Author’s response to reviews

Title: The impact of income support systems on healthcare quality and functional capacity in workers with low back pain: a realist review protocol

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Author’s response to reviews:

Dear Editor,

We thank the reviewers for their insightful and helpful comments on our manuscript, “The impact of income support systems on healthcare quality and functional capacity in workers with low back pain: a realist review protocol”. We were pleased to have our manuscript reviewed by experts in the science of realist reviews. The addition of links to further reading and information was most welcome.

We have responded to each of the reviewer’s comments and recommendations. These have been marked with ‘tracked changes’ in the attached manuscript. Figures 1 and 2 were also modified, and we have attached the new versions as PDF copies to our submission. Finally, we have also addressed your comments and recommendations directly in the table below.

We hope you find this revised manuscript acceptable for publication in the journal.

Kind regards,

Michael Di Donato (on behalf of all authors).
Comment:
This is a protocol for a realist review exploring the influence of 'income support systems' on two outcomes for workers with low back pain. The realist approach seems ideal for this complex topic: as the authors rightly recognise, this review has the potential to deliver new insights about the role of context in determining how and when income support systems influence healthcare quality and functional capacity for those with this condition. The overall justification for the study and its design as a realist review is clear, especially in light of the existing literature that signals the potential influence of a wide range of contextual factors and the nature of income support systems themselves on the chosen outcomes (lines 84-85, 88-91, 95-99). The identified research questions (lines 123-126) are straightforward, easy to understand and important. However, there are several aspects of the protocol that require clarification or modification:

Response:
Thank you for reviewing our manuscript, and for confirming the relevance of the realist review method for this research topic.

Comment:
1. Could the authors provide further information on the inclusion of the 'healthcare quality' outcome, and how it will be defined during the review? (e.g. as described in lines 84-86, 219). How will the authors cope with variation in 'healthcare quality' outcomes in the literature? More importantly, could they provide more detail on the relationship between this outcome and the final 'functional capacity' outcome? The authors assert that 'healthcare quality' will 'indirectly' influence capacity (lines 138-139), but the link between these two is not interrogated and seems to me to have the potential to vary, not least in relation to how 'quality' is interpreted and measured. The step between 'quality' and 'capacity' might be better framed as a hypothesis that could be tested in this (or another) review.

Response:
We address this in the revised manuscript on page 4 (lines 85-91), where we have identified that healthcare quality for NSLBP is defined by the substantial existing evidence base for treatments and diagnostics. We have also clarified that whilst there is some evidence for the link between the quality of treatments and diagnostics and functional capacity, this is not the focus of the review. We agree that it would be interesting to test this further in future research.

Comment:
2. Some aspects of the description of the realist review approach are not quite correct. The description of the 'philosophy of realism' (lines 104-106) reads as if realism somehow simply embodies both a constructivist and positivist outlook simultaneously, but this ignores realism's distinct ontological position, which understands reality as layered and deep, and the fact that both positivist and constructivist approaches are ultimately concerned only with the 'empirical' level of reality (as measured or interpreted). An accessible summary of these philosophical differences is available amongst the RAMESES training materials (http://www.ramesesproject.org/media/RAMESES_II_Philosophies_and_evaluation_design.pdf). In addition, the reference to 'realist evaluation' as the 'central component of a realist review' (line 107) confuses two distinct study designs: 'realist evaluation' refers to an evaluation (primary research) study, probably employing a mixed methods approach to produce programme theories, whereas 'realist review' is a distinctive approach for evidence synthesis (secondary research).
Thank you for this helpful comment and resources. The provided summary and Westhorp’s (2014) explanation of realism were most insightful. We agree that our definition required some modification, and have updated it accordingly on page 4, lines 110 to 114. We have also removed ‘realist evaluation’ from our explanation of realist reviews.

