





# BMJ Open Models of care for low back pain patients in primary healthcare: a scoping review protocol

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**To cite:** Duarte ST, Nunes C, Costa D, *et al.* Models of care for low back pain patients in primary healthcare: a scoping review protocol. *BMJ Open* 2022;**12**:e053848. doi:10.1136/bmjopen-2021-053848

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2021-053848>).

Received 25 May 2021

Accepted 25 February 2022



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## ABSTRACT

**Introduction** Low back pain (LBP) is the most prevalent musculoskeletal condition worldwide and it is responsible for high healthcare costs and resources consumption. It represents a challenge for primary care services that struggle to implement evidence-based practice. Models of care (MoCs) are arising as effective solutions to overcome this problem, leading to better health outcomes. Although there is growing evidence regarding MoCs for the management of LBP patients, an analysis of the existing body of evidence has not yet been carried out. Therefore, this scoping review aims to identify and map the current evidence about the implementation of MoCs for LBP in primary healthcare. Findings from this study will inform policy makers, health professionals and researchers about their characteristics and outcomes, guiding future research and best practice models.

**Methods and analysis** This protocol will follow the Joanna Briggs Institute methodological guidelines for scoping reviews. Studies that implemented an MoC for LBP patients in primary healthcare will be included. Searches will be conducted on PubMed, EMBASE, Cochrane Central Register of Controlled Trials, PEDro, Scopus, Web of Science, grey literature databases and relevant organisations websites. This review will consider records from 2000, written in English, Portuguese or Spanish. Two researchers will independently screen all citations and full-text articles and abstract data. Data extracted will include the identification of the MoC, key elements of the intervention, organisational components, context-specific factors and patient-related, system-related and implementation-related outcomes.

**Ethics and dissemination** As a secondary analysis, this study does not require ethical approval. It will provide a comprehensive understanding on existing MoCs for LBP, outcomes and context-related challenges that may influence implementation in primary healthcare, which is meaningful knowledge to inform future research in this field. Findings will be disseminated through research papers in peer-reviewed journals, presentations at relevant conferences and documentation for professional organisations and stakeholders.

## INTRODUCTION

Low back pain (LBP) is a major public health problem, acknowledged for being the most prevalent musculoskeletal condition worldwide.<sup>1 2</sup> According to Global Burden of Disease studies, it affects about 568 (95% UI

## Strengths and limitations of this study

- As far as we know, this is the first scoping review that aim to map the current evidence base about models of care (MoCs) designed for low back pain (LBP) patients in primary healthcare.
- This study will follow the Joanna Briggs Institute Methodological Guidelines and Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews.
- A wide variety of study designs and reports will be included through a comprehensive search strategy in peer-reviewed journals and grey literature databases, as well as through handsearching in relevant journals and organisation websites. Records inclusion is limited to articles written in English, Spanish or Portuguese languages since 2000.
- Findings of this review should be carefully interpreted in terms of implications for practice as no quality appraisal of the studies will be performed.
- This study will provide a broader overview of the characteristics of the MoCs implemented for the management of LBP in primary healthcare, which is fundamental new information to underpin future research implementation studies on this topic.

505 to 641) million people of all age groups and it is the leading cause of disability in 160 countries.<sup>3</sup> Globally, LBP contributes for 64 (95% UI 45 to 85) million years lived with disability and 60.1 million disability-adjusted life-years, an increase of 47% and 54% since 1990, respectively.<sup>4 5</sup> Current trends show this burden is still rising alongside the increasing and ageing population.<sup>4 6</sup>

Most cases of LBP are defined as non-specific because it is not possible to identify its pathoanatomical cause.<sup>7</sup> LBP episodes are associated with long-term disability and poorer health-related quality of life,<sup>5 8</sup> as well as with additional health problems, such as sleep disorders, anxiety and depressive symptoms.<sup>9</sup> Therefore, it has been suggested that the individual and societal impact of LBP embodies a growing demand for healthcare

systems. The pooled prevalence rate of healthcare utilisation for LBP was estimated at 56% (95% CI 45 to 67) in the general population and 48% (95% CI 33 to 63) in Europe.<sup>10</sup> Clinical factors, such as higher intensity of pain and disability, have been proposed as the main responsible aspects for LBP patients seeking healthcare.<sup>8 10</sup> This consumption of resources leads to important healthcare costs associated with more medical appointments, emergency department visits, physiotherapy and other treatments, imaging tests, medication, among others.<sup>11-14</sup>

