PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Low Back Pain Management in Primary Healthcare: Findings from a Scoping Review on Models of Care
AUTHORS	Duarte, Susana; Moniz, Alexandre; Costa, Daniela; Donato, Helena; Heleno, B; Aguiar, Pedro; Cruz, Eduardo

VERSION 1 – REVIEW

REVIEWER	Ryan, Clare Solent NHS Trust, Physiotherapy Service
REVIEW RETURNED	26-Oct-2023

GENERAL COMMENTS	Thank you for the opportunity to review your work. This scoping review had been undertaken using a recognised method and with rigor and has the potential to make a useful contribution to the literature. Further work is, however, needed to be concise, to minimise the overlap between the text in the figures and tables, and to emphasise the 'so what' of your findings. In addition, I suggest the contribution of the paper would be significantly stronger if you reported on all of your objectives in this paper. I hope that these suggestions, and those detailed below, are useful. Abstract • Objectives: I suggest clarifying what 'context features' are. • Conclusions: final sentence, second part starting 'which may contribute' is vague. Article summary strengths and limitations • Second point: would 'aid' work better than 'safeguard'? • Third point: is it 'heterogeneity' rather than 'uncertainty'? • Final point as in my point above about the abstract conclusion, the second part of this point is vague. Introduction • Line 95: is it 'burden' rather than 'demand'? • Line 110: I'm not sure that 'auspicious' is the right word. • I suggest you provide a more detail about what a model of care is, how it is different to a guideline and a care pathway. • Several systematic reviews of care pathways have been published (e.g., Murphy et al 2020 (one of your references), and I suggest you identify what your review will add to that body of work. • Again, the final sentence needs work to sell the potential impact of this review. Methods • Line 144: is it 'informed' or 'determined' rather than 'driven'? • I suggest justifying why patients and the public were not included in the design, conduct or reporting of this review. • Research questions: are these objectives rather than research questions? • I suggest listing only the objectives you will address in this paper. • I suggest objective one needs re-wording as it doesn't quite make

	sense. • Line 166: I think this is the first time you use PCC, so write out in full. • The inclusion criteria could be much more succinct, as they are in your abstract. • Search strategy: minimise overlap between the main text and that included Figure 1. • Study selection, data charting and synthesis: reducing the detail included in the method. Murphy et al's (2020) systematic review of clinical pathways (you've referenced this paper) provides a good example of the level of detail needed. • Line 241: Is it 'includes' rather than 'concerns'? Results • Line 260: Is it 'search results' rather than 'literature search'? • Literature search: minimise overlap between the main text and that included Figure 1. • Line 271: I'm not sure 'designation' is the right word. • Minimise overlap between the main text and that included Table 1 and ensure the text used refers to the table, highlights the most salient findings. • Line 315: again, I suggest rewording 'context features'. • Line 344 'leading entry point' needs rewording. • Line 352: is it 'The health professionals who most commonly deliver MOCs'? Discussion • Line 441 suggest rewording 'solid', well established? • In each paragraph of the discussion ensure that the 'so what' of the point you make is clear. E.g., why does it matter that there is heterogeneity in the MOC? • Line 453 suggest rewording 'contemporary trends'. • I suggest that many of the points you raise in the discussion would be better placed in the relevant results section. You would then be able to use the discussion to emphasize and elaborate on the 'so what' of your findings. As written, it's hard to quickly grasp the key important take aways from the paper. • I suggest adding subheadings for 'strengths and limitations' and 'implications'. • Limitations: what do you think the limitations are of working with such an inclusive definition of MOC? Conclusion • I suggest starting this section at 'This study', moving the first twelve words to the beginning of the next sentence (and then adjusting the first sentence). • I suggest elaborating on or rewording 'care continuum' (or give examples) so the reader quickly grasps what you are referring to.

REVIEWER	Ben-Ami, Noa Ariel University, Faculty of Health Sciences
REVIEW RETURNED	15-Jan-2024

GENERAL COMMENTS	This study maps the evidence regarding the core characteristics and key elements of Models of care implemented in primary healthcare to manage Low Back Pain. It is important to understand the models of care for low back pain that are being implemented around the globe. The authors provided a comprehensive overview, but I noticed that there was no mention of the Enhanced Transtheoretical Model Intervention (ETMI)- a model of care for low back pain that was implemented in a public Health Maintenance Organization in Israel. (see references below - Disclosure – my Lab work)

