

Nursing's Role in Prevention Interventions and Therapeutic Education for Patients with Critical Limb-Threatening Ischemia: a Scoping Review Protocol

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Abstract

Introduction. Chronic Limb-Threatening Ischemia (CLTI) represents the advanced stage of Peripheral Artery Disease (PAD), a condition with increasing prevalence worldwide due to the rising burden of risk factors and comorbidities, and consequently, escalating healthcare costs. CLTI is a highly morbid condition, often leading to limb loss, chronic pain, and significantly impaired health-related quality of life. Despite its severe consequences, CLTI remains underrecognized. Patients often realise the severity of the disease at a late stage, when revascularisation attempts may no longer be useful. Primary prevention interventions are essential for early diagnosis and correct patient pathway. The trained nurse could have an important role in the community in identifying and managing this disease. This scoping review aims to evaluate the literature

version and the Version of Record.

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on knowledge of nurses about preventive interventions and therapeutic education, and how, and raising awareness of this disease among professionals and individuals from a community medicine perspective, this topic can be developed using the potential of nurses in the team.

Methods. The Joanna Briggs Institute Reviewers' Manual and the framework developed by Arksey and O'Malley were used as the guidelines for the scoping review that is suggested in this protocol. Accordingly, the PCC (Population, Concept, Context) model was adopted. The Preferred Reporting Items for Systematic and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) will be followed for reporting the research and the results. The databases will include MEDLINE/ PubMed, Cochrane, CINAHL and grey literature sources.

Expected results. The main expected results will be the mapping of available evidence and the implementation of knowledge regarding available nursing interventions as well as improved adherence to educational interventions.

Keyword: Chronic Limb Ischemia, CLTI, Nursing, Prevention, Education Health

Introduction

Critical ischemia of the lower limbs (CLI), defined as ischemic pain at rest or non-healing injury resulting from arterial insufficiency, is the most serious and life-threatening peripheral arterial disease condition of the lower limbs and affects adults, on average, over 60 years of age.¹

The global prevalence of PAD is 1.52%; it increases with age and is higher in females than in males (18.03% vs. 10.56% in the same age group). PAD prevalence rose by 72% from 1990 to 2019, considering a 45% growth rate in the world population.² Globally, Chronic Limb-Threatening Ischemia (CLTI) is estimated to affect approximately 1–2% of the adult population.¹ CLTI affects more than 2 million people in the United States and has an estimated mortality risk of 24% within the first year of diagnosis and 60% over 5 years.³

In Italy, it is estimated that approximately 26 700 new cases of critical limb ischemia (CLI) occur each year, corresponding to 468 new patients per million inhabitants.⁴

Despite its severe consequences, CLTI remains underrecognized, often diagnosed late, leaving patients at risk of ulcers, emergency admissions, limb amputation, and life-threatening complications.

The term Critical Limb Ischaemia (CLI) was first introduced in 1982. Its definition has long been debated, as it could include a broad group of patients at risk of amputation, considering various degrees of ischaemia based on classification systems such as WIFI^{3,4}, GLASS⁵, Fontaine-Leriche classification—many of which are still in use today. The 2019 Global Vascular Guideline (GVG) defined CLTI to include a broader and more heterogeneous group of patients with varying degrees of ischaemia, which can delay wound healing and increase the risk of amputation.¹

Epidemiological data show that PAD prevalence varies across contexts: men are more affected in high-income countries (HICs), whereas women show a higher prevalence in low- and middle-income countries (LMICs). As global life expectancy rises, the burden of PAD is expected to increase, particularly in LMICs, with a substantial number of cases occurring in individuals under 55 years old.⁵

The scientific literature reiterates the importance of teams consisting of nurses, podiatrists, and vascular surgeons in the management and prevention of CLTI, but we found little literature regarding the interventions and potential of nurses in the community to foster greater awareness in primary prevention.^{6,7} Most articles focused on management and treatment,

but few addressed nursing interventions in primary prevention, the identification of signs and symptoms by nurses to foster early diagnosis, or the role of health education in increasing this awareness.^{8,9}

Aware of the potential that nurses, podiatrists, and primary care physicians in the community could have to foster early diagnosis, this review aims to deepen and systematically investigate the literature on nursing interventions in this area.