Greater efforts on improving decision-making in first-contact consultations are advocated as a possible strategy to address the burden of LBP.<sup>2 15</sup> Most patients with LBP are managed in primary healthcare services<sup>16 17</sup> and recommendations in clinical guidelines are consistent. The first approach is to provide advice to remain active, education or reassurance about the absence of serious pathology.<sup>17-22</sup> As LBP has a benign nature, this will be enough for many patients.<sup>17-22</sup> Imaging tests should be prescribed only for patients with red flags or when imaging is likely to change treatment.<sup>15</sup> Also, medication should be avoided, but if needed, it should start with a non-steroidal anti-inflammatory drug at the lowest effective dose for the shortest time.<sup>17-22</sup> Second step approaches include physical (exercise and manual therapy), psychological (psychologically informed physiotherapy and cognitive behavioural therapy) or complementary therapies (eg, mindfulness).<sup>17-22</sup> The last stage is multidisciplinary pain management, which involves a combination of physical, psychological, social and work-related components, but it is only recommended for specific subgroups of LBP patients.<sup>15</sup>

However, evidence shows that current patterns of care in LBP may vary between settings and lack alignment with clinical guidelines.<sup>2 23 24</sup> Imaging tests are overprescribed,<sup>11 25</sup> referrals to surgery and secondary care specialists are common<sup>26 27</sup> and overuse of medication still a widespread problem.<sup>2 28</sup> For example, a randomised controlled trial showed only 58% of the LBP patients on waiting lists for surgery have visited, at least one time, a physiotherapist within 12 months prior to a spine surgeon appointment.<sup>29</sup> Likewise, one systematic review highlighted that one in every three physical therapists do not provide recommended care for back pain and only 52% of physical therapists agree that electrotherapy should not be provided to these patients.<sup>30</sup> Although there is scientific support to move away from medicalised management, many LBP patients still receive unnecessary care that is inconsistent with guidelines and the healthcare process tends to be fragmented, with many healthcare practitioners giving conflicting information.<sup>2 31 32</sup> These evidence-to-practice gaps waste healthcare resources and inhibit patients from receiving high value-based healthcare,<sup>27 32</sup> leading to poorer clinical outcomes.<sup>7 25</sup>

Over the years, some promising solutions have been developed to overcome these evidence-to-practice gaps, aiming to promote high-quality, efficient and sustainable healthcare.<sup>32 33</sup> Several countries are designing

strategic frameworks and models of care (MoCs), which create national and/or local responses to the burden of LBP.<sup>19 34-36</sup> An MoC is a framework 'that describe the principles of disease-specific, evidence-informed healthcare that should be delivered to consumers in a given setting; that is, the right care, at the right time, delivered by the right team, in the right place, using the right resources'.<sup>37</sup> Also recognised as 'clinical pathways', 'integrated care models' or 'clinical frameworks', MoCs focus on person-centred care and they are developed considering their applicability in local settings.<sup>38</sup> MoCs allow the shift from usual patterns of care towards the implementation of value-based care, supporting best practices and minimising evidence-to-practice gaps.<sup>37</sup> They drive evidence into policy and practice through changes at health system (macro), service delivery (meso) and clinical practice (micro) levels.<sup>39 40</sup> In the context of musculoskeletal conditions, MoCs develop system responses to support musculoskeletal health. It has been reported they lead to the improvement of several outcomes, such as access to health services, health outcomes, healthcare experience of the patients, use of healthcare resources and satisfaction of the health professionals with care delivery.<sup>34 35</sup>

Considering the promising results reported in the literature, several MoCs for LBP have been implemented and continue to be developed worldwide.<sup>34 35 41 42</sup> 'The Global Spine Care Initiative', created by the World Spine Care organisation, developed an evidence-informed, practical and sustainable model for prevention and care of spinal disorders.<sup>42</sup> This MoC aims to improve spine care delivery and reduce the burden of spinal disorders in different socioeconomic environments. Although this MoC require a thorough evaluation in local contexts, it could be implemented in communities with different levels of resources through a six-step implementation plan.<sup>42</sup>

