Research designs and instruments to detect physiotherapy overuse of low-value care services in low back pain management: A scoping review protocol

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Protocol

Abstract

Background

The provision of low value care services in low back pain management is a problem of global scope. Inappropriate imaging, overmedication and overused invasive therapies are prevalent in physician services. Yet, little is known about overused low-value physiotherapy services. Most studies addressing physiotherapy overuse in low back pain management arose from countries in which physiotherapy is established in primary care. However, measures and instruments addressing physiotherapy overuse limitedly fit legislative conditions of health systems in which physiotherapy is a service of secondary care. Thus, this scoping review's purpose is to map existing research designs and instruments aiming to detect overused low-value physiotherapy services taking specific healthcare settings and aspects of the medical overuse into account.

Methods

The development of this scoping review is guided by the Arksey and O'Malley framework. A three-step, peer reviewed search strategy in accordance to the PRESS checklist will be conducted on Medline (PubMed), Web of Science and CINHAL. Additionally, grey literature will be searched on googlescholar. Preprints of empirical studies will be included. Initially, two reviewers will independently screen articles for eligibility by title and abstract. A third reviewer will mediate discrepancies. Uncertainties will be eliminated by full text analysis or by contacting the corresponding authors. A four-step analytical process will guide result reporting focusing on major research questions outlined in this protocol. Numerical and narrative tables, graphics and narrative summaries will be methods to summarize and collate results. In the final step, the German health system will serve as an exemplary setting and frame to practically apply results.

Discussion

Results of this scoping review will help researchers to systematically select overuse measures referring to aspects of the overuse typology, specific healthcare settings and physiotherapy services. It will further provide information on limitations of present studies and will give advice how to address them. Moreover, this review will illustrate to what degree existing studies succeed to comprehensively cover the concept of the overuse typology.

Registration

This protocol has been registered on open science framework. (https://osf.io/vzq7k DOI: 10.17605/OSF.IO/PMF2G)

Background

Globally, low back pain (LBP) represents the main cause of disability [1]. In LBP management, physiotherapy (PT) holds a key role as it is a frequently utilized health care service [2]. However, existing

studies indicate a prevalence of overused low-value PT services. Across 19 countries, 35% of applied PT services for musculoskeletal health conditions are estimated to follow no evidence-based guideline recommendation [3]. In LBP, 28% of delivered services were considered to be inappropriate [4]. Unfortunately, most studies addressing PT overuse concern countries with direct access legislation [5]. In Germany, direct access to PT services is still a goal to achieve and thus, limits the options of PT overuse measures since authorities of independent diagnostics and medication prescribing are not part of occupational curricula [6]. Due to unique legal regulations for PT services in Germany, this scoping review aims to map existing research approaches addressing PT overuse in LBP management fitting primary and secondary care conditions.

Medical overuse of low-value care services comprises healthcare delivery which is ineffective, inefficient and misaligned to patient preferences [7, 8]. From a clinician perspective, ineffective care lacks of evidence-based benefits, has the potential to cause harms and its benefits do not outweigh its risk. From a societal perspective, inefficient services are effective in nature but modes of delivery, frequencies and intensities of services produce no measurable patient benefits and have the potential to produce preventable costs. From a patient perspective, misaligned services are effective in nature but do not match patient preferences [8]. Unfortunately, most studies investigating medical overuse of PT services for LBP focus on aspects of ineffective care [3, 9]. In this regard, authors use terms as *appropriateness of care, overtreatment, overdiagnosis, overmedication, guideline adherence* or *medical misuse* to approximate the complexity of medical overuse of low value care services.

Data sources and measures to detect aspects of medical overuse are described in direct and indirect measures: Direct measures contain audits of clinical registries or patient records. Indirect measures contain quality indicator applications, survey studies of patients and healthcare providers or claims data analysis of regional differences in healthcare delivery [7]. However, research on medical overuse detection of low value care is still in its early stages: Authors of a critical review identified that most of overuse measures for LBP management aimed at imaging services [10] but even there, an international consent of definitions and measures of imaging appropriateness in LBP is still not achieved [11]. Despite detections of inappropriate imaging services, a lacking availability of systematically collected administrative patient-level data still prohibits comprehensive overuse measures and fail to provide information about motives on individual low-value service provision [12]. In PT services, the identification of suitable overuse measures is even more complex since measures predominantly need to focus on therapeutic courses. Especially in countries with limited PT access, diagnostic quality indicators fail to provide needed information about PT overuse in LBP management.

