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BMJ Open Psychosocial patient perspectives following major lower-limb amputation due to vascular aetiology: a protocol for a systematic meta-aggregation study

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ABSTRACT

Introduction Persistent psychosocial problems in people with lower-limb amputation due to vascular aetiology indicate a great need for long-lasting holistic rehabilitation. An in-depth understanding of the psychosocial problems is essential for the guidance of health professionals in meeting and normalising patients' experiences and emotions. Furthermore, identifying the psychological problems may help develop effective rehabilitation and counselling programmes. This meta-aggregation study aims to explore the psychosocial perspectives of individuals who have undergone a major lower-limb amputation due to vascular aetiology during the post-discharge rehabilitation phase.

Methods and analysis A systematic meta-aggregation study will be performed to identify full-text, peer-reviewed journal articles reporting on patients' psychosocial perspectives on major lower-limb amputation due to vascular aetiology from post-discharge to several years afterward. The databases Embase, CINAHL Ultimate, APA PsycInfo, PubMed and Scopus will be searched with no limitations regarding the publication year. Studies that satisfy the eligibility criteria will be critically appraised using an acknowledged checklist and synthesised using the Joanna Briggs Institute three-phase approach for the synthesis of meta-aggregation studies. The GRADE-CERQual (Grading of Recommendations Assessment, Development and Evaluation-Confidence in Evidence from Reviews of Qualitative research) tool will be used to determine the level of confidence in the qualitative evidence, and the PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis) reporting guidelines will be followed throughout the review process.

Ethics and dissemination Ethical approval is not required for the study, as the review is built on pre-existing available data in the literature. Findings from the review will be disseminated through publication in a peer-review journal.

PROSPERO registration number CRD42022377114.

INTRODUCTION

Vascular disease is the major cause of lower-limb amputations (LLAs) in high-income countries, with dysvascularity (diabetes, peripheral artery disease and infection)

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Study selection, data extraction, quality assessment and level of confidence determination will be performed independently by three researchers to reduce the risk of publication and personal biases. A fourth will arbitrate on any disagreements.
- ⇒ All articles selected for inclusion will be subjected to critical appraisal using the Joanna Briggs Institute Critical Appraisal Checklist for Qualitative Research.
- ⇒ The Grading of Recommendations Assessment, Development and Evaluation-Confidence in Evidence from Reviews of Qualitative research tool will be undertaken to determine the level of confidence in the qualitative evidence.
- ⇒ The review does not analyse original data due to the nature of meta-aggregation; the synthesis relies on the data reported by the primary researchers.
- ⇒ Studies which are not published in English, Danish, Norwegian, German or Swedish will not be included. This limitation may cause language bias.

being the underlying cause of more than 90% of cases.¹⁻³ The population is characterised by multiple comorbidities and a high age (mean age >70 years).^{1 4 5} The prevalence of LLA due to dysvascularity varies by country.⁵ However, when looking at diabetes-related causes in an isolated manner, an estimated 6.8million LLAs were performed globally in 2016 according to the Global Burden of Diseases, Injuries and Risk Factors Study.⁶ The number of LLAs caused by vascular diseases is expected to rise in the coming years due to the continued growth of the elderly population and the rising prevalence of type 2 diabetes.^{1 2 7}

Having an LLA constitutes a major life-changing event in a person's life,⁸ potentially impacting all areas in terms of physical, psychological and social consequences.⁹ The focus in recent years has especially been on the pronounced psychosocial consequences

associated with LLAs.^{15 9 10} In a systematic literature review of the quality of life in people with LLA, it was demonstrated that the quality of life in this group was significantly impaired compared with controls.⁵ In this regard, studies have found that deterioration in quality of life does not only relate to the perioperative phase—or the time immediately afterward—but is generally persistent 12 and 18 months post-amputation.¹⁵ Other studies have shown that an LLA is associated with a significantly increased risk of developing anxiety disorders, depression and symptoms of post-traumatic stress disorder (PTSD).^{9 10} One review found that the prevalence of psychiatric disorders in patients with LLA was in the range of 32%–84%, including PTSD rates of 3.3%–56.3% and depression rates of 10.4%–63%.¹¹

The persistent psychosocial problems in people with LLA indicate a great need for long-lasting holistic rehabilitation, as the detection and treatment of psychosocial problems in this patient group are important for preventing derived psychosocial problems and towards better patient quality of life.¹² In this regard, it has been found that adapting well to one's new life situation after an LLA is highly correlated with health-related quality of life.¹³ However, despite the need for holistic care and support, studies indicate that healthcare professionals often focus on practical and physical issues while there is limited focus on the patients' emotional and existential suffering after an LLA.^{8 14–18} This is despite the fact that, in recent years, there has been increasing focus on a holistic approach among health professionals, for instance through initiatives such as the Fundamentals of Care Framework.¹⁹