Comment:
3. I would suggest that the authors revisit and clarify their working definitions of 'mechanism' and 'context':
   a. At the moment, no clear definition of 'mechanism' is provided. The authors' initial theories refer to 'the mechanisms describing how income support systems may impact healthcare quality and functional capacity' (lines 130-131), but the 'mechanisms' identified (illustrated in Figure 1) seem here to be possible features of 'income support systems' and so might be more accurately characterised as interventions or policies. The descriptive texts provided in Figure 1 do seem to hint at potential generative mechanisms (in the realist sense) related to these features. For example, for 'mechanisms' 1, 3 and 4 it is clear that funding structures will shape the incentives faced by healthcare providers/employers and their responses to these incentives may well be the active mechanisms here. Figure 2 goes further, hypothesising a 'target income' type of mechanism in operation in the identified contexts, leading to an outcome of unnecessary treatment (although again here the relationship between 'lower healthcare quality' and 'lower functional capacity' is assumed to be straightforward). It is likely that it is not possible to fully characterise 'mechanisms' in the realist sense at this early stage of the review, but the authors might consider using alternative terminology when describing aspects of income support systems, to avoid confusion later.

Response:
We have now provided a brief definition of mechanism within the theory-development section of the review (page 5, line 142). Figures 1 and 2 (attachments) have been updated with the necessary theoretical / conceptual corrections. This involved separating the 'policies' (e.g., funding restrictions imposed by income support systems) and mechanisms (e.g., healthcare provider response with income maintenance strategy) within the context of a characteristic inherent to a given system (e.g., financially driven private funding of healthcare in private healthcare systems).

Comment:
3b. The description of 'context' that the authors provide (lines 148-154) is quite confusing. The authors initially suggest that this will include features of particular income support and healthcare systems (lines 148-149, and borne out in Figure 2), but then go on to say that contextual factors are 'not directly related to an income support, healthcare or workplace system'. As currently worded, these seem contradictory statements and some clarification would be welcome.

Response:
Upon reflection we agree that the description of context was confusing. We have altered this description to accurately reflect what we mean (page 6, lines 161-167).

Comment:
4. Information relating to the methods that will be employed to gather evidence for the review could be much clearer. Figure 3 is straightforward but the text is confusing. Specifically:
   a. Does the described 'purposive, iterative search strategy' (line 179) refer to the searches already undertaken during theory development, or some new searches?
Response:
We have clarified that purposive searching was conducted to develop the protocol, and iterative searching will be used in the review (Page 8, lines 205-206).

Comment:
4b. What do the authors mean by 'select searches' of databases? I have never come across this terminology before.

Response:
We initially intended ‘select searches’ to indicate that we would target database searches to each initial theory. We will instead search databases for literature regarding all initial theories. To avoid confusion, we have removed the term ‘select searches’ (Page 8, line 207).

Comment:
4c. The authors seem to suggest that they will run 5 separate searches, relating to each of their initial theories (lines 180-181), but the description of the search strategy itself (lines 195-199) does not seem to reflect this plan. If the authors could provide more detail on the proposed search strategies, or the method by which the search strategies will be developed later, this would help to make their approach more transparent.

Response:
We have clarified that we will conduct one search for evidence associated with all of our initial theories (Page 8, lines 204-221). Also, we have further clarified the search process to better reflect the detail of Figure 3 (attached). We also point to further information about the search strategy being available in the following section ‘Search Strategy’ (Page 8, lines 222-228).

Comment:
5. In relation to eligibility criteria for inclusion in the review, could the authors do more to clarify the difference between 'general eligibility' and 'relevance'? It seems most likely that screening will proceed on the basis of the 'general eligibility' criteria (as outlined in Table 1) first, before criteria of 'relevance' and 'rigour' are applied, and perhaps the authors could do more to describe the approach that will be used for screening.

Response:
We have clarified that we will assess eligibility based on our eligibility criteria, and use ‘Relevance and Rigour’ to appraise included studies (Page 10, lines 272-283; and Page 12, lines 304-310).

Comment:
Will the author who conducts the searches apply these screening criteria before all the authors independently consider the identified 'subset of important literature for each initial theory’?

Response:
Yes, one author will conduct the searches and apply the eligibility criteria with another author to assess a random 10% sample of titles and abstracts and full-texts (Page 10, lines 269-272).

Comment:
Will any other authors be involved in double screening, or will all authors screen and extract data from all search results (as seems to be implied in line 228)? It would be helpful if these processes could be clarified. In addition, it would be useful if the authors could expand on some of their intended
exclusion criteria.