Thus, this scoping review aims to contribute to the field of medical overuse research by systematically mapping existing designs and instruments detecting domains of PT overuse of low-value services in LBP management in healthcare conditions with and without direct PT access.

Methods

Design and Registration

This study will be conducted by a multidisciplinary team with proven expertise in clinical PT, health services research and rehabilitation sciences. The study design is following the Arksey and O'Malley framework [13] and comprises five consecutive steps: (I) Identification of the research question, (II) Identification of relevant studies, (III) study selection, (IV) data charting, and (V) compiling and reporting of results. Study execution will be reported in concordance with the established reporting guidelines for Scoping Reviews (PRISMA P; PRISMA ScR) (see supplementary file 1 for reporting checklist of the study protocol PRISMA P) [14, 15]. In terms of research transparency, this protocol has been registered on the Open Science Framework database.

Stage 1: Identifying the research question

The rationale of this scoping review is directed by the following research questions:

RQ1: How is medical overuse of PT services in LBP management being measured?

RQ2: To what extent are domains of the medical overuse typology equally approached and represented?

RQ3: Which methods fit the legal conditions of the German healthcare system?

Stage 2: Identifying relevant studies (Eligibility criteria)

Eligibility criteria of this scoping review will follow the Population-Concept-Context (PCC) framework recommended by the Joanna Briggs Institute [16]. The PCC framework of this protocol is shown in Table 1 and is extended by the additional domain of "types of evidence".

Table 1
PCC Framework

Criteria	Characteristics
Population	- LBP patients (ICD: M54.3; M54.4; M54.5; M54.8; M54.9) - All stadiums of LBP
Concept	- All studies aiming to detect of medical overuse of physiotherapy care in low back pain management regarding effectiveness, treatment efficacy and alignment of care
Context	- Physiotherapy care across all sectors of health services (inpatient, outpatient and rehabilitation healthcare settings)
Types of evidence	- All types of empirical studies - Studies across all countries - Articles published in English or German language - Published and unpublished studies

The scoping review will include LBP patients according to the International Classification of Diseases (ICD) Version 10 (M.54). Specifically, diagnostics of ischialgia (M54.3), lumboischialgia (M54.4), back pain (M54.5), other back pain ((M54.8) and unspecified back pain (M54.9) will be included. Studies investigating medical overuse of PT care for specific back pain events containing nerve compressions, fractures, spinal cancer, traumata, infectious diseases or musculoskeletal birth anomalies will be excluded. According to classifications of time or severity of pain, all stadiums of LBP (acute, sub-acute, chronic, and recurrent) [17] and all grades of chronic pain severity established by von Korff et al. [18] will be included.

Regarding the concept of medical overuse, all studies aiming to detect overuse of low-value PT care in LBP management will be included and subsequently categorized to domains of the continuum of care model introduced by Michaleff et al. [7]. This model represents a tailored and continued development of the overuse typology of Verkerk et al. [8] fitting the context of PT care for musculoskeletal health conditions. Given the objective to provide an overview of existing evidence of medical overuse measures, studies of all sectors of PT care (inpatient, outpatient, and rehabilitative care settings) will be included. The time period of included publications will not follow any restrictions and will reach up until October 2021. Despite, the authors will include articles of all regions and countries in the world.

This review will include all types of experimental studies, quasi-experimental studies, analytical observational studies, cross-sectional studies, and all types of systematic or non-systematic review studies. To avoid publication bias, available preprint studies, will be included. Additionally, grey literature such as health insurance reports or other reports of governmental entities will be included. Opinion paper, editorials, commentaries and case reports will be excluded as these article types do not provide requested information on conducted research designs and instruments. A comprehensive overview of eligibility criteria for included articles is listed below.