	The omission of the ETMI raises questions about its exclusion from the literature search, prompting the need to investigate its absence and ensure that no other Models of Care were inadvertently overlooked. Some specific comments Introduction Line 105: “which succinctly endorses the delivery of nonpharmacological interventions, such as education, exercise and manual therapy” Manual therapy is not a first-line recommendation. (see LANCET series (No 2) Methods Line 151 – I am curious about the rationale behind not posing the most critical inquiries regarding the outcomes and success of the implementation. Given the frequent failures observed in implementation studies, it becomes imperative to grasp the complete panorama. Take, for instance, The Lancet trial 2021 titled 'Stratified care to prevent chronic low back pain in high-risk patients: The TARGET trial.” Despite its comprehensive approach, the trial revealed no differences in the transition to chronic LBP among patients presenting with acute LBP using a stratified approach to care. Can you please elaborate on this issue? Discussion In reference to Line 470, where it states, 'Considering its successful implementation in terms of clinical and cost-effectiveness (24,25,36,46),' it is crucial to note that clinical success was not consistently observed. See example: Effect of Low Back Pain Risk-Stratification Strategy on Patient Outcomes and Care Processes: the MATCH Randomized Trial in Primary Care. J Gen Intern Med. 2018 References on ETMI 1. Feldman R, Haleva-Amir S, Pincus T, Ben Ami N. Physiotherapist perceptions of implementing evidence-based practice for patients with low back pain through the Enhanced Transtheoretical Model Intervention: a qualitative study. Physiotherapy Theory and Practice. 2022; 6;1-12 . DOI: 10.1080/09593985.2022.2062690. 2. Feldman R, Pincus T, Ben Ami N. Implementation of the Enhanced Transtheoretical Model Intervention for low back pain patients in primary care: study protocol. Israel Medical Association Journal (IMAJ). 2022; 24: 375-381. https://pubmed-ncbi-nlm-nih-gov.mgs.ariel.ac.il/35734836/ 3. Feldman R, Nudelman Y, Haleva-Amir S, Ben Ami N. Patients' prior perceptions and expectations of the Enhanced Transtheoretical Model Intervention for chronic Low back pain: a qualitative study. Musculoskeletal Care. 2022; 20(2):371-382. DOI: 10.1002/msc.1600. 4. Feldman R, Nudelman Y, Haleva-Amir S, Pincus T, Ben Ami N. Patients' perceptions of the Enhanced Transtheoretical Model Intervention for chronic Low back pain: a mix method study. International Journal of Environmental Research and Public Health. 2022; 19, 6106. https://doi.org/10.3390/ijerph19106106. 5. Ben Ami N, Mirovsky Y, Chodick G, Pincus T, Shapiro Y. Increasing recreational physical activity in patients with chronic low back pain: A pragmatic controlled clinical trial. Journal of Orthopedic and Sports Physical Therapy (JOSPT). 2017; 47(2), 57-66. DOI: 10.2519/jospt.2017.7057. 6. Canaway A, Pincus T, Underwood M, Shapiro Y, Chodick G, Ben-Ami N. Is an enhanced behaviour change intervention cost-effective compared to physiotherapy for patients with chronic low back pain?

	Results from a multi-center trial in Israel. BMJ Open 2018;8:e019928. DOI: 10.1136/bmjopen-2017-019928.

REVIEWER	Verhagen, Arianne University of Technology Sydney, Physiotherapy
REVIEW RETURNED	27-Jan-2024

GENERAL COMMENTS	This manuscript concerns a scoping review. The authors aim to synthesize existing evidence related to models of care for people with low back pain in primary care. Generic comments 1. It remains unclear what a 'model of care' exactly is. In the abstract the authors describe a model of care as 'evidence-informed healthcare'. In their introduction they describe a model of care as a 'person centred and principle-based guide that describes evidence informed best practice'. Nevertheless, I do not understand what is different between a model of care and an evidence-based guideline for instance. Looking at what they included, I see targeted treatment approaches, like the STaRT-Back tool or BetterBack. I would like the authors to better describe the term 'model of care' in the introduction. 2. The authors have published a protocol, and they also deviated from this protocol. This deviation is completely understandable, but I would prefer the authors to mention all deviations in a specific paragraph, preferably at the end of the method section. This way the manuscript clearly answers two aims, and the reader will not be confused with the original 4 aims (which indeed is a bit much for one paper). 3. Overall, this manuscript is lengthy and contains a lot of repetition. For instance, referring to the protocol in Open Science Framework is done at least four times, once is enough. Most sentences are long, vague, sweeping and with a lot of padding and packaging. Especially the discussion section is too long and might benefit from some subheadings, like strength and limitations, future directions (or implications). Please try to be clearer and more precise in the writing. Specific comments 4. In the result sections of the abstract as well as the main document authors use terms like: most, some etc. Please add the actual number also as otherwise it remains vague. 5. The conclusion should contain text that answers the study aim(s). In the abstract this is not the case, and similar the conclusion of the main text is not clearly answering the aims. 6. In the method section, selection criteria, you use the abbreviation PCC without a clear description. As this should be the only place where you mention this framework (the other times you mention it are redundant; a repetition), please write it in full and delete all other mention. 7. There is a lot of text redundant, see for instance the sentences in lines 181-185. This paragraph does not fit in the method section, and doubles text in the intro and discussion. Please delete. Same for lines 237-238. In addition, please delete the headings related to study question 1 and 2, also redundant. 8. Please explain why the authors did not search before 2000 and did not included studies of all languages. These restrictions can introduce bias and need to be prevented. The aim of (scoping) reviews is to get an overview of all evidence, using these restrictions means you do not aim to include all evidence.

VERSION 1 – AUTHOR RESPONSE

To Mrs. Clare Ryan, Solent NHS Trust, University of Southampton (Reviewer 1):

4. Thank you for the opportunity to review your work. This scoping review had been undertaken using

a recognised method and with rigor and has the potential to make a useful contribution to the literature.

Further work is, however, needed to be concise, to minimise the overlap between the text in the figures

and tables, and to emphasise the ‘so what’ of your findings. In addition, I suggest the contribution of

the paper would be significantly stronger if you reported on all your objectives in this paper. I hope that

these suggestions, and those detailed below, are useful.

We extend our gratitude for your thorough review and insightful feedback on this manuscript. Your constructive

input has been instrumental in enhancing our work. We have made several revisions to ensure conciseness

and focus, eliminating information redundancy. Furthermore, we have changed the discussion to be more

succinct regarding the study's impact.

However, addressing all objectives was not feasible due to the substantial volume of information, as reported

in the Research Questions section. Although we acknowledge that incorporating the last objectives would enrich

the conclusions of our work, it is challenging maintain the level of information’s detail that we aim to provide.

Therefore, we have chosen to emphasize the specific contribution of this article, striving to address the "so

what" aspect you highlighted.