An in-depth understanding of the psychosocial problems of patients with LLAs is essential for the guidance of health professionals in meeting and normalising patients' experiences and emotions related to the amputation and helping them use adaptive coping mechanisms.²⁰ Furthermore, identifying the psychological problems associated with LLA may help develop effective rehabilitation and counselling programmes.²¹ According to a comprehensive systematic review from 2019, few existing clinical practice guidelines and recommendations for the management of limb amputations, including the management of psychosocial issues, are high-quality, indicating a need for improved evidence-based guidelines within the field.²² A meta-aggregation study—a qualitative method of systematic review—would be highly relevant in this regard. Meta-aggregation studies are known to mirror the processes of quantitative reviews, enabling generalisable statements that can lead to recommendations for healthcare decision-making and guidance for policymakers.^{23–25} Several systematic reviews reporting qualitatively on psychosocial aspects related to major LLA offer valuable information in understanding the psychological consequences of limb amputation.^{3 5 26 27} However, only one³ of these reviews is focused exclusively on vascular causes of LLAs. The remaining reviews^{5 26 27} do not distinguish between the reasons for amputation; this is considered

problematic, as the psychosocial challenges experienced by patients with trauma and cancer are expected to differ from those in patients with vascular aetiology due to, for instance, age differences and diverse courses of treatment.²⁸ Furthermore, only one review²⁶ is reported as a meta-aggregation study. However, this study does not distinguish between the reasons for amputation and has some methodological limitations. For instance, the search was limited to searches in PubMed and Google Scholar and no assessment of confidence in the findings were performed, thus impacting the quality of the review.²⁹ Therefore, the meta-aggregation study does not provide a robust theoretical framework for interpreting the identified psychological problems in patients with LLA.

Based on the above, the aim of the present systematic meta-aggregation study is to explore the psychosocial perspectives of individuals who have undergone a major LLA due to vascular aetiology in the post-discharge rehabilitation phase, with the aim of gathering qualitative research that may contribute to awareness among health professionals and to the facilitation of evidence-based holistic rehabilitation guidelines and services. In this study, the post-discharge rehabilitation phase is considered to be the period after discharge from the hospital through the following several years. This characterisation differs from that in the previously mentioned review³ focused exclusively on vascular causes, as this review extends from the decision-making process around the amputation to several years after discharge. Thus, this is considered a relatively broad focus that results in less in-depth findings about psychosocial perspectives related to the post-discharge phase.

METHODS AND ANALYSIS

The systematic review protocol follows the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) checklist³⁰ and is reported with inspiration from the article 'A Guide to Writing a Qualitative Systematic Review Protocol to Enhance Evidence-Based Practice in Nursing and Health Care' by Butler *et al.*³¹

The systematic meta-synthesis will be reported according to the PRISMA guidelines,³² and a search protocol registered on 15 February 2023 on PROSPERO will form the basis of the review process. Ethical approval is not required for the study, as the review is built on pre-existing available data in the literature.

The start date of the review was 8 August 2022 and the expected completion date is 31 December 2023.

Review question

The question of the systematic meta-synthesis is as follows: What are the psychosocial perspectives of individuals who have undergone a major LLA due to vascular aetiology during the post-discharge rehabilitation phase (which, in this study, refers to the several years following discharge from the hospital)?

Eligibility criteria

We will include full-text, peer-reviewed journal articles reporting on qualitative studies focusing on patient perspectives on psychosocial aspects related to major LLA due to vascular disease from discharge to several years after (no upper limit). Participants in the studies should be adults (≥ 18 years of age) and have undergone unilateral or bilateral major LLA. In this study, major LLA will refer to an amputation above the ankle (ie, transtibial or transfemoral amputation), as these procedures can be categorised as a type of major LLA.³³ In the review, this will also cover joint disarticulation levels of amputation. Furthermore, patients without or with the use of a prosthesis will be of interest.

Studies focusing on amputation due to trauma or cancer or those which do not distinguish between the reasons for amputation will be excluded. However, studies will be considered if the data is extracted and presented separately. Likewise, studies involving both upper- and lower-limb amputations will only be included if data relating to LLA is extracted separately.

Studies that include different types (patients, health providers or relatives) of psychosocial perspectives will only be included if information concerning patients' perspectives is reported separately.

Qualitative interview studies will be included if they produce data relevant to the research question regardless of the data collection methods. Mixed-methods studies will only be included if the qualitative data is extracted and presented separately. We will exclude studies that evaluate specific interventions, as this review focuses only on individuals' psychosocial perspectives.

The search will not be limited in terms of publication year, but only articles in English, Danish, Norwegian, German and Swedish will be considered fit for inclusion.

Search strategy

A preliminary non-systematic search for articles relevant to psychosocial perspectives in relation to LLA has been conducted using Google Scholar, PubMed and CINAHL Ultimate to assess the volume of potentially relevant studies and to identify search terms from the titles, abstracts and keywords of relevant studies to be used in the structured search.^{23 34}

The unsystematic search will be followed by a comprehensive systematic literature search in five relevant databases: CINAHL Ultimate, PubMed, Embase, APA PsycInfo and Scopus. No limitations will be set in terms of the date of publication. To aim for an exhaustive search, the search will include a combination of thesaurus and free-text searches, a wide range of search terms (including synonyms, near-synonyms and acronyms), and different search functions (truncation, advanced search, phrase search, and the use of Boolean operators).²³ The free-text searches will be limited to 'title/abstract' to ensure precision in the search.³⁴ All authors will be involved in the database search, and a search librarian will be consulted to validate the search strategy. An example of the search

in PubMed is available in online supplemental material S1. A rerun of the searches will be carried out prior to submission in August 2023.