Inclusion criteria
To be eligible for this review, articles must comply the following criteria:
Population of LBP patients (ICD-10: M54 group)
Studies investigating any aspect of medical overuse in the context of PT care
Studies conducted in any health care sector
Articles published at any time until 10/2021
Studies conducted in any country or region of the world
Studies reported in English or German language
Any studies, regardless of their study design
Health insurance reports or reports of governmental entitites
Exclusion criteria
Articles meeting the following criteria will be excluded:
Articles including patients with specific back pain conditions
Articles that do not measure aspects of PT overuse
Stage 3: Study selection (search strategy)

Databases for the selection of eligible studies will be Medline (PubMed), Web of Science, CINHAL and Google Scholar. The search strategy will contain keywords and subject headings from referring domains of the PCC framework. Within domains, keywords and index terms will be combined with the Boolean operator "OR". If applicable, keywords and index terms will be truncated. To connect domains, the operator "AND" will be applied. The search strategy will follow a three-step study selection approach and is led by the Joanna Briggs Institute's (JBI) Reviewer Manual [16]. In step one, an initial, limited search of set databases will be conducted with predefined keywords and index terms (see supplementary file 2) which will be used to screen retrieved articles for additional keywords and index terms. In step two, a second search including all identified keywords and index terms will be performed. In terms of a snowball principle, reference lists of included articles will be screened for additional sources in step three. The study selection process will be peer reviewed by applying the Peer Review of Electronic Search Strategies (PRESS) checklist [19]. Retrieved articles will be imported to Endnote20 (Philadelphia, USA).

The screening process of included articles will be performed in two consecutive steps: First, two reviewers (LK, LL) will independently conduct a title and abstract screening by consensus. To solve disagreements, it will be referred to a third party (AC). Primary reasons for article exclusion will be recorded. Secondly, a full text screening will be conducted following the principles of step one. To manage the study selection process, the online application RAYYAN Version 2021 (Cambridge, USA) will be used. A comprehensive flow of the study selection process will be illustrated by the PRISMA-ScR flowchart.

Stage 4: Data charting (data extraction)

To guarantee an appropriate illustration of study characteristics, a preliminary data extraction chart tailored to objectives of this review is illustrated in Table 2. The chart is developed in concordance with JBI's Reviewer Manual [16]. Chart elements are complemented by associated questions which is inspired by recently published Scoping Review Protocols [20–22]. The data extraction process will be performed in Microsoft Excel. The chart will be piloted by two researchers (LK, LL) and adjusted if necessary. As this is an iterative process, further adjustments at later points in time will also be taken into account. One researcher (LK) will take the lead in data extraction and will be checked by a second reviewer (LL).

Table 2
Preliminary data extraction chart

Chart elements	Associated questions
Publication details	
Author(s)	Who wrote the article?
Year of publication	When was the article published?
Country of origin	Where was the study conducted and published?
Type of PT access	How are the legislative conditions for PT services in the country of origin? How is the access to PT services regulated? What occupational rights do therapists have?
Publication type	What type of publication is this? (empirical study, grey literature)
Study details	
Aims/purpose	What were the aims of the study?
Methodological design	What methodological design was applied?
Population and sample size	Who was the target population and how many were included in the study?
PT services	Which PT services were of primary interest?
Conceptualization and measurement details	
Medical overuse definition	How is medical overuse of PT services in LBP-management conceptualized?
Conceptual framework	Is the concept based on a practical/theoretical framework, theory or typology?
Domains and perspectives of the low-value care typology	Which domains of the low-value care typology introduced by Verkerk et al. [8] are investigated? (domains: ineffective care, inefficient care, misaligned care; perspectives: provider, society, patient)
Number of domains and perspectives	How many domains and perspectives of the low-value care typology were included?
Measurement	What research instrument was used for measurement (e.g. quality indicators, scaling, questionnaire, interview guide)? What level of measurement was used (nominal, ordinal, interval, ratio)? Were measures of direct or indirect nature?
Instrument psychometric properties	If applicable: Was the instrument validated? What was the reliability statistic? What was the content validity? Which guidelines or evidence synthesis were referenced to set thresholds
Limitations and challenges	Were there any reported limitations or quality issues (not a critical appraisal)?
Recommendations for further studies?	Were there any recommendations for further studies?