Abstract

5. Objectives: I suggest clarifying what ‘context features’ are.

Thank you very much. Your suggestion prompted us to reconsider what was encompassed by “context

features". This terminology was initially used to group data concerning the characterization of MoCs (e.g.

geographical distribution, local/regional/national implementation) and contextual factors related to

implementation. Since we did not address this research question in this paper, we agree that this terminology

loses its meaning, and therefore, we decided to remove it. In the abstract, we made the following changes:

'Objective: To synthesise research evidence regarding core characteristics and key common elements of MoCs

implemented in primary healthcare for the management of LBP'. (Page 2 lines 45-46)

6. Conclusions: final sentence, second part starting 'which may contribute' is vague.

We thank the reviewer for placing this question, as we found it highly relevant. As this is a scoping review without

a quality assessment of the included studies, we refrained from making practical recommendations on health

services and policies. However, we outlined implementation planning and research needs based on our findings

to underscore the study's contribution. We provided the following sentence:

'Conclusions: This study examines the features of MoCs for LBP, highlighting that research is in its early

stages and stressing the need for better reporting to fill gaps in care delivery and implementation. This

knowledge is crucial for researchers, clinicians and decision-makers in assessing the applicability and

transferability of MoCs to primary healthcare settings'. (Page 2 lines 64-67)

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Article summary strengths and limitations

7. Second point: would 'aid' work better than 'safeguard'?

Thank you. We have incorporated your suggestion into the sentence:

'To aid the transparency and methodological rigour of this study, it followed the Joanna Briggs Institute

Methodological Guidelines and Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension

for Scoping Reviews'. (Page 3 line 76)

8. Third point: is it 'heterogeneity' rather than 'uncertainty'?

Once again, we value and concur with the reviewer's suggestion and have adjusted the sentence accordingly:

'One limitation of this review is potential selection bias due to search strategies and language restrictions, as

well as heterogeneity in MoC terminologies'. (Page 3 line 80)

9. Final point as in my point above about the abstract conclusion, the second part of this point is vague.

Following the feedback on the abstract conclusion (point 6), we have included additional information in the

sentence:

'This study offers a comprehensive understanding of key characteristics of the MoCs implemented for LBP

patients in primary healthcare, which may help clinicians and decision-makers to plan implementation of MoCs

in real-world settings, as well as researchers defining avenues to overcome the current evidence-to-practice

gaps'. (Page 3 lines 84-87)

Introduction

10. Line 95: is it 'burden' rather than 'demand'?

Thank you for the suggestion. The change in wording was made to prevent repetition of the word "burden" within

the sentence. The adjustment has been implemented:

'Thus, LBP represents a growing burden for individuals, society and healthcare systems.' (Page 4 line 95).

11. Line 110: I'm not sure that 'auspicious' is the right word.

In response to your input, which we agreed, we have replaced 'auspicious' with 'promising'. (Page 4 line 109)

12. I suggest you provide a more detail about what a model of care is, how it is different to a guideline

and a care pathway.

We are grateful for the reviewers' comment on this issue and we agree that this distinction needs to be clearer.

Consequently, we added the following sentences in the manuscript:

'A Model of Care (MoC) is a person-centred approach that outlines evidence-informed best practices for

managing specific health conditions(21–23). It details the optimal care that should be provided and the methods

for its implementation. MoCs are built upon clinical guidelines - drawing from up-to-date recommendations –

and they primarily serve to translate these recommendations into actionable strategies(23). While clinical

pathways focus on the integrated delivery of care to patients with a specific condition, MoCs go beyond this

aspect, focusing much of their attention on the factors that determine a successful implementation(22,23).

‘(Page 4 lines 110-117)

13. Several systematic reviews of care pathways have been published (e.g., Murphy et al 2020 (one of

your references), and I suggest you identify what your review will add to that body of work.

4

Acknowledging the importance of this comment and the next one related to the potential impact of the review,

we have addressed it by changing the last paragraph of the Introduction:

‘Two recent reviews(26,27) have analysed the evidence on initiatives for implementing LBP management. One

review focuses specifically on MoCs implemented in Australia(26). The other, a systematic review(27), aims to

describe clinical pathways and care integration across different levels of care, without focusing on the details of

care delivery and implementation. Therefore, our work seeks to expand on these contributions by providing a

broader overview of the diversity, content and resource requirements of MoCs for LBP patients. This is important

information to support policy makers, managers, clinicians in the development and implementation planning of

MoCs, as well as pinpoint evidence gaps related to implementation in real-world settings.’ (Page 5 lines 136-

143)

14. Again, the final sentence needs work to sell the potential impact of this review.

In alignment with the feedback on points 6 and 9, we have revised the last paragraph. Please see the previous

answer on point 13. (Page 5 lines 139-143)

Methods

15. Line 144: is it ‘informed’ or ‘determined’ rather than ‘driven’?

In response to your input, we have replaced ‘driven’ with ‘determined’ as suggested. (Page 5 line 149)

16. I suggest justifying why patients and the public were not included in the design, conduct or reporting

of this review.

Thank you very much for the suggestion. Patients and the public were not included in this review, because our

target audience are researchers, clinicians and policy makers. The Patient and Public Involvement statement

was added as a subheading (BMJ Open editor’s suggestion) and the following sentence was included:

‘Patient and public involvement

Patients and public were not included in the design, conduct, or reporting of this research as it is targeted for

researchers, clinicians, managers and policy makers.’ (Page 5 lines 155-157)

17. Research questions: are these objectives rather than research questions?

We appreciate the reviewer's pertinent comment, which led us to think thoughtfully on this issue. Indeed, we

identified four questions in the protocol, but when considering only this manuscript, we have one main question,

which is: What are the key characteristics of MoCs implemented for patients with LBP attending primary

healthcare services? Objetives are related with the reasons to develop the scoping review. To better reflect this

alignment, we have integrated the objectives into the ‘Research question and aims’ subheading and removed

them from the last paragraph of the Introduction section.