The aim of this scoping review is to investigate and review the existing literature on prevention and therapeutic education interventions carried out by nurses. The research question is: “Which nursing interventions for education and prevention of CLTI have been described in the literature?” The research question is structured as follows:

- Population: patients with suspected CLTI / patients at risk of CLTI;
- Concept: literature mapping of therapeutic-education interventions and thus prevention of CLTI in non-hospitalized patients carried out by nurses;
- Context: community/home care.

In the context of modern, community-based healthcare systems, increasing awareness and early recognition of conditions like CLTI could play a key role in preventing severe patient outcomes and reducing healthcare-system strain. Scoping reviews are a valuable method for addressing broad research questions and mapping existing prevention strategies for CLTI, including those based on health education and physical-activity programs.

Methods

This protocol was developed in accordance with the methodological guidance provided by the Joanna Briggs Institute (JBI), with the aim of rigorously defining the objectives of the review and ensuring methodological transparency throughout the process.^{10,11} The protocol was prospectively registered and made publicly available on the Open Science Framework (OSF) registry (<https://osf.io/w2b39/>) prior to the commencement of data collection.

The forthcoming scoping review will be conducted in alignment with the JBI Manual for Evidence Synthesis and, accordingly, will utilize the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist.^{3,12} The scoping review methodology is considered

the most appropriate approach for this study, as it allows for comprehensive mapping of the existing literature, facilitates the clarification of key concepts and definitions, and supports an in-depth examination of how research in this field has been designed and conducted.

The methodological framework will follow the recommended structure, focusing on the elements of Population, Concept, and Context (PCC), and will proceed through five key stages:

1. identification of the research question,
2. identification of relevant studies,
3. selection of studies,
4. charting of the data,
5. collation and summarization of the results.

An initial exploratory search of the databases was conducted prior to the formal systematic search, which was carried out up to September 2024. Following this, data analysis is currently ongoing, with progression through the subsequent phases of the review, including study selection, data extraction, synthesis of findings, and preparation of the manuscript. The systematic database search was initiated after registration of the protocol.

Eligibility criteria

Considering the Population, Concept, and Context described earlier, the following inclusion criteria were established:

- Patients over the age of 18
- Patients with suspected CLI or at risk of CLI, evaluated using the Leriche-Fontaine classification
- Patients residing in the community/territory
- Studies addressing therapeutic education or prevention of CLI
- Articles written in English or Italian
- Published within the last 5 years
- Patients with a diagnosis of PAD

The exclusion criteria are as follows:

- Paediatric patients
- Hospitalized patients
- Patients with ischemic leg ulcers

The authors aim to investigate the literature on nursing interventions for the early recognition and management of individuals in the initial phase of Chronic Limb-Threatening Ischemia (CLTI). This scoping review does not focus on the treatment of skin ulcers, hospitalized patients, or individuals in the advanced stages of the disease.

Expected outcomes

The main expected outcomes will include the following:

1. Nurses' knowledge of CLTI prevention in community settings.

Secondary outcomes:

1. Adherence to therapeutic education

- interventions, as measured by the incidence of new injuries.
2. Management of pain in patients with CLTI.
3. Improvement in personal autonomy.
4. Improvement in health-related quality of life.

Strengths and limitations of this study

Scoping reviews represent a valid methodological approach for addressing broad research questions and, as such, are well suited to provide an overview of CLTI prevention programmes focused on health education, including physical activity interventions. A rigorous search strategy was developed in collaboration with a librarian experienced in systematic and scoping review methodologies. This review will include studies published in English and Italian. Articles published in other languages will be excluded due to the unavailability of adequate translation resources. Given the exploratory nature of the scoping review, a critical appraisal of study quality and risk of bias will not be undertaken.

Information sources and search strategy

The authors conducted searches in the following electronic bibliographic databases up to September 2024, including randomized studies, observational studies, controlled studies, guidelines, and published systematic reviews: PubMed, EMBASE, Cochrane Library, and CINAHL. Additional bibliographic sources for grey literature were also consulted: Google Scholar (titles from the first 10 pages of search results were screened, as a stopping rule), Open Access Theses and Dissertations, GreySource, Web of Science, the US National Institutes of

Health Trials Register (<https://clinicaltrials.gov/>), and the WHO International Clinical Trials Registry Platform (<https://trialsearch.who.int/>).

The bibliographic search strategy was initially developed for PubMed. The translated search strategies will be reviewed for accuracy and then adapted to each of the additional databases, including EMBASE, CINAHL, and the Cochrane Library (see Table 1).

The searches will be conducted at the scientific library of the San Matteo Polyclinic in Pavia, with the support of an experienced librarian.