Response:
One author will conduct searches and screening (as above), and authors will work in pairs to extract data. Authors will then work collectively to analyse and synthesise results (Page 10, lines 269-272; and Page 11, lines 290-291).

Comment:
Specifically, what is the rationale for excluding opinion pieces and letters (which could potentially contribute to theory building), and how will the authors handle studies that include, for example, some participants of working age alongside those of non-working age, or participants with NSLBP caused by traumatic injury alongside those without this aetiology (or indeed studies that do not provide this information)?

Response:
We initially chose to exclude opinions pieces and letters as we sought to include only empirical studies / data. However, this expert comment and a similar expert comment from the second reviewer are most welcome, and we will now include opinions pieces and letters in our review as we understand the potential value (page 10, line 275; and Page 11, Table 2). We also clarify that we will exclude studies that include any serious pathologies or any individuals not of working age (Page 11, Table 2).

Comment:
6. The authors propose characterising income support and healthcare systems in different countries and regions with reference to 'policies, policy summaries, and legislation relevant to the country or region' (lines 244-245). They refer to the 'concrete boundaries' of differing approaches, which seems an implicit acknowledgement that such documents are likely to be technical, and omit 'soft' information about how such systems work and are understood by those who run and use them in practice. The authors indicate that they hope that their interviewees may provide additional insight in this area, but it's not clear that this concern will form part of the sampling strategy for this group, and it would be useful here I think to explicitly acknowledge this potential limitation, and perhaps whether it could also be addressed via the inclusion of other kinds of secondary literature in the review.

Response:
Yes, the policy documents we are looking for are likely to be technical documents describing income support and healthcare systems.
Whilst interviewing individual actors within a system would be helpful, we are unable to conduct exhaustive interviews with several types of 'system actors'. Pending the outcome of this review, we hope a future realist evaluation study might address this research gap (Page 15, lines 358-361).

Comment:
7. In relation to the proposed semi-structured interviews, could the authors provide a rationale for their choice of approach, and analysis? It seems notable that the authors have not chosen to adopt a 'realist interviewing' approach.

Response:
We initially chose this form of interview technique as it was proposed and used in a previous realist review, and is suitable for policy research. If we were conducting a full realist evaluation then the realist interviewing technique may be more pertinent. However, given interviews in this review were designed to supplement our understanding from the main literature review, we opted for only a basic
realist interview logic (i.e., asking interviewees whether or not they agree with a theory and why) rather than a full realist interview technique (Page 14, lines 349-362).

Comment:
There are also a couple of minor points to address:
1. Could the authors provide citations to support the statement "Research...has simply revealed there may be an interaction" (lines 96-99).
2. In line 310, should this sentence read, 'realist reviews are an iterative, non-linear process'? If the authors mean 'interactive', in what way?

Response:
We have provided citations for this statement, and also changed ‘interactive’ to ‘iterative’ – this was a typo.

-- Reviewer #2 --

Comment:
Thank you for asking me to peer-review this manuscript.
I am not a content expert, though as a General Practitioner, have some understanding of the importance of this topic to patients and the wider society.
As such, my comments are mainly methodological in nature.

Response:
Thank you for reviewing our manuscript.

Comment:
Lines 103 to 104:
This description of realism would benefit from refinement. The ordering of the wording should be switched around.
The form of realism espoused by Pawson would argue that the is a 'real' world that is 'mind independent' of individuals but our knowledge of its true nature is limited because we can only access it through our senses.
Using terms such as constructivism and positivism is misleading in the context of this sentence. Realism mere 'sits' between these diametrically opposite poles.

Response:
We agree that our definition required some modification, and have updated it accordingly (Page 4, lines 110-114).

Comment:
Line 107:
Realist evaluation is not the central component of realist reviews.
See: http://ramesesproject.org/media/RAMESES_II_RE_RS_RR_whats_in_a_name.pdf

Response:
We have removed ‘realist evaluation’ from our explanation of realist reviews, identifying that they are unique study designs (Page 5, line 115).
Comment:
Lines 113 to 114:
More precisely realist programme theories have within them CMO configurations.

Response:
We have corrected this definition (Page 5, line 122).