‘Research Question and Aims

The research question of this review is ‘What are the key characteristics of MoCs implemented in primary

healthcare for patients with LBP?’ Our objectives are to identify which MoCs have been implemented for LBP

management, describe their main characteristics and commonalities in care delivery, and highlight any gaps in

knowledge regarding their real-world implementation.‘ (Page 5 lines 161-165)

18. I suggest listing only the objectives you will address in this paper.

Thank you very much for this suggestion. Indeed, we have opted to remove the questions/objectives that will

not be addressed in this manuscript. We kept the explanation in ‘Protocol Deviations’, a new subheading at the

end of the Methods, that we added to ensure the transparency of the reporting.

5

‘Protocol Deviations

Four research questions were framed in the protocol of this study(30). However, during the processes of data

extraction and analysis, it became clear that the complexity of the topic and richness of the available data

justified a rigorous description and interpretation of the findings. Therefore, findings on patient-, system- and

implementation-related outcomes of MoCs and context-specific factors (macro, meso, micro and multiple levels)

contemplated in their implementation will be reported in a subsequent paper. Additionally, one criterion was

added to those published in the protocol, which is the MoC is not digital (e.g. telemedicine, telerehabilitation,

web-based programs and/or mobile apps).’ (Page 7 lines 215-222)

19. I suggest objective one needs re-wording as it doesn’t quite make sense.

Considering your previous comments, we made substantial changes in this section. So, please see our answer

on point 17. (Page 5 lines 163-165)

20. Line 166: I think this is the first time you use PCC, so write out in full.

A full description of PCC was added to the manuscript:

‘Eligibility criteria were defined through the Population, Concept, Context (PCC) framework.’ (Page 6 line 168)

21. The inclusion criteria could be much more succinct, as they are in your abstract.

Thank you very much for your comment. We have summarized the information in the following paragraph:

‘Eligibility criteria were defined through the Population, Concept, Context (PCC) framework(28,29). Target

population are LBP patients, with or without radicular pain, of any duration, excluding specific causes or serious

pathologies. Records including broader populations, such as “musculoskeletal pain” or “spinal pain”, were also

excluded. MoC was defined as the provision and delivery of care in a local setting, including service planning,

care coordination and management of services(21,22,31). Operational criteria were defined to differentiate a

MoC from intervention programmes(22,30). Regarding the context, MoCs were included if they were developed

in primary healthcare or other levels of healthcare delivery, as long as they included primary care interventions

in the clinical pathway(31).’ (Page 6 lines 168-175)

22. Search strategy: minimise overlap between the main text and that included Figure 1.

Once again, we appreciate your valuable suggestions to synthetize our work. We have adjusted the sentence

accordingly:

‘A comprehensive search was conducted on MEDLINE(PubMed), EMBASE, Cochrane Central Register of

Controlled Trials, PEDro, Scopus, and Web of Science, as well as grey literature sources (Figure 1). Hand

searching was performed in peer-reviewed journals and relevant organisation websites(32). Additional studies

were identified through reference list screening. Initial searches conducted in May 2021 used key terms like

"low back pain," "model of care" and "primary care". Subsequent tailored searches across all databases were

performed (Supplementary File 2). Only records published since 2000 were considered as we aim to examine

evidence-based and coordinated healthcare delivery for LBP, reflecting the current concept of MoC. Language

restrictions for English, Portuguese, or Spanish were established due to practical constraints related to the

availability of translation resources. The search commenced in January 2022 and was last updated in December

2022, with search strategies reviewed and conducted by an experienced information scientist (HD).' (Page 6

lines 178-188)

23. Study selection, data charting and synthesis: reducing the detail included in the method. Murphy et

al's (2020) systematic review of clinical pathways (you've referenced this paper) provides a good

example of the level of detail needed.

6

We appreciate the reviewer's insightful comment, prompting us to consider the issue carefully. We rewrote all

the Methods section (Page 6 line 193- Page 7 line 213)

'Study Selection

Records were imported to EndNote X9 (Clarivate Analytics, USA) for screening and duplicate removal. Two

reviewers independently screened titles and abstracts (STD and DC). Eligibility criteria were tested with a

random sample of 25 records. Afterwards, full-text screening was performed by two researchers (STD and AM),

with a pilot test on 10 studies for consistency. Disagreements were discussed with a third reviewer (DC).

Data Charting

To ensure data extraction transparency(28), a standardised form (Supplementary File 3) was developed and

piloted, covering a summary of the studies, the identification and description of the MoC (name, country, target

population, main objectives) and respective key elements (levels of care and settings, health professionals

involved, type of care delivered and core components of health interventions). Two researchers (STD and AM)

extracted data independently and resolved uncertainties with the research team. Only relevant data to the

research question were extracted, and when necessary, the authors were contacted for clarifications. Regular

video meetings were held for data review and process updates.

Synthesis and Presentation of Results

Findings were synthesised through deductive content analysis in 3 phases: preparation, organisation, and

reporting(33). Data is presented in narrative, tabular, and chart formats for each MoC for LBP management.

Descriptive results include the identification of the MoCs, their general description, and key elements, while

quantitative results refer to frequency counts of the data.'