Additional searches will include backward (reference tracking) and forward (citation tracking) snowballing.³² This will include searches of reference lists and citations of included and other relevant articles to identify additional papers. Grey literature databases will not be included in the search strategy.

All review authors are involved in the search.

Study selection

All identified records from the search strategy will be collated and uploaded into RefWorks (RefWorks, RefWorks-COS, ProQuest RefWorks V.2.0, 2010). In RefWorks, the functions *Exact duplicates* and *Close duplicates* will be used for duplicate removal. Titles and abstracts will then be screened independently by three review authors for assessment against the research question and the eligibility criteria of the review. The remaining records will be retrieved in full and screened in detail by the same three review authors against the research question and the eligibility criteria. Any disagreement between the reviewers in the study-selection process will be resolved through discussion or by including other review authors in the decision-making. Records on which the review authors finally agree will be included in the systematic meta-synthesis.

The reasons for the exclusion of studies during the full-text screening will be recorded and reported in the review. Furthermore, the study selection will be reported in full in the review and supplemented with a PRISMA flow chart, as shown in online supplemental material S2.

Quality appraisal

All articles selected for inclusion in the systematic meta-synthesis will be subjected to critical appraisal by two independent reviewers (SHL and TMC) using the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for Qualitative Research³⁵ or the Mixed Methods Appraisal Tool.³⁶ The scoring system presented in the guide by Butler *et al* will be used for each individual study.³¹ Each checklist item will be assigned a score corresponding to 'No' (0 points), 'Not clear' or 'Not applicable' (0.5 points) or 'Yes' (1 point). This will be followed-up with an overall quality assessment of the individual article based on the total score of the 10 questions. If the total score is 6 or lower, the article is excluded.

Data extraction

Data will be extracted from each included study by three review authors independently using the table function in Microsoft Excel 2016. The extracted data will include the following study details for each study: authors, year of publication, study aim, study design and data collection methods, participants, setting, data analysis, and key findings.

Any disagreements between the review authors will be resolved through discussion or by consulting additional review author(s).

Synthesis

The JBI three-phase approach for the synthesis of meta-aggregation studies will be used to synthesise the data.³⁷ Phase one, *Finding*, will include the extraction of all the findings from the included studies with an accompanying illustration (quotation, field-work observation or other supporting data) and an allocated level of credibility for each finding. The level of credibility will be completed using JBI's System for the Unified Management, Assessment and Review of Information (SUMARI). Phase two, *Category*, will include the development of categories for findings with ≥ 2 like findings per category accompanied by a category description that represents the meaning of a group of similar findings. Finally, phase three, *Synthesised finding*, will include the development of ≥ 1 synthesised finding(s) of ≥ 2 categories that can be used to generate recommendations for practice and policy. Each synthesised finding will be accompanied by an explanatory statement that represents the meaning of a group of similar categories. Three review authors (SHL, HLR and TMC) will be included in all phases of the synthesis. All categories and synthesised findings will be independently cross-checked for accuracy and reviewed by a fourth review author to ensure consensus is reached.

Assessment of confidence in findings

The Grading of Recommendations Assessment, Development and Evaluation- Confidence in Evidence from Reviews of Qualitative research tool will be undertaken independently by three review authors (TMC, HLR and SHL) to determine the level of confidence in the qualitative evidence.^{29 38} Thus, the tool will be applied to appraise each review finding (ie, for each theme generated) in terms of its informative value and trustworthiness within four different domains: (1) methodological limitations; (2) coherence; (3) data adequacy; and (4) data relevance.²⁹ The assessment of the methodological limitations was based on the quality appraisal of each included study.

We will grade the confidence in each review finding as high, moderate, low or very low. Any disagreements between the authors will be discussed; otherwise, other review authors will be involved. The confidence judgement for each review finding and an explanation of the judgement will be presented together with the review findings in a 'Summary of the Qualitative Findings' table.²⁹

Patient and public involvement statement

There will be no patient or public involvement in this study.

ETHICS AND DISSEMINATION

This meta-aggregation study does not require ethical approval, as the review is built on pre-existing available data in the literature. But the aim is to be as faithful to the original data as possible. The review will be published in a peer-reviewed journal. Findings from the review will be disseminated through publication in a peer-review journal.

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Contributors DS and PHP conceived the idea for the review. SHL, HLR, DS, PHP and TMC were responsible for the study design and protocol. SHL, DS and PHP drafted the manuscript with input from HLR and TMC. SHL, HLR, DS, PHP and TMC have read and approved the final protocol manuscript. The corresponding author SHL guarantees that the authorship contribution statement is correct.

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