STUDY PROTOCOL

What contextual factors and mechanisms facilitate male involvement in women's sexual and reproductive health in Sub-Saharan Africa? A rapid realist review protocol [version 1; peer review: 2 approved with reservations]

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Open Peer Review

Invited Reviewers

1. Ferdinand Mukumbang1, University of Washington, Seattle, USA
2. Katherine Semrau1, Harvard Medical School, Boston, USA

Any reports and responses or comments on the article can be found at the end of the article.

Abstract

Background: Sexual and reproductive health (SRH) outcomes of women within low resource contexts continue to be of concern to policymakers. Notably, sub-Saharan Africa (SSA) continues to lag behind other regions of the world in improving SRH outcomes for women in the region. A key suggested strategy is male involvement through interventions that respect, promote and facilitate women in taking care of themselves and their new-borns. However, factors such as social-cultural barriers may preclude men's involvement in these programmes. There is a need for a context-specific understanding of gender dynamics and interaction and the mechanisms that enhance or impede men's involvement.

Methods: We will employ a rapid realist review (RRR) methodology to examine what mechanisms and contextual factors are essential to facilitate the involvement of men in women's SRH programmes in SSA. In keeping with the realist literature we will follow six steps, which will include: (1) developing a theory, (2) developing a search strategy, (3) selecting and appraising documents, (4) extracting data, (5) analysing data and synthesising the evidence, and (6) presenting and disseminating a revised theory. We will also engage with key stakeholders who will provide local contextual insights and with experts in the subject area. The review findings will be shared with relevant stakeholders using a variety of avenues including through publications, at conferences and on social media platforms.

Discussion: This review will identify the mechanisms and contextual factors that facilitate or hinder men's involvement in women's SRH programmes in SSA. The rationale for adopting an RRR approach is to
help gather the information within a relatively short period to ensure relevance of findings to policymakers in SSA. Results from this work also have the potential to be adapted to the other contexts, for example, Ireland and the UK, which have a growing population of people from SSA.

**Keywords**
Sexual and Reproductive Health, Women's Health, Male Involvement, sub-Saharan Africa, Rapid Realist Review
Introduction
Sexual and reproductive health (SRH) outcomes of women within low resource contexts continue to be a subject of concern. Although there has been a notable improvement in key health outcomes globally over the past two decades, sub-Saharan Africa (SSA) continues to lag behind other regions. For example, the region accounts for 66% of global maternal mortality. This has been attributed majorly to socio-economic and health system factors such as poverty, low literacy levels and limited health, human and physical infrastructure. Male involvement in women’s SRH has been recommended as a critical strategy for the improvement of health outcomes for this cohort. It is relevant to realise the global sustainable development goals 3 and 5. Male involvement in women’s SRH is a broad term whose scope includes not only men’s physical presence during women’s reproductive care but also socio-economic and emotional support for women’s health decision making. This is based on the premise that, in most societies, men act as gatekeepers and primary decision-makers regarding resource utilisation and access to critical services, including reproductive health. Their decisions at all levels of society, both communal and at the basic family unit, can either impede or facilitate access to essential health services. This impacts on the health of women and girls.

Evidence suggests that despite challenges, male involvement in women’s health, particularly in low and middle-income countries, is yielding positive outcomes. For example, some programmes have reported increased adherence to ante-natal care attendance, birth readiness and delivery at a health facility where a male partner was involved while other programmes have shown an increase in the number of couples availing for HIV testing and those taking antiretroviral prophylaxis. However, challenges to male involvement have also been noted; despite their gatekeeping and decision-making roles, men have not been traditionally involved in women’s health. Social-cultural barriers, such as societal constructions of masculinity, appear to prevent men from active involvement. Women and girls’ sexual and reproductive health is mainly perceived as “female business”, with men taking on the role of the provider of funds.