24. Line 241: Is it 'includes' rather than 'concerns'?

We made several changes in the text based on your previous comment:

'Findings were synthesised through deductive content analysis in 3 phases: preparation, organisation, and

reporting(33).' (Page 7 lines 210-211)

Results

25. Line 260: Is it 'search results' rather than 'literature search'?

Thank you for the suggestion. The subtitle was modified accordingly. (Page 7 line 226)

26. Literature search: minimise overlap between the main text and that included Figure 1.

Thank you once again. We have incorporated your suggestion:

'The PRISMA flow diagram (Figure 1) outlines the search and selection process. From the 4081 records yielded

in first instance, 29 studies(34–62), published between 2011 and 2022, were included. They portray 11 MoCs

implemented in primary healthcare.' (Page 7 line 227-229)

27. Line 271: I'm not sure 'designation' is the right word.

We agree with your suggestion and we have changed the sentence accordingly:

'Table 1 identifies each MoC and their corresponding studies.' (Page 8 line 232)

28. Minimise overlap between the main text and that included Table 1 and ensure the text used refers to

the table, highlights the most salient findings.

We appreciate the reviewer's pertinent comment. We adjusted this section accordingly:

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‘Quantitative studies (n=19) mainly consisted of randomised controlled trials (n=9) and observational cohorts

(n=9). These studies assessed the clinical effectiveness and efficacy of 9

MoCs(34,39,42,44,46,48,49,51,55,57,58,60–62) and healthcare resources utilisation of 7 MoCs(34,39,46,52–

54,56–58,60–62). Only BetterBackJ was evaluated for healthcare quality(43) and economic evaluations were

solely performed for 3 MoCs(34,35,46,58,60,61). Qualitative studies (n=5; 5 MoCs) focused on implementation

outcomes and strategies(36,37,41,45,59), while mixed methods studies (n=5; 3 MoCs) investigated patient and

organisational outcomes, as well as the experiences of different stakeholders(38,47,50). Detailed

characteristics of the studies, including eligibility criteria, sample sizes, outcomes and outcome measures, can

be found in Supplementary File 4.’ (Page 8 lines 232-240)

29. Line 315: again, I suggest rewording ’context features’.

As mentioned on point 5, we agree with your comment and have decided to remove this terminology. The

contents of this section were included in the subheading ‘General description’. (Page 8 line 244)

30. Line 344 ‘leading entry point’ needs rewording.

Thank you for bringing our attention to this matter. The following changes were made in the sentence:

‘General practices serve as the entry point for 8 MoCs, being important in the initial management of LBP

patients.’ (Page 9 lines 288-289)

31. Line 352: is it ‘The health professionals who most commonly deliver MOCs’?

Thank you. The sentence was modified to:

‘The health professionals who most commonly deliver care in MoCs are general practitioners and

physiotherapists.’ (Page 9 lines 295-297)

Discussion

32. Line 441 suggest rewording ‘solid’, well established?

Once again, thank you. We reworded the sentence accordingly:

‘Eleven MoCs were found, all of them implemented in high-income countries with strong primary healthcare

services, where general practitioners and physiotherapists serve as the main referrers.’ (Page 12 lines 379-381)

33. In each paragraph of the discussion ensure that the ‘so what’ of the point you make is clear. E.g.,

why does it matter that there is heterogeneity in the MOC?

In alignment with your feedback, we have revised the Discussion section. We hope to have been more objective

and clearer in presenting the key messages and implications of the study. Please check pages 12 to 14 in the

manuscript.

34. Line 453 suggest rewording ‘contemporary trends’.

We replaced “contemporary trends” be “recent studies” and we have reformulated the sentence:

‘Recent studies show that LBP patients receiving treatments aligned with guidelines see better clinical outcomes

and less healthcare usage(64).’ (Page 12 lines 390-391)

35. I suggest that many of the points you raise in the discussion would be better placed in the relevant

results section. You would then be able to use the discussion to emphasize and elaborate on the ‘so

what’ of your findings. As written, it’s hard to quickly grasp the key important take aways from the

paper.

8

Once again, we agree with your comment and revised the Discussion section to better emphasize the “so what”

of our findings. As aforementioned in point 33, we reorganized and rewrote the discussion to meet this purpose.

(pages 12-14, lines 377-461)

36. I suggest adding subheadings for ‘strengths and limitations’ and ‘implications’.

Thank you for the suggestion. We added both subheadings in the manuscript. (Page 13 line 430 and line 445)

37. Limitations: what do you think the limitations are of working with such an inclusive definition of

MOC?

The inclusive definition of MoC posed challenges on the screening phase, creating doubts regarding the

inclusion of specific clinical interventions. However, these issues were minimized through regular discussions

between reviewers and several adjustments in operational criteria and the standardized extraction form. As we

find very pertinent the question you raised, this reference was incorporated in the Strengths and Limitations

subheading:

‘Variations in MoC terminologies in literature, the inclusive definition of MoC, and the ambiguity between specific

evidence-based interventions and MoCs posed additional issues. Despite a focus on LBP-related MoCs, other

relevant studies concerning spinal disorders may have been missed. To mitigate these issues, a broad and

sensitive search strategy, an overinclusion approach during screening, several adjustments to the extraction

form and regular reviewer discussions were employed.’ (Page 13 lines 436-441)

Conclusion

38. I suggest starting this section at ‘This study’, moving the first twelve words to the beginning of the

next sentence (and then adjusting the first sentence).

Thank you for your feedback. We changed the sentence accordingly:

‘This study provides a broad overview of the key common elements of eleven MoCs implemented for LBP

patients in primary healthcare worldwide.’ (Page 14 lines 464-465)

39. I suggest elaborating on or rewording ‘care continuum’ (or give examples) so the reader quickly

grasps what you are referring to.

Once again, thank you. We agree that the concept of "care continuum" may not be understood by all readers

and, for this reason, we have made the following change to the manuscript:

‘However, most studies were very heterogeneous in reporting care coordination and its delivery over time.’