Specifically for LBP, some examples concern the 'STarT Back' in the UK,<sup>34</sup> 'Betterback Model of Care' in Sweden,<sup>35</sup> 'GLA:D Back' in Denmark<sup>36</sup> and the 'Model of Care Management of People with Acute Low Back Pain' in Australia.<sup>19</sup> The most widely known MoC is the STarT Back, which is based on risk stratification and where patients with higher risk of poor outcomes are offered more comprehensive care.<sup>34 41</sup> This approach is based on the best available evidence, it links to strategic plans at different levels (micro, meso and macro levels) and it is developed through a collaborative general practitioner and physiotherapist integrated model of service delivery. Evidence shows it significantly reduced disability, time off work and health costs by making better use of health resources.<sup>34</sup>

Other MoCs have also been implemented in primary healthcare recently, showing promising results regarding their effectiveness and cost-effectiveness.<sup>35 42</sup> However, despite the majority of clinical guidelines recommend the implementation of stepped or stratified approaches to manage LBP patients,<sup>18-20</sup> these value-based strategies still underused and/or require further testing. There is no evidence that one particular MoC is superior to

another<sup>41</sup> and their complexity and heterogeneity may influence local implementation and outcomes. MoCs for LBP differ in terms of overall approach to treatment decisions, content of care and healthcare context, among other features. Given there is no published reviews with the specific purpose to map the literature available on the MoCs for LBP, it is expected the results of this study would provide a broader overview of their nature and diversity, as well as inform future research on different approaches to develop and implement MoCs.

Therefore, this scoping review aims to synthesize research evidence regarding MoCs designed for the management of LBP patients in primary healthcare services. The primary objective is to identify MoCs developed to manage LBP and describe their characteristics and key common elements. Second, we aim to describe the outcomes of MoCs and to detail context-related features influencing the implementation in primary healthcare, as these characteristics may affect their sustainability and transferability. These contextual factors will be divided into four levels of healthcare: macro (eg, policies, guidelines, legislation), meso (eg, readiness to change, organisational support and structures), micro (eg, patients' needs and preferences) and multiple levels (eg, social relationships, financial resources, leadership).<sup>43</sup> This study leans thematically on 'The Framework to Evaluate Musculoskeletal Models of Care', which is focused on improving patient and system-relevant outcomes for musculoskeletal conditions and provides a 'gold standard' approach for the implementation of MoCs.<sup>38</sup> To the best of our knowledge, this is the first scoping review protocol focused on synthesizing MoCs developed for LBP patients.

## METHODS AND ANALYSIS

A scoping review is a valid form of knowledge synthesis that addresses an exploratory research question for mapping key concepts, types of evidence and gaps in research related to a defined topic.<sup>44</sup> Scoping reviews examine the emerging evidence through systematic methods, providing a comprehensive overview of large, complex and heterogenous research subjects.<sup>45</sup> In order to ensure the methodological rigour and transparency of the findings, this review will be guided by the Joanna Briggs Institute Methodological Guidelines for scoping reviews<sup>46</sup> and Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews (online supplemental file 1).<sup>47</sup> Additionally, this protocol is registered in the Open Science Framework Registries (<https://osf.io/rsd8x>).

### Research questions

Considering the objectives aforementioned, this study aims to answer the following research questions:

- ▶ Which MoCs have been implemented for patients with LBP attending primary healthcare services?
- ▶ What are the key elements of the MoCs (these include, but are not limited to, interventions and their

characteristics, healthcare professionals involved, programmes duration and funding)?

- ▶ What are the patient-related, system-related and implementation-related outcomes of the MoCs and how have they been measured?
- ▶ What are the context-specific factors contemplated in the implementation of the MoCs at macro (system), meso (organisational), micro (patient) and multiple levels (as described in the Introduction section)?

### Inclusion criteria

Inclusion criteria will be defined through the 'PCC' mnemonic (Population, Concept and Context), as recommended by the Joanna Briggs Institute (JBI) guidelines.<sup>45</sup>

### Population

We will consider studies that included adults, primarily diagnosed with LBP, of any duration. These should be individuals who live in the community and do not reside in any institution, such as hospitals, nursing homes, psychiatric centres, military institutions or prisons. LBP conditions related to specific causes, such as pregnancy, fracture, inflammatory diseases, infection or other serious pathologies will be excluded.