Furthermore, the accompaniment of women by their partners to health facilities is perceived as a form of emasculation, through crossing rigid lines of gender roles and norms, set by a highly patriarchal society. Other barriers to male partner involvement include economic barriers related to missed work opportunities due to accompaniment to health facilities as well as additional costs such as transport, more especially for men in the low-income bracket. The perceived negative attitudes of staff at health facilities and in other cases, a lack of privacy at facilities, may preclude men’s involvement. Limited knowledge among men on the importance of engaging in women’s health as well as lack of interest in women’s health are other notable barriers. Due to the vital role that men play in society within the SSA context, it is essential to further investigate critical drivers for facilitating their participation in women’s SRH.

The need to facilitate men’s involvement in women’s SRH in SSA is well articulated in the literature. It includes several systematic reviews that synthesis and assess available evidence to enhance and promote evidence-informed policymaking. However, systematic reviews fail to demonstrate how programmes work in diverse settings and within different populations, information that would be critical for informing policy decisions.

In this paper, we provide a protocol for a rapid realist review (RRR) that examines what contextual factors and mechanisms are essential in facilitating men to get involved in women’s SRH in SSA. The RRR methodology, developed by Saul and colleagues, is based on the realist philosophy whose premise is to ascertain how programmes or interventions operate, or why they fail short, in particular environments and conditions. Accordingly, because observations on their own cannot explain causal linkages between variables, it becomes necessary to demonstrate why relationships occur and to show what it is that leads to specific outcomes. The outcome of an intervention, therefore, depends on particular decisions taken (or not) in regards to intervention and how actors’ reason about opportunities or resources availed by the intervention.

In realist reviews (RR), the Context + (plus) Mechanism = Outcome (CMO) links form the fundamental principles. Context denotes the history, culture, norms, beliefs, social networks as well as pre-existing structural organisations of the communities in which the interventions are conducted. Mechanisms refer to the ‘triggers’ that lead participants to get involved or not in interventions and relates to their responses to the various intervention strategies and resources. Outcomes are the intended or unintended results based on the interplay between mechanisms and context. In RRRs, the emphasis tends to be on the links between the interventions and outcomes, and RRRs use programme theories to help explain how and why particular interventions produce specific outcomes within specific populations.

The main review objective is to examine what contextual factors and mechanisms play a role in facilitating men to get involved in women’s SRH programmes in SSA.

Specific objectives include:

1. To understand the different forms and types of male involvement in women’s SRH
2. To identify contextual conditions and mechanisms that facilitate or impede men’s involvement and develop an explanatory programme theory
3. To produce guidelines for consideration in the development of interventions to promote male involvement in women’s SRH

Methods
For the proposed study, we adopt the RRR methodology as it is best suited in contexts where evidence is limited and allows
for the synthesis of knowledge in a considerably shorter time, compared to a traditional RR, making it possible to respond to time-sensitive policy decisions.

A critical strength of RRRs lies in the engagement of local reference groups and expert panels in the review process. Local reference groups contribute local contextual knowledge and include those individuals who are the target of the review findings, for example, policymakers, local community groups, the private sector, or charitable organisations. As this review will inform the development of strategies to tackle the practice of female genital mutilation/cutting (FGM/C), the local reference groups will consist primarily of individuals from nongovernmental organisations (NGOs) with this remit. Potential local reference groups will include representatives from these organisations; the Ministry of Health, Kenya; anti-FGM/C organisations, including Men-End FGM network, AkiDwA (Akina Dada wa Africa), an organisation that seeks to enhance justice and equality for women in Ireland; and CARA projects, an Irish NGO working in Kenya with a focus on child protection. The local reference group will share their knowledge and experience and help identify reports that can be included in the review and ultimately ensure that results have relevance for the local context. In preparation for this review, the first author, PM, has met with potential individuals and groups who will be part of the local reference panel.