(Page 14 line 469)

Reviewer: 2

Dr. Noa Ben-Ami, Ariel University

Comments to the Author:

40. This study maps the evidence regarding the core characteristics and key elements of Models of care

implemented in primary healthcare to manage Low Back Pain. It is important to understand the models

of care for low back pain that are being implemented around the globe. The authors provided a

comprehensive overview, but I noticed that there was no mention of the Enhanced Transtheoretical

Model Intervention (ETMI)- a model of care for low back pain that was implemented in a public Health

Maintenance Organization in Israel. (see references below - Disclosure – my Lab work). The omission

of the ETMI raises questions about its exclusion from the literature search, prompting the need to

investigate its absence and ensure that no other Models of Care were inadvertently overlooked.

9

We sincerely appreciate your thorough review of our manuscript and the valuable feedback provided. We

acknowledge your concerns regarding the exclusion of the Enhanced Transtheoretical Model Intervention

(ETMI). It is important to emphasize that the research conducted by your lab and the insights gained from ETMI

are significant contributions to both patients with LBP and healthcare professionals.

Indeed, our search strategy did capture ETMI, and the decision not to include it was made after a detailed fulltext screening process. We recognized ETMI as a complex, evidence-based intervention that is theory-informed,

with a well-defined operational plan and clear outcomes. However, ETMI consists of a single intervention

programme with four specific components. Our inclusion criteria specified a focus on multi-interventions even if

provided by a single profession, while single interventions without longitudinal coordination were excluded. ETMI

does not include continued care provision when the first intervention does not achieve the desired results. In

our MoC concept, we emphasize the importance of care coordination or a pathway with varying levels of care.

Despite ETMI matches care according to the readiness for change behaviors, it is still the same intervention

and not different interventions. Following a thorough evaluation and discussions between reviewers, we

determined that ETMI did not meet all our eligibility criteria.

We are very grateful for adding the references of the ETMI at the end of your review, which have been

considered and screened one more time. We assure you that we did our best to conduct a rigorous and

comprehensive review process, considering all perspectives to enhance the quality of our manuscript.

Introduction

41. Line 105: “which succinctly endorses the delivery of nonpharmacological interventions, such as

education, exercise and manual therapy”. Manual therapy is not a first-line recommendation. (see

LANCET series (No 2)

Thank you very much for your comment. Indeed, we acknowledge that the information was not sufficiently

accurate, so we made the following changes in the sentence:

‘Current patterns of care may vary between settings and lack alignment with clinical practice guideline

recommendations, which succinctly endorses the delivery of nonpharmacological interventions, such as

education and exercise, and manual therapy as an adjuvant treatment(8,11–14)’. (Page 4 lines 102-105).

Our statement is informed by the findings of this systematic review, published after the Lancet Series: Lin, I.,

Wiles, L., Waller, R., Goucke, R., Nagree, Y., Gibberd, M., Straker, L., Maher, C. G., & Sullivan, P. P. B. O.

(2020). What does best practice care for musculoskeletal pain look like? Eleven consistent recommendations

from quality clinical practice guidelines: systematic review. Br J Sports Med, 54, 79–86.37.

DOI: 10.1136/bjsports-2018-099878

Methods

42. Line 151 – I am curious about the rationale behind not posing the most critical inquiries regarding

the outcomes and success of the implementation. Given the frequent failures observed in

implementation studies, it becomes imperative to grasp the complete panorama. Take, for instance, The

Lancet trial 2021 titled 'Stratified care to prevent chronic low back pain in high-risk patients: The

TARGET trial." Despite its comprehensive approach, the trial revealed no differences in the transition

to chronic LBP among patients presenting with acute LBP using a stratified approach to care. Can you

please elaborate on this issue?

Thank you once again for your insightful comment. We understand your curiosity and agree that this study would

benefit from addressing the outcomes and results of the implementation. However, as explained in the

manuscript, the amount of information is extensive to provide a proper description and interpretation of the

findings. Therefore, we have decided to use two different approaches to discuss them. The first based on a

descriptive nature of the MoCs, and a second one (which is also already finished and submitted for peer review),

based on an interpretative nature, regarding the outcomes and implementation processes. The upcoming article

will cover the implementation results, and the example you mentioned regarding the TARGET will be discussed.

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Nonetheless, the current manuscript focuses on other aspects, specifically the similarities and differences

between MoCs, as well as the current gaps in research and reporting. The main objective of the present

manuscript is to provide a comprehensive overview of the characteristics of the MoCs to support the

development and planning for implementation by researchers, clinicians and decision-makers.

Discussion

43. In reference to Line 470, where it states, 'Considering its successful implementation in terms of

clinical and cost-effectiveness (24,25,36,46),' it is crucial to note that clinical success was not

consistently observed. See example: Effect of Low Back Pain Risk-Stratification Strategy on Patient

Outcomes and Care Processes: the MATCH Randomized Trial in Primary Care. J Gen Intern Med. 2018

Thank you very much for your observation. The sentence in question is aligned with the context of the preceding

sentence, which specifically pertains to the UK STarT Back and IMPacT Back trials. Our intended message was

to convey that the successful outcomes of the UK studies prompted adaptations of this MoC in different countries

and settings. Therefore, to clarify this idea in the manuscript, the following changes were made:

‘Considering the successful implementation of the STarT Back(34) in UK on clinical and costeffectiveness(34,35,46,56), adaptations of this MoC were developed to other countries. Recently, a systematic

review found that a stratified care approach provides substantial clinical, economic and health related cost

benefits in the medium and high-risk subgroups compared with usual care in short- and medium-term followups(67). This may explain why MoCs tend to follow a stratified or hybrid approach to deliver care using the

STarT Back Screening Tool. However, evidence shows that some adaptations of the MoC in other countries,

such as in the USA, failed to show its clinical effectiveness.’ (Page 12 lines 397-404).