Stage 5: Collating, summarizing and reporting results

To guide the report of results, this stage will contain four consecutive steps. In the first step, a narrative summary comprising a numerical table about generic details of included articles will be provided. The table will be led by the domains of the PCC framework and will further contain information about the number of included articles, study designs, instruments and measures, investigated PT services, LBP stadiums and referred guideline recommendations.

In step 2, the first research question (*RQ1: How is medical overuse of PT services in LBP management being measured?*) will be addressed. An in depth narrative description of identified measures and instruments will be provided. In an illustrative form (bubble chart or comparable figure), trends of methodical approaches for specific aspects of PT overuse, specific PT services or specific healthcare settings will be visualized. Result reporting of *RQ1* will be completed by a narrative summary connecting research trends with reported limitations and recommendations (with special focus on instrument validity for overused low-value PT services exposure) for future research intends.

In step 3, result reporting of *RQ2 (To what extent are domains of the medical overuse typology equally approached and represented?)* will be approached by a narrative description of the numerical distribution of domains. Additionally, the development of a pie chart is intended to illustrate results. The chart also aims to highlight distributional differences in relation to specific PT services (e.g. diagnostics, treatments, prescriptions, advice) and healthcare settings (primary and secondary care). This is to identify potential trends of researched domains and perspectives of the medical overuse typology with referral to specific services and contexts. Thus, this potentially shows in which situations scientific methods measuring overuse domains are insufficient or not available.

In step 4 of the analysis, findings will dichotomously be mapped to health systems in which PT services are provided in primary or secondary care. Since this review particularly focuses on overuse measures for secondary care conditions, the German health system setting will serve as an exemplary context to pragmatically tailor and collate results. In this regard, a framework will be developed which assigns identified measures and results of this review to the occupational law of German PT's. In this way, we attempt to answer *RQ3 (Which methods fit the legal conditions of the German healthcare system?)*.

Discussion

Medical overuse of low-value care services is a problem of global scope [23, 24]. In LBP care, overuse and drivers of overuse are predominantly reported for physician services [25–29] although PT is determined by intensive patient contacts along rehabilitation. Studies addressing PT overuse of low-value services frequently concentrate on ineffective care as it appears to be less complex to distinguish services in binary categories of "good" and "bad" [3, 4]. However, these measures do not provide sufficient information on how care was delivered. Was it delivered efficiently and aligned to patient preferences? And if so, how do we manage destructive patient preferences? These aspects are of even more relevance for PT services provided in secondary care settings as quality indicators or other types of binary overuse measures referring to diagnostics, prescribing patterns or treatment choices only have limited applicability. Due to the multifaceted complexity of the medical overuse typology and unestablished academic research traditions, countries like Germany fail to supply valid information on overused low-value PT services in LBP management [30]. Thus, this review aims to contribute to medical overuse research by providing guidance in the choice of research methods taking healthcare settings, PT services and specific domains of medical overuse into account.

To the best of our knowledge, this review is the first of its kind and will contribute to a sustainable application of PT services putting evidence-based, patient-centered care into primacy of action.

Abbreviations

ICD International Classification of Diseases

LBP Low back pain

PCC Participants, Concept, Context

Declarations

Acknowledgments

Protocol amendments

If any amendments after the publication of this protocol occur, we will provide detailed information about dates, contents, and reasons for changes in future publications.

Authors' contribution

LK conceptualized the research strategy for this scoping review and wrote the draft of the protocol manuscript. AC and LL co-edited the manuscript. LK pre-tested the initial search strategy. All authors approved the final version of the manuscript.

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Availability of data and materials

Not applicable.

Ethics approval and consent to participate

For this scoping review, ethical approval or consent forms are not required.

Consent for publication

All authors of this review consented for publication.

Competing interests

There are no competing interests to declare.

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