Source selection and data charting process

All records will be deduplicated by one author using Rayyan. Additional manual checks for duplicates will be performed prior to initiating the review process. Titles and/or abstracts of studies retrieved through the search strategy, as well as those identified from additional sources, will be independently screened by two reviewers using Rayyan to identify studies that potentially meet the inclusion criteria described above. The full texts of potentially eligible studies will be retrieved and independently assessed for eligibility by both reviewers. Any disagreements regarding the inclusion of specific studies will be resolved through discussion with a third reviewer.

Studies excluded during this phase will be recorded in a PRISMA flow diagram, along with the corresponding reasons for exclusion. Discrepancies will be discussed and resolved through consensus with a third reviewer.

Following the screening process, data will be extracted and entered into a structured Excel-based data extraction tool. Data extraction will be performed independently by two reviewers using a customized extraction form. The extraction protocol will be piloted on the first five included studies to ensure consistency in the process; any necessary modifications to the data extraction form will be made and documented accordingly. Subsequently, each reviewer will independently extract data from half of the included articles.

Data to be extracted will include the following domains: publication details, participant characteristics, description of interventions, comparison groups (if applicable), and study results.

Data extracted from each article will include:

- Study details (e.g. name of first author, year of publication, country, funding source, setting);
- Description of the study population and participant demographics, including baseline characteristics;
- Study design and methodology;
- Information on the intervention(s);
- Details of any comparison group(s);

Table 1. Data charting form. Items considered for data extraction.

ITEMS CONSIDERED	COMMENTS
Authors	
Years	
Title	
DOI	
Population	Patient with CLTI and PAD
Concept	Concept or aim of the study
Context	Community or Hospital
Type of study	Case study, observational study, review, trial, other...
Results	The primary and additional outcomes being measured in the study
Role of nurses in prevention of CLT	In specific information about nurses' intervention in CLTI prevention
Notes	Additional comment or notes

- Study recruitment and completion rates;
- Reported outcomes and timing of measurements;
- Description of the prevention interventions implemented;
- Information relevant to risk of bias assessment.

Corresponding authors will be contacted to provide clarification in cases of missing or unclear data, when appropriate. Authors who do not respond after three follow-up emails will be classified as non-responders.

Data items

This scoping review aims to address the following questions:

- What research has been conducted in this field?
- What gaps exist in the current literature?
- Which populations have been studied?
- What progress has been made in the field?
- How have policies evolved over time?
- What are the key concepts and terminology used in this area of research?
- How is research typically conducted in this field?
- Is the existing literature sufficient to support a systematic review?

Ethics and dissemination

Ethical approval is not required for this scoping review, as it involves the analysis of previously published studies and does not include any primary data collection involving human participants. The authors intend to disseminate the findings of this review through presentations at scientific conferences and publication in peer-reviewed journals.

Expected results

Despite ongoing efforts to promote public health awareness and education regarding the prevalence of peripheral arterial disease (PAD), the ischemic limb at risk remains underrecognized in a significant proportion of patients with critical limb ischemia (CLI). Broader implementation and development of both primary and secondary prevention strategies are needed, alongside improved dissemination of guideline recommendations to healthcare professionals and patients with PAD and CLI.

This scoping review aims to increase awareness of the condition among both healthcare professionals and the general public. It also seeks to examine and evaluate the existing literature in order to enhance prevention strategies, particularly within community and territorial healthcare settings.

The findings will be synthesized and presented through tables and conceptual maps.

Patient and public involvement

We plan to disseminate the results of the scoping review through conference presentations and peer-reviewed publications. The objective is to support stakeholder engagement and raise awareness among key audiences, including nurses, general practitioners, physiotherapists, patients, and caregivers.

Authors' contributions

RC, as the project lead, contributed to the formation of the research team and the development of the protocol, and collaborated with CZ on its reporting. YL and GT were responsible for the methodological components of the study, with GT also managing the use of Rayyan. VS, an expert librarian at the Scientific Library of San Matteo Hospital, Pavia, Italy, supported the literature search strategy.

CM, ADM, AC, EZ, CZ, and RC composed the review team, contributing to data extraction and manuscript preparation. Two authors with methodological expertise supervised the assessment of methodological quality. Six authors, organized into three independent pairs, conducted article screening and analysis. In the case of disagreements, the project lead intervened to facilitate resolution.

All authors contributed to and approved the final version of the manuscript.

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