References on ETMI

1. Feldman R, Haleva-Amir S, Pincus T, Ben Ami N. Physiotherapist perceptions of implementing

evidence-based practice for patients with low back pain through the Enhanced Transtheoretical

Model Intervention: a qualitative study. Physiotherapy Theory and Practice. 2022; 6;1-12 . DOI:

10.1080/09593985.2022.2062690.

2. Feldman R, Pincus T, Ben Ami N. Implementation of the Enhanced Transtheoretical Model

Intervention for low back pain patients in primary care: study protocol. Israel Medical

Association Journal (IMAJ). 2022; 24: 375-381. https://pubmed-ncbi-nlm-nihgov.mgs.ariel.ac.il/35734836/

3. Feldman R, Nudelman Y, Haleva-Amir S, Ben Ami N. Patients' prior perceptions and

expectations of the Enhanced Transtheoretical Model Intervention for chronic Low back pain: a

qualitative study. Musculoskeletal Care. 2022; 20(2):371-382. DOI: 10.1002/msc.1600.

4. Feldman R, Nudelman Y, Haleva-Amir S, Pincus T, Ben Ami N. Patients' perceptions of the

Enhanced Transtheoretical Model Intervention for chronic Low back pain: a mix method study.

International Journal of Environmental Research and Public Health. 2022; 19, 6106.

https://doi.org/10.3390/ijerph19106106.

5. Ben Ami N, Mirovsky Y, Chodick G, Pincus T, Shapiro Y. Increasing recreational physical activity in patients with chronic low back pain: A pragmatic controlled clinical trial. Journal of Orthopedic and Sports Physical Therapy (JOSPT). 2017; 47(2), 57-66. DOI: 10.2519/jospt.2017.7057.

6. Canaway A, Pincus T, Underwood M, Shapiro Y, Chodick G, Ben-Ami N. Is an enhanced behaviour change intervention cost-effective compared to physiotherapy for patients with chronic low back pain? Results from a multi-center trial in Israel. BMJ Open 2018;8:e019928. DOI: 10.1136/bmjopen-2017-019928.

Reviewer: 3

Prof. Arianne Verhagen, University of Technology Sydney

11

Comments to the Author:

This manuscript concerns a scoping review. The authors aim to synthesize existing evidence related to

models of care for people with low back pain in primary care.

Generic comments

45. It remains unclear what a ‘model of care’ exactly is. In the abstract the authors describe a model of

care as ‘evidence-informed healthcare’. In their introduction they describe a model of care as a ‘person

centred and principle-based guide that describes evidence informed best practice’. Nevertheless, I do

not understand what is different between a model of care and an evidence-based guideline for instance.

Looking at what they included, I see targeted treatment approaches, like the STaRT-Back tool or

BetterBack. I would like the authors to better describe the term ‘model of care’ in the introduction.

We appreciate the reviewer's pertinent comment, which led us to think about and review our definition of MoC.

We made the following changes in the Introduction section to operationalize and simplify the definition, as well

as to distinguish MoCs from evidence-based guidelines:

‘A Model of Care (MoC) is a person-centred approach that outlines evidence-informed best practices for

managing specific health conditions(21–23). It details the optimal care that should be provided and the methods

for its implementation. MoCs are built upon clinical guidelines - drawing from up-to-date recommendations –

and they primarily serve to translate these recommendations into actionable strategies(23). While clinical

pathways focus on the integrated delivery of care to patients with a specific condition, MoCs go beyond this

aspect, focusing much of their attention on the factors that determine a successful implementation(22,23)’.

(Page 4 lines 110-117)

46. The authors have published a protocol, and they also deviated from this protocol. This deviation is

completely understandable, but I would prefer the authors to mention all deviations in a specific

paragraph, preferably at the end of the method section. This way the manuscript clearly answers two

aims, and the reader will not be confused with the original 4 aims (which indeed is a bit much for one

paper).

Thank you for bringing our attention to this matter. Although our goal is to increase transparency in reporting,

we agree that references to the protocol are too many. As you suggested, we added a subheading with this

information:

‘Protocol deviations

Four research questions were framed in the protocol of this study(59). However, during the processes of data

extraction and analysis, it has become clear that the complexity of the topic and richness of the available data

justify a rigorous description and interpretation of the findings. Therefore, findings on patient-, system- and

implementation-related outcomes of MoCs and context-specific (macro, meso, micro and multiple levels)

contemplated in their implementation will be reported in a subsequent paper. Additionally, one criterion was

added to those published in the protocol, which is the MoC is not digital (e.g. telemedicine, telerehabilitation,

web-based programs and/or mobile apps).' (Page 7 lines 215-222)

47. Overall, this manuscript is lengthy and contains a lot of repetition. For instance, referring to the

protocol in Open Science Framework is done at least four times, once is enough. Most sentences are

long, vague, sweeping and with a lot of padding and packaging. Especially the discussion section is

too long and might benefit from some subheadings, like strength and limitations, future directions (or

implications). Please try to be clearer and more precise in the writing.

We are grateful for your feedback on this matter. As mentioned in the previous point, we reduced the references

to the protocol, adding a subheading with the information. (Page 7 lines 215-222) We also made efforts to

rewrite the article, making it simpler and more objective. Taking your suggestions into account, we made

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significant changes to the discussion to make it more synthetic and with an emphasis on the main key ideas.

Please see these changes in the manuscript. (Pages 12-14 lines 377-461)

Specific comments

48. In the result sections of the abstract as well as the main document authors use terms like: most,

some etc. Please add the actual number also as otherwise it remains vague.