Comment:
Lines 127 to 175:
Theory development section
Please explain why this section is not in the Methods section.
Please also explain what types of theories you are developing in this section. For guidance see:
http://ramesesproject.org/media/RAMESES_II_Theory_in_realist_evaluation.pdf
(NB there is overlap between the types of theories used in realist evaluations and realist reviews/syntheses).

Response:
We have moved the ‘Theory Development’ section to the methods section. We have identified that we
are developing programme theories (i.e., they are theories about policies) (Page 5, line 137-201).

Comment:
Lines 130 to 131:
Please clarify what you mean here.
Do you mean that you initial theories contained mechanisms that cause the impacts of income support
systems?

Response:
We have now provided a brief definition of mechanism within the theory-development section of the
review (page 5, line 142). Figures 1 and 2 (attachments) have been updated with the necessary
theoretical / conceptual corrections. This involved separating the ‘policies’ (e.g., funding restrictions
imposed by income support systems) and mechanisms (e.g., healthcare provider response with income
maintenance strategy) within the context of a characteristic inherent to a given system (e.g., financially
driven private funding of healthcare in private healthcare systems).

Comment:
Lines 134 to 137:
It maybe be more logical to place these sentences into the data analysis section of you manuscript.

Response:
We originally chose to have these sentences in this section to frame the concept of CMO configurations
for the remainder of the protocol. We would prefer to leave them there.

Comment:
Line 138:
Refers to Figure 1.
Additional thought needs to be given to how "Mechanism" has been conceptualised in Figure 1.
Whilst there are differing conceptualisations of mechanism in different 'schools' of realism, if you are
following the realist review approach put forward by Pawson, then you should reconsider how you
have conceptualised this concept.  
For example see:  
http://ramesesproject.org/media/Realist_reviews_training_materials.pdf  
(section 2.1)  
or  
http://ramesesproject.org/media/RAMESES_II_What_is_a_mechanism.pdf  
(the conceptualisation of mechanism for realist evaluation and realist review is the same)  

Response:  
We have reconceptualised our mechanisms in this diagram. Please see the attached Figure 1 for changes.  

Comment:  
Lines 147 to 154:  
It is generally accepted that context does not act on outcomes, but does on mechanisms that cause certain outcomes.  
Thought needs to be given to how you have conceptualised and will use the concept of "context" in your review.  
For example see:  
http://ramesesproject.org/media/RAMESES_II_Context.pdf  
(the concept of context is the same within realist evaluation and realist review).  

Response:  
Thank you for these resources. We have updated our conceptualisation of context at this point of the protocol and throughout (Page 16, lines 161-167).  

Comment:  
Lines 155 to 160  
These lines refer to Figure 2.  
More thought needs to be given to how you have conceptualised "context" and "mechanism" in this example.  
(Please see my earlier comments on these two concepts).  
Might the mechanisms in this context-mechanism-outcome-configuration be (to put it very crudely) 'greed' or 'survival'??  
What may be functioning as context may be 'performance targets' or perhaps 'income expectations'??  

Response:  
We have updated our conceptualisation of context at this point of the protocol and throughout (Page 16, lines 161-167). We also have made the necessary conceptual updates to mechanism and context throughout the protocol and in Figures 1 and 2 (attached).  

Comment:  
Lines 165 to 175:  
Consideration needs to be given to how mechanism has been conceptualised in this paragraph  

Response:  
We have now provided a brief definition of mechanism within the theory-development section of the review (page 5, line 142). Figures 1 and 2 (attachments) have been updated with the necessary theoretical / conceptual corrections. This involved separating the ‘policies’ (e.g., funding restrictions
imposed by income support systems) and mechanisms (e.g., healthcare provider response with income maintenance strategy) within the context of a characteristic inherent to a given system (e.g., financially driven private funding of healthcare in private healthcare systems).

Comment:
Line 177:
Please consider changing this heading as the two paragraphs it refers to appear to contain more of an overview of your review processes.
For sake of clarity and to save the reader from having to keep referring back to this section, it may be worth while moving some of these details on review processes to their relevant sections in the following parts of this manuscript.

Response:
We have changed the heading of this section to ‘Overview’ (page 6, line 203).

Comment:
Lines 194 to 200:
Please provide details of who will do the searching and if any support from a librarian / information specialist will be used.