### Concept

The concept of interest in this review is MoC, which is defined as a 'a person-centred and principle-based guide, usually presented as a document, that describes evidence-informed, best practice care for particular health conditions'.<sup>38</sup> This definition includes *what* care should be provided, concerning the principles of care for a given condition, and *how* it should be delivered in a local setting, regarding the guidance on how those principles could be implemented.<sup>37 38</sup> In order to clarify the concept, a distinction between MoCs and 'models of service delivery' should be made. A 'model of service delivery' entails the operationalisation of an MoC, translating its principles into recommendations and activities relevant to the local context, modes of service delivery and evaluation, considering resources, infrastructure and workforce capacity requirements.<sup>37</sup>

Based on 'The Framework to Evaluate Musculoskeletal Models of Care'<sup>38</sup> and also 'The Global Spine Care Initiative' for the implementation of an MoC for spinal disorders,<sup>42</sup> operational a priori criteria were established to differentiate an MoC from other types of interventions. For the purposes of this review, only studies that address MoCs and fulfil all the following criteria will be considered for inclusion:

- ▶ Define the optimal way to deliver healthcare for people with LBP according to an underlying evidence-informed strategy, framework or pathway.
- ▶ Describe the operationalisation of the MoC, explaining who deliver care, when and where care is best delivered and the details of how it is to be delivered and re-evaluated.



- ▶ Address how the MoC was tailored according to the local context and environment.
- ▶ Care is integrated and coordinated longitudinally.
- ▶ The MoC has clear patient, system and/or implementation objectives.

We will include studies a priori that describe, but are not limited to: (1) which MoC was implemented: identification of the MoC and/or underlying frameworks/theories; (2) what and how care is provided, and by whom: underlying interventions at patient-level, professionals training, services involved, organisation of care, among others; (3) how the MoC is assessed and what were its outcomes at patient's level (eg, pain, disability or health-related quality of life, collected with self-reported questionnaires or interview questionnaires or performance measures), at system-level (eg, rate of prescribed examinations, healthcare costs, waiting times, quality indicators, perceptions/perspectives of stakeholders) and implementation outcomes (eg, acceptability, adoption, feasibility, fidelity, penetration, sustainability)<sup>38 48 49</sup>; (4) what are the aspects, if any, of the MoC that are context-specific at macro, meso, micro and multiple levels. Data from different studies that refer to the same MoC will be collected and reported together as the identified MoC is the concept of interest.

### Context

We will include MoCs implemented in primary healthcare services. In 2018 Astana Declaration, primary healthcare was conceptualised by the WHO as 'the most effective, efficient, and equitable approach to enhancing health', being 'at the core of integrated health systems, multi-sectoral policy and action, and empowered people and communities'.<sup>50</sup> According to clinical practice guidelines LBP should be managed in primary healthcare and it is one of the most common reasons for general practice visits worldwide.<sup>10 17</sup> This review will comprise MoCs developed in primary healthcare services and also MoCs that involve other levels of healthcare delivery, as long as they include primary care interventions in the clinical pathway of LBP patients.

### Types of sources

This review aims to cover a broad spectrum of the literature through the inclusion of sources that typically contain information on the implementation of MoCs. Therefore, quantitative, qualitative and mixed methods study designs will be considered for inclusion. These include, but are not limited to randomised controlled, observational, quasi-experimental, hybrid, phenomenological and feasibility studies, among others. Grey literature will comprise policy documents, organisational audit reports, research reports, dissertations and theses, pilot studies and conference proceedings. Reviews, meta-analysis, guidelines, books, book chapters, editorials, expert opinions and presentations will be excluded, but reference lists will be checked to identify potential additional studies.

Considering this review intends to map interventions related to the implementation of MoCs for the management of LBP, studies referring to the effectiveness or efficiency of specific clinical interventions will be excluded. As the distinction between the two types of intervention is not always clear in the literature, an overinclusion approach will be adopted at the title and abstract screening phase. At this stage, whenever doubts arise, studies will be included to avoid the premature exclusion of any relevant data. For full-text screening, we will include studies in which the experimental group is compared with usual care (at the same or at another healthcare setting), waiting list or no treatment whenever the title and/or abstract suggests an underlying MoC.<sup>51</sup>

Eligible evidence must be available in peer-reviewed journals or grey literature in English, Portuguese or Spanish languages. The timeframe for inclusion will be literature published since 2000 as it should reflect contemporary paradigms of healthcare delivery regarding the implementation of MoCs for LBP patients.<sup>33</sup>

### Search strategy

Electronic databases searches on MEDLINE (PubMed), EMBASE, Cochrane Central Register of Controlled Trials, PEDro, Scopus and Web of Science will be conducted. Searches will also be carried out on grey literature databases (Grey Literature Report and MedNar Search Engine) in order to improve the comprehensiveness of the available evidence.