Once again, thank you for your comment. We agree that being more objective is important to ensure the rigor

of the manuscript. Therefore, we reviewed the document and replaced the "most/some" references with the

specific frequency or added the correct frequency in parentheses after that reference. These changes were

made throughout the manuscript, mainly in the abstract and results:

Abstract – Results

'Ten MoCs included a stratified care approach. Assessment of LBP patients typically occurred in primary

healthcare, while care delivery usually took place in community-based settings or outpatient clinics. Care

provided by general practitioners and physiotherapists was reported in all MoCs. Education (n=10) and exercise

(n=9) were the most common health interventions.' (Page 2 lines 58-62)

Results (example)

'Four models also include osteopaths, chiropractors, and acupuncturists(44,45,50–52), depending on the

integration of these professionals within the specific healthcare system of each country.' (Page 9 lines 297-299)

49. The conclusion should contain text that answers the study aim(s). In the abstract this is not the

case, and similar the conclusion of the main text is not clearly answering the aims.

We are grateful for the reviewers' comment on this issue. The aims of this study are related to the detailed

description of the MoCs and the identification of common elements, information that is clearly presented in the

results of the abstract. To avoid repetition of ideas in the abstract, we focused the conclusion on the contribution

of the study, which is important to highlight the "so what" of this work.

'Conclusions: This study examines the features of MoCs for LBP, highlighting that research is in its early

stages and stressing the need for better reporting to fill gaps in care delivery and implementation. This

knowledge is crucial for researchers, clinicians and decision-makers in assessing the applicability and

transferability of MoCs to primary healthcare settings.' (Page 2 lines 64-67)

Considering your comment, we made changes to the Conclusion section to meet the objectives and substantiate

the study's contribution:

'Conclusion

This study provides a broad overview of the key common elements of eleven MoCs implemented for LBP

patients in primary healthcare worldwide. These MoCs are aligned with clinical practice guideline

recommendations. Primary healthcare is the entry point for patients into the health system and they are offered

stratified care approaches, based on education, exercise and manual therapy. More complex interventions or

referral to secondary and tertiary care are feasible options when first approaches fail. However, most studies

were very heterogeneous in reporting care coordination and its delivery over time. Additionally, most MoCs are

not integrated into health systems and are still in the early stages of research. These findings highlight the need

for guidelines to support the research, development and implementation of MoCs in real-world settings.' (Page

14 lines 464-472)

50. In the method section, selection criteria, you use the abbreviation PCC without a clear description.

As this should be the only place where you mention this framework (the other times you mention it are

redundant; a repetition), please write it in full and delete all other mention.

Thank you very much. We wrote PCC in full in selection criteria and deleted other mentions, as you suggested.

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'Eligibility criteria was defined through the Population, Concept, Context (PCC) framework(57,58).' (Page 6 line

168).

51. There is a lot of text redundant, see for instance the sentences in lines 181-185. This paragraph does

not fit in the method section, and doubles text in the intro and discussion. Please delete. Same for lines

237-238. In addition, please delete the headings related to study question 1 and 2, also redundant.

Thank you very much for your comment. We completely agreed with your suggestion for lines 181-185, given

that this information is described in the protocol of the study. Therefore, we deleted this information from the

main text.

Regarding the suggestion for lines 237-238, we agree with it, but we have some concerns. When the protocol

was reviewed to be published, both reviewers raised questions regarding the quality assessment of the included

studies. Therefore, we decided to keep this justification in the manuscript, as it may be enlightening for readers

who are not familiar with the methods of a scoping review. However, we moved the sentence to the Implications

subheading (Page 14 lines 452-453)

About the headings to research questions, we deleted them, as suggested. Please see Results section to check

this alteration.

52. Please explain why the authors did not search before 2000 and did not included studies of all

languages. These restrictions can introduce bias and need to be prevented. The aim of (scoping)

reviews is to get an overview of all evidence, using these restrictions means you do not aim to include

all evidence.

Thank you for your question. In fact, we understand that research restrictions lead to potential study selection

bias. However, these decisions were taken for both theoretical and practical reasons. In this study the definition

of MoC includes the concept of evidence-informed practice. This means that MoCs must use the best available

evidence to make informed patient-care decisions. It is very unlikely that studies published before 2000 would

reflect healthcare driven by recommendations, as clinical guidelines for LBP were published after 2005. Our

findings reflect this assumption as the oldest study included was published in 2011.

Regarding language restrictions, they were defined to avoid research team inaccuracies when translating

studies. Considering the amount of data to be collected, it would be likely mistakes related to misinterpretation

or some data would not be collected. Therefore, we accepted the possibility of a bias, which was identified in

the limitations of the study.

To clarify this issue, we made the following changes to the manuscript:

‘Only records published since 2000 were considered as we aim to examine evidence-based and coordinated

healthcare delivery for LBP, reflecting the current concept of MoC. Language restrictions for English,

Portuguese, or Spanish were established to reduce bias due to practical constraints related to the availability of

translation resources.' (Page 6 lines 183-186).

VERSION 2 – REVIEW

REVIEWER	Ben-Ami, Noa Ariel University, Faculty of Health Sciences
REVIEW RETURNED	11-Apr-2024

GENERAL COMMENTS	I thank the authors for addressing my comments. I have nothing more to add.

REVIEWER	Verhagen, Arianne University of Technology Sydney, Physiotherapy
REVIEW RETURNED	04-Apr-2024

GENERAL COMMENTS	Thank you for being able to review the revised version of the manuscript on models of care. The manuscript majorly improved based on the guidance and comments of the editor and reviewers. Still the manuscript is a bit long, but any reduction will be at the discretion of the editor.