Response:
One author will conduct searches and screening (as above), and authors will work in pairs to extract data. Authors will then work collectively to analyse and synthesise results (Page 10, lines 269-272; and Page 11, lines 290-291). Given the author teams’ previous experience with literature reviews, no support from a librarian / information specialist will be sought.

Comment:
Lines 204 to 226:
Eligibility criteria section.
In lines 180 to 181, you mention that one author will conduct the searches, but is the same author also screening the citations returned from searching?
If so, will there be any processes in place for consistency checking?
Will there be a process for resolving uncertainties about inclusion / exclusion of documents.

Response:
One author will conduct searches and screening (as above), and authors will work in pairs to extract data. Authors will then work collectively to analyse and synthesise results (Page 10, lines 269-272; and Page 11, lines 290-291). We have also shifted our use of relevance and rigour to document appraisal only, not within eligibility criteria (Page 12, lines 304-310).

Comment:
Lines 206 to 207:
You may wish to consider a more up to date definition of rigour. For example see:
http://ramesesproject.org/media/Realist_reviews_training_materials.pdf
Section 6

Response:
Thank you for this important point. We have updated our definition rigour to the more up to date definition as per your suggestion (Page 12, lines 305-306).

Comment:
Line 222: Table 1
Whilst they are not necessarily the most trustworthy source of relevant data, Opinion pieces and Editorials may provide some relevant data (e.g. in providing analogy to your findings or in theory development).
Line 222: Table 1
You may want to consider being a bit more flexible in the outcomes for your eligibility criteria. The reason being that as you refine your initial programme theory, more proximal outcomes may emerge as being important and data are needed to make sense of these within the more refined programme theory.

Response:
We initially chose to exclude opinions pieces and letters as we sought to include only empirical studies / data. However, this expert comment and a similar expert comment from the second reviewer are most welcome, and we will now include opinions pieces and letters in our review as we understand the potential value (page 10, line 275; and Page 11, Table 2). We also clarify that we will exclude studies that include any serious pathologies or any individuals not of working age (Page 11, Table 2). Other than being the main point of question in the review, we chose to include articles where healthcare quality or worker functional capacity as the outcome, because we expected an unmanageable volume of literature regarding excluded outcomes such as ‘pain’ and ‘cost’. We will therefore leave the outcomes as they are.

Comment:
Lines 225 to 226:
Please clarify what this sentence means.

Response:
We have removed this sentence to improve clarity.

Comment:
Lines 227 to 239:
If I am not mistaken up to 4 people will independently extracting and appraising the data from included documents. Will you be piloting and refining your processes at this stage? Are there processes for checking and/or reconciling differences in interpretations and inferences made? If so, please provide details. If not, why not?

Response:
We have now clarified that reviewers will extract data and appraise documents in pairs (Page 11, lines 290-291). We have also clarified that we have (1) piloted the data extraction tool already, and (2) will
collectively discuss any differences in data extraction (i.e., interpretations / inferences) (Page 12, lines 300-303).

Comment:
Lines 242 to 269:
This section appears to be your search strategy for searching for grey literature.
Is there a reason why it is provided as a separate section to the main searches?
It may be easier for the reader to follow if this section is incorporated into the main search section.

Response:
We have moved the pragmatic searches section to the ‘Search Strategy’ section (Page 9, lines 232-258).

Comment:
Lines 276 to 278:
I suspect that it is more likely that the included documents will be 'thin' on details regarding mechanisms.

Response:
Thank you, we have noted this in this section (Page 14, line 347).

Comment:
Lines 278 to 279:
Why are you not using a realist logic of analysis?

Response:
We initially chose this form of interview technique as it was proposed and used in a previous realist review, and is suitable for policy research. If we were conducting a full realist evaluation then the realist interviewing technique may be more pertinent. However, given interviews in this review were designed to supplement our understanding from the main literature review, we opted for only a basic realist logic (i.e., asking interviewees whether or not they agree with a theory and why) rather than a full realist interview technique (Page 14, lines 349-362).

Comment:
Line 283:
What you have described here are both data analysis and synthesis.
So it is worth changing the heading of this section to "Data analysis and synthesis".

Response:
We have changed the heading accordingly (Page 15, line 363).