be stored securely and accessed only by the research team.

Voluntary Participation

Participants will not be forced or pressured to take part in the study. They may refuse to answer any question or withdraw from the study at any stage.

Risk to Participants

The study involves minimal risk. Possible risks include discomfort when discussing symptoms, illness, food insecurity, or conflict-related hardship. Participants will not be exposed to invasive procedures.

Benefits to Participants

Participants may not receive direct financial benefit. However, the study may help identify health needs, improve understanding of burning feet symptoms, and support future clinical or nutritional interventions in affected communities.

Referral and Support

Participants with severe symptoms, alarming features, or suspected uncontrolled medical conditions will be advised to seek medical consultation at the nearest available health facility where feasible.

Data Protection

Data will be stored in password-protected electronic files. Any paper forms will be kept in a secure location. Data will be used only for research purposes.

Expected Outcomes

The study is expected to:

1. Describe the clinical profile of Burning Feet Syndrome among adults in Ombada locality.
2. Estimate the proportion of participants with severe pain.
3. Identify nutritional and systemic factors associated with severe symptoms.
4. Provide evidence for clinical screening and nutritional assessment.
5. Support future research and intervention planning in conflict-affected communities.

Dissemination Plan

The findings will be disseminated through:

1. Submission of a manuscript to a peer-reviewed journal.
2. Presentation to relevant health authorities and ethical bodies.
3. Sharing results with healthcare providers and humanitarian health actors.
4. Use of findings to guide future community health interventions.

Limitations

This study may have several limitations:

1. The cross-sectional design cannot establish causality.
2. Convenience sampling may limit generalizability.
3. Self-reported symptoms may be affected by recall bias.
4. Laboratory confirmation of nutritional deficiencies may not be available.
5. Conflict-related insecurity may affect participant recruitment and data completeness.
6. The study is more suitable for describing symptomatic individuals than estimating community prevalence.

Work Plan

Activity	**May 2026**	**June 2026**	**July 2026**	**Augst 2026**
Ethical approval				
Questionnaire preparation and training				
Data collection				
Data cleaning and analysis				
Report writing				
Manuscript preparation and submission				

Budget

Item	Estimated Cost
Questionnaire printing or digital data collection	250,000 SDG
Data collectors' transportation	10,000
Communication costs	10,000
Data entry and cleaning	10,000
Statistical analysis	50,000
Report printing	10,000
Miscellaneous	10,000
Total	**350,000 SDGs**

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2. World Health Organization. Malnutrition. Geneva: World Health Organization.
3. International Committee of the Red Cross. Health care in danger: making the case. Geneva: ICRC.
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5. Bouhassira D, Attal N, Alchaar H, et al. Comparison of pain syndromes associated with nervous or somatic lesions and development of a neuropathic pain diagnostic questionnaire. Pain.
6. Pop-Busui R, Boulton AJM, Feldman EL, et al. Diabetic neuropathy: a position statement. Diabetes Care.
7. Allen LH. Causes of vitamin B12 and folate deficiency. Food and Nutrition Bulletin.
8. Said G. Diabetic neuropathy: a review. Nature Clinical Practice Neurology.

Declaration by the Investigator

I confirm that this study will be conducted according to ethical principles of human research, including voluntary participation, informed consent, confidentiality, respect for participants, and protection from harm. The collected data will be used only for scientific purposes.

Principal Investigator Name: Dr. Mohammed Hamed Ibrahium Badi

Date: 06-06-2026