

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (Error! Hyperlink reference not valid.) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Engaging communities in non-communicable disease research and interventions in low- and middle-income countries: a realist review protocol
AUTHORS	Klingberg, Sonja; Adhikari, Bipin; Draper, Catherine; Bosire, Edna; Tiigah, Priscilla; Nyirenda, Deborah; Mukumbang, Ferdinand

VERSION 1 – REVIEW

REVIEWER	Anand, Krishnan All India Institute of Medical Sciences, Center for Community Medicine
REVIEW RETURNED	17-Mar-2021

GENERAL COMMENTS	<p>This is a protocol for a qualitative study which is a rarity. Usually, protocols are published in advance of cohorts and trials so as to enable the reader of subsequent papers to identify any protocol changes and also to save space for future papers from devoting space for detailed methods.</p> <p>This paper is an interesting exploration of community engagement in NCDs with an open mind allowing negative outcomes to also be identified, depending upon of course these being reported in the first instance, as this is a systematic review. Due to its inherent realistic design, the authors say that many aspects of review are undecided now except a broad framework. This is understood by the reviewer, but again raises the need for a protocol to be published for this.</p> <p>While I think the authors have done an excellent job of building a case for their work, I am a bit hesitant to accept this as a protocol. The paper serves as a good review paper on the issue and can end with the framework rather than calling this as a protocol paper.</p>
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REVIEWER	Zhang, James University of Chicago, Medicine
REVIEW RETURNED	31-Mar-2021

GENERAL COMMENTS	<p>Step 3: Appraise studies and extract data.” This is the critical step in the proposed review protocol and will likely form the foundation for any meaningful contribution to the advancement of understanding of community engagement in this context. However, the texts are overly terse and the readers are left uncertain what novel approach this study has proposed beyond</p>
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the existing literature. The single citation of Reference 44 looks light. The readers will be better served if the authors can delineate a more detailed, thought-out approach to developing “existing quality assessment criteria for different study designs, and a consideration of ‘fitness for purpose’”. Some high-level conceptual diagram will be helpful.

“Step 4: Synthesise evidence and draw conclusions.” This is another critical step in the proposed review protocol, and the meaningful contribution of the review will be heavily hinging on this. The authors mentioned a few termed words such as “abductive thinking and retroductive theorizing” and “Counterfactual thinking” but the reference citation is very light (only 1) and the readers are left uncertain about what the authors really meant. A more detailed, clarified, thought-out approach to this with more references and critical assessment will help readers to better understand the significance/relevance of this proposed review protocol.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1 Comments to the Author:	Response
<p>This is a protocol for a qualitative study which is a rarity. Usually, protocols are published in advance of cohorts and trials so as to enable the reader of subsequent papers to identify any protocol changes and also to save space for future papers from devoting space for detailed methods. This paper is an interesting exploration of</p>	<p>Thank you for these comments. We have added some further details about our methods, including the initial search strategies as a Supplementary file, and appraisal and synthesis processes. This realist review protocol puts forward the approach that will be followed in the realist review itself (including the initial framework</p>