Hand searching will be performed in relevant peer-reviewed journals, such as *Implementation Science*, *JBI Evidence Synthesis*, *Health Services Research*, *BMC Health Services Research*, *Musculoskeletal Science and Practice*, *BMC Musculoskeletal Disorders* and *Best Practice & Research: Clinical Rheumatology*. We will also hand search websites of important organisations, such as WHO, Global Spine Care Initiative, The Global Alliance for Musculoskeletal Health, Musculoskeletal Australia, Agency for Clinical Innovation Musculoskeletal Network, Agency for Healthcare Research and Quality, National Institute for Health and Clinical Excellence and The Bone and Joint Initiative. Handsearching will be performed regularly, using a list with information on the dates of search and whether the search has been completed, which aim to minimise duplication and effort of the procedure for the next handsearching activities.

A three-step search strategy will be used in this review.<sup>46</sup> An initial limited search of PubMed was undertaken in May 2021, using the 'PCC' mnemonic, so the key terms "low back pain", "model of care" and "primary care" were included. Text words contained in the titles and abstracts, index terms describing the articles, Medical Subject Headings and truncation were used to develop a full search strategy (online supplemental file 2). A second search using a tailored strategy will be performed across all databases, including grey literature databases, with the required adjustments to the features of each one. The aforementioned key terms will also be used in the handsearching procedures. Third, reference lists of the

eligible literature and published reviews will be screened to identify additional studies that meet the inclusion criteria.

The searches will be carried out between September 2021 and April 2022 with assistance from a research librarian. When submitting the review for publication, a final search will be carried out to check whether potentially relevant literature has been published. Also, we will email authors of the included studies to clarify uncertain information and/or to request missing data related to the MoC. This new information will be included until the conclusion of the data synthesis process. If authors do not respond, the missing data will be identified in the charts.

### Study selection

Based on the previously mentioned inclusion criteria, records selection will start with the independent screening of both titles and abstracts by two researchers (STD and DC). In order to diminish ambiguity and to ensure that the evidence selected is relevant for full-text retrieval, reviewers will meet during the titles and abstracts review process to discuss uncertainties related to study selection and the need to refine the search strategy. Pilot testing to assess reviewer agreement will also be performed, randomly selecting 25 titles and abstracts. Screening by both reviewers will start only when is achieved an agreement equal or greater than 75%.<sup>46 52</sup>

At an early stage, all the records will be uploaded to EndNote X7.8 (Clarivate Analytics, USA), all citations will be imported and duplicates will be removed prior to the title and abstract screening. We will retrieve full-texts for all records included by at least one reviewer. Details of excluded sources at full-text review will be reported with reasons for their exclusion. A Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram showing details of the study selection process will be provided.<sup>47</sup> Search will be manually handled and results will be securely stored with restrict access.

### Data charting

A data charting form will be developed for this review. The initial headings comprise details that are meaningful to the research questions and specific objectives (table 1). At least five records will be selected for pilot testing, which aims to test the data charting form and the reliability of the reviewers' extracting data. It will be performed by the same two reviewers (STD and DC), who will perform the data extraction independently. The data to be included will be refined at the review phase and the form will be updated accordingly, whenever needed.<sup>44</sup> All adjustments that may occur during the data extraction process will be reported.

The review team will independently read and abstract data of each included record. Any disagreements that may arise will be addressed through discussion until consensus is reached. As each MoC is the unit of interest in this review, multiple records of the same MoC will be linked and reported together for the purposes of data extraction and presenting the results.

**Table 1** Data extraction according to scoping review research questions

Data to be extracted	
Summary	<ul style="list-style-type: none"> <li>▶ Authors</li> <li>▶ Title</li> <li>▶ Year of publication</li> <li>▶ Citation</li> <li>▶ Source of information (peer-reviewed or grey literature)</li> <li>▶ Study designs</li> </ul>
Research question 1: identification of the MoC	<ul style="list-style-type: none"> <li>▶ MoC Identification (name, if applicable)</li> <li>▶ Country</li> <li>▶ Population (acute, subacute or chronic LBP)</li> <li>▶ Sample size</li> </ul>
Research question 2: key elements	<ul style="list-style-type: none"> <li>▶ Underlying theory/framework</li> <li>▶ Characteristics of the interventions</li> <li>▶ Organisational elements (eg, healthcare professionals involved, workforce capacity, programs duration, funding, care coordination)</li> </ul>
Research question 3: outcomes and outcome measures	<ul style="list-style-type: none"> <li>▶ Outcomes addressed and outcome measures</li> <li>▶ Main results (outcomes at organisation and patient levels)</li> <li>▶ Evaluation of implementation success (if applicable)</li> </ul>
Research question 4: context-specific factors	<ul style="list-style-type: none"> <li>▶ Macro level</li> <li>▶ Meso level</li> <li>▶ Micro level</li> <li>▶ Multiple level</li> </ul>

LBP, low back pain; MoC, model of care.

Reviewers will not perform a quality or risk of bias assessment of the included studies as the aims of this scoping review differ from a systematic review.<sup>46</sup> This approach is in accordance with the JBI methodological guidelines for scoping reviews.

### Synthesis and presentation of results

Findings will be synthesized through a descriptive qualitative content analysis.<sup>53</sup> Once the results have been displayed in a tabular format, a narrative summary of the data will detail how they answer to the research questions and objectives of this scoping review. A map of the data will be also developed in order to foster greater awareness for the extracted contents.

Results will be presented regarding each MoC implemented for the management of LBP, including its identification, key elements of the intervention, organisational components, context-specific factors, outcomes and outcome measures and evaluation of implementation success of the respective studies. We will also report as quantitative data, using a descriptive numerical summary, the overall number of studies, study designs, years of publication, types of intervention, characteristics of the study population and geographical distribution of studies.



### Consultation with relevant stakeholders

Consultation is an important step as it adds methodological rigour to the review and involves a knowledge translation activity.<sup>54</sup> As one member of the research team (EBC) have developed and implemented an MoC for LBP in different portuguese primary healthcare settings, it is expected that his expertise will strengthen the trustworthiness of the analysis. Additionally, we will collaborate closely on the ongoing 'MyBack' research project, which aims to compare the effectiveness of a personalised self-management programme for LBP recurrences and usual care compared with usual care alone, in patients seeking primary healthcare, while also seeking to pilot test the acceptability, feasibility and results of an implementation strategy designed to facilitate its adoption across patients and health professionals, through a hybrid type I, randomised, controlled and multicentre study of effectiveness and implementation. The 'MyBack' project is developed by a group of experienced researchers in the field of LBP. Thus, for the consultation step process, a purposive sample of researchers will be invited to fulfil an electronic survey, where preliminary analysis and findings of the review will be displayed.<sup>55</sup> In this survey, they will answer questions regarding the interpretation and translation of the preliminary and final findings, as well as research gaps not identified by the team.

### Patient and public involvement statement

Patients and/or members of the public were not involved in the design, conduct, reporting or dissemination plans of this research.

### DISSEMINATION AND ETHICS

As a scoping review is a secondary analysis of the available literature, ethical approval is not required. This study is meant to provide an overview of the current and emerging MoCs for patients with LBP in primary healthcare services. It is expected that this knowledge will underpin future implementation research studies, encouraging policy makers, health professionals and researchers to develop value-based solutions for LBP patients. Findings will be disseminated through publication in a peer-reviewed publication, conference presentations and documentation for healthcare organisations and key stakeholders. Additionally, we will prepare a brief summary of our findings to share among frontline clinicians in primary healthcare settings and enhance knowledge translation.

The first draft of the manuscript should be completed by the end of the first semester of 2022. All amendments to the protocol will be dated and reported through a detailed description of the rationale for the adjustments.

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**Acknowledgements** The authors gratefully acknowledge the members of the MyBack project for insightful comments on the development of this manuscript.

**Contributors** STD, CN and EBC conceived the study, STD outlined the protocol and drafted this manuscript, STD, DC, CN and EBC jointly developed the research

questions and inclusion criteria, HD supported the formulation of search strategy. All the authors revised and accepted the final version of the manuscript.

**Funding** This project is supported by national funds through FCT - Fundação para a Ciência e a Tecnologia, I. P., under the PhD grant awarded to STD (UI/BD/150882/2021) and MyBack project (PTDC/SAU-SER/7406/2020), in which EBC is the principal investigator.

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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