<p>community engagement in NCDs with an open mind allowing negative outcomes to also be identified, depending upon of course these being reported in the first instance, as this is a systematic review. Due to its inherent realistic design, the authors say that many aspects of review are undecided now except a broad framework. This is understood by the reviewer, but again raises the need for a protocol to be published for this. While I think the authors have done an excellent job of building a case for their work, I am a bit hesitant to accept this as a protocol. The paper serves as a good review paper on the issue and can end with the framework rather than calling this as a protocol paper.</p>	<p>that will be built on through reviewing and synthesising literature). The findings of the review, as well as any departure from this protocol, will be reported on separately. We have also cited an article by Booth et al. 2020, which reflects on the iterative and to some extent unpredictable nature of realist searches and reviews (new text in red):</p> <p>“The realist search and review process is iterative and not as linear or rigid as a traditional systematic review.[53 + Booth et al.2020] It is, therefore, complex and not fully predictable, with decisions and changes being made along the way as opposed to all criteria and specifications being predefined.”</p> <p>We would also like to state that this protocol paper addresses the complex review process, i.e. realist review. The non-linearity of the literature, iterative nature of the review and</p>
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	<p>synthesis together with the expertise from multi-disciplinary team are major investments. The relative novelty of the methods, and increasing interests in the topic, have also motivated us to present it as a protocol paper so that researchers, experts and policymakers can utilise and learn from this process. We very much believe that this protocol paper will be a useful contribution, in terms of both methods and content, in the field of community engagement (CE) around noncommunicable diseases (NCDs). Also, in our opinion, given the vastness of the topic and challenges in synthesising evidence around CE through systematic reviews (see for instance this realist review rationale https://wellcomeopenresearch.org/articles/51), this protocol paper will be an important reference document for future research.</p>
<p>Reviewer 2 Comments to the Author:</p>	<p>Response</p>
<p>“Step 3: Appraise studies and extract data.” This is the critical step in the proposed review protocol and will likely form the foundation for any meaningful contribution to the advancement of understanding of community engagement in this context. However, the texts are overly terse and the readers are left uncertain what novel approach this study has proposed beyond the existing literature. The single citation of Reference 44 looks light. The readers will be better served if the authors can delineate a more detailed, thought-out approach to developing “existing quality assessment criteria for different study designs, and a consideration of ‘fitness for purpose’”. Some high-level conceptual diagram will be helpful.</p>	<p>Thank you for these comments. We have added some details into this part of the methods section (new text in red):</p> <p>“Data extraction and appraisal will be carried out using a template that will be developed and piloted specifically for this realist review, covering both any data relevant to inform CMO configurations and study characteristics needed for conducting a quality assessment of each study. The template and data extraction process will also be informed by a realist approach to thematic analysis, which incorporates different forms of reasoning (inductive, deductive, abductive and retroductive) into thematic analysis, and requires all three ontological layers to be considered.[52] While the use of a data extraction template resembles a codebook approach to thematic analysis, the realist approach will be utilised to consider both manifest semantic content, such as outcomes, as well as latent content, such as potential mechanisms. This approach will enable us to start eliciting theories already at the data extraction phase.”</p> <p>We have also added the following details about appraisal tools: “The starting point for quality assessment will be to use the relevant design-specific Critical Appraisals Skills Programme (CASP) checklist[68] to appraise each peerreviewed study, and Tyndall’s checklist for grey literature.[66]. Additional designspecific appraisal</p>

	<p>tools may be sought where needed, and their use will be reported transparently in the review.</p> <p>The reference (originally 44) to Pawson et al. 2005 is used frequently due to it being the original comprehensive source of methodological guidance for realist reviews, and it outlines the steps we are following in our review. This influential paper has been cited over 2300 times, and is considered a key methodological publication in this field, with Ray Pawson remaining a relevant expert and authority on realist reviews to this day. Nevertheless, we have also repeated the citations to RAMESES guidelines and added details and references throughout the manuscript.</p>
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<p>“Step 4: Synthesise evidence and draw conclusions.” This is another critical step in the proposed review protocol, and the meaningful contribution of the review will be heavily hinging on this. The authors mentioned a few termed words such as “abductive thinking and retroductive theorizing” and “Counterfactual thinking” but the reference citation is very light (only 1) and the readers are left uncertain about what the authors really meant. A more detailed, clarified, thought-out approach to this with more references and critical</p>	<p>Thank you for pointing this out. We have provided the following definitions and clarifications to those key concepts in Table 1:</p> <p>“Abductive thinking: A form of inventive and intuitive (‘hunch-driven’) thinking that allows a researcher to creatively imagine, for example, potential mechanisms to be investigated.[44,56]</p> <p>Retroduction: Theorising and testing of hidden causal mechanisms that have, for</p>
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<p>assessment will help readers to better understand the significance/relevance of this proposed review protocol.</p>	<p>example, been imagined through abductive thinking or inductively inferred from descriptions of existing studies.[44,48,56]</p> <p>Counterfactual thinking: The consideration and application of contradictory evidence or alternative explanations to an interpretation, such as a CMO configuration, to further test and refine it.[47,57]”</p> <p>The reference we frequently provide is to a key publication (Jagosh 2019) detailing the use of these forms of thinking and theorising in realist research in the tradition of Pawson and Tilley. In addition, we have provided the following example of this synthesis approach under Step 4:</p> <p>“Counterfactual thinking (Table 1) will be applied with the help of evidence that seems to refute or disagree with the emerging conclusions. For example, there could be an emerging conclusion that remuneration and related expectations</p>
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	around community engagement are a dominant mechanism determining outcomes, such as participant retention, in contexts of poverty and inequality. This observation would be considered against evidence of community engagement through which high participant retention has been successfully achieved without significant material gains being expected or received by the community.”
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VERSION 2 – REVIEW

REVIEWER	Zhang, James
REVIEW RETURNED	University of Chicago, Medicine 09-Jun-2021

GENERAL COMMENTS	This is a stronger manuscript with improved clarity. One question remains about “contextual elements” in NCD though. According to the authors, the contexts are “The conditions (e.g. individual, organisational and environmental features), historical elements or relational and dynamic features that can potentially (dis)activate existing or introduced mechanisms” (Table 1). The readers may benefit from the understanding of these conditions, historical elements or relationship and dynamic feather the authors are looking for in the case of NDC, and how this differs from the systematic review. It should be noted in Limitations if those contexts are expected not be fully found.
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VERSION 2 – AUTHOR RESPONSE

Comments from Reviewer 2

This is a stronger manuscript with improved clarity. One question remains about “contextual elements” in NCD though. According to the authors, the contexts are “The conditions (e.g. individual, organisational and environmental features), historical elements or relational and dynamic features that can potentially (dis)activate existing or introduced mechanisms” (Table 1). The readers may benefit from the understanding of these conditions, historical elements or relationship and dynamic feather the authors are looking for in the case of NDC, and how this differs from the systematic review. It should be noted in Limitations if those contexts are expected not be fully found.

Authors’ response

Thank you for the feedback. The difference between how context is examined in a realist review compared to a systematic review is that only contextual elements that are relevant for CMO configurations are contextual elements (C) in a realist review. Systematic reviews may either not consider contexts to any significant degree (this is a common criticism of systematic reviews that

synthesise findings without accounting for contextual differences), or may include some consideration of the setting in which an intervention is delivered without necessarily differentiating between contextual elements that influence the intervention and those that do not.

We provide an updated (new text in red) example of a CMO configuration under Step 1: Clarify scope:

“For example, a historically good relationship between a community and researchers (C) can engender trust (M1), and thus openness to researchers’ requests (M2), which can lead to outcomes (O) such as high research participation.”

Here, a historically good or strong relationship between the community and researchers is only relevant as a contextual element because it triggers mechanisms and outcomes – it is therefore not a generic characteristic of the setting but part of the configuration. In this way, any conditions we identify as Cs in the realist review will be part of a causal configuration i.e. seen to be triggering (activating or disactivating) mechanisms (M) and outcomes (O), rather than mere background information separate from causal trajectories. Exploring how a particular outcome (intended or unintended) is yielded in a certain context through a particular mechanism is the specific focus of realist reviews, in contrast to systematic reviews that typically examine quantifiable effects of interventions on specific, predefined outcomes.

We have added the following clarifying notes (new text in red) to Table 1., which together with Figure 3 and the examples in the text should give the reader a complete picture of contextual elements:

“Context: The conditions (e.g. individual, organisational and environmental features), historical elements or relational and dynamic features that can potentially (dis)activate existing or introduced mechanisms.[47,48,55] This is not the same as ‘setting’ or ‘context’ in a generic sense of providing background information, and only captures those aspects of the context that have a bearing on mechanisms and outcomes.”

We have also added the following under Strengths and limitations of this study:

“A realist review cannot produce an exhaustive account of all contexts, mechanisms and outcomes of potential relevance to non-communicable disease prevention.”