Expert panels include individuals knowledgeable in the content area. They are usually tasked with ensuring that the scope of the review remains focused and the process of searching for relevant literature is streamlined. In addition, they participate in the synthesis of findings while ensuring appropriate interpretation of the results. For the proposed review, the expert panel will consist of seven members with experience in women’s health, methodologies that promote public involvement, nursing, public health, medical anthropology, psychology and health systems. We will employ a snowballing process to establish a panel of experts with experience in the field under study. In contrast, the local reference panel membership will be agreed by the expert panel. The time commitment required by the expert and reference groups will be kept to a minimum and highlighted in the invitation.

Search strategy
In keeping with the realist literature, we will follow six steps in conducting the review (Pawson et al. and Wong et al.). This will entail: (1) developing a theory, (2) developing a search strategy, (3) selecting and appraising documents, (4) extracting data, (5) analysing data and synthesising the evidence, and (6) presenting and disseminating a revised theory.

Before the review commences, the expert panel will hold their first meeting to agree and clearly define the scope of the RRR, decide on terms to be included when searching the literature, and on the databases to be searched. The primary researcher (PM) will carry out an initial search of the literature to develop familiarity with the various male involvement strategies relevant to women’s SRH in SSA. To search for relevant literature, the ‘intervention’, ‘population’ and ‘context’ will be included. The interventions to be studied include SRH programmes or initiatives, for example, family planning, ante-natal care and post-natal care programmes, and programmes for couples’ counselling. The population of interest will be men (husbands, partners, spouses) involved in these interventions or programmes. The review will include studies located in SSA and conducted in any type of setting, including community, household, hospital or other health care facility settings. No restrictions will apply to research articles’ study designs or to the year they were published. However, studies not addressing male involvement in women’s SRH, not conducted in SSA and those in languages other than English will be excluded. We will also exclude commentaries, letters to editors and opinion pieces.

PM and ADB will undertake a search of the literature in consultation with a University faculty librarian. Databases are likely to include Web of Science, PubMed, EMBASE, MEDLINE, and PsycINFO, based on other reviews conducted in the SSA context. We anticipate that the literature for this topic will be diverse and hence we will use extensive searching of grey sources, such as OpenGrey, Google Scholar and DODRIA – Africa’s data directory – for relevant documents. Documents and articles, as identified by the local reference and expert panel members, will supplement the initial search. We will also search websites, such as those of the United Nations Children’s Fund (UNICEF), United Nations Population Fund (UNFPA) and the World Health Organization (WHO). The search will be iterative and refocused as the review evolves. PM and ADB will screen titles and abstracts for relevant literature.

Data extraction
Data extracted will include information that helps identify contextual conditions and mechanisms that would facilitate male involvement in women’s SRH programmes. Such data would consist of i) the form and types of these programmes (family planning, ante-natal, post-natal), ii) pre-involvement activities such as communication campaigns (through media, mobile phones) sporting activities, the formation of men’s clubs, men’s health clinics, workshops, seminars, iii) settings where programmes are introduced, and the iv) outcomes associated with these programs (for example increased ante-natal care attendance; reduced mortality and morbidity (mother and baby); decreased/increased intimate partner violence).

Two reviewers (CK and EK) will independently extract the data through a selection of text excerpts. We will use a modified version of the template for Intervention Description and Replication (TIDieR) to extract data. In the case of disagreements between the reviewers, consensus or engagement of a third reviewer will follow. The search for evidence and data extraction is expected to take between 12–14 weeks. The team will hold weekly data sessions to assess the review process. Extracted data will be reviewed for completeness by TK and EM.

Synthesising the evidence
The experts, as mentioned earlier, and reference panels will scrutinise initial review findings, synthesis, examine and discuss
the identified CMOs based on their experiences. Data will be synthesised to generate a ‘programme theory’ that aligns with the focus and scope of the review22 and the ‘programme theory’ will be refined through group and individual discussions30. This RRR will adhere to the realist publication standards guidelines, some recent RRRs will also inform Realist And MEta-narrative Evidence Syntheses: Evolving Standards (RAMESES)37 and the methodology.

During the initial planning stages of this protocol, an advisory group made up of anti-FGM/C experts working at the grassroots level in Kenya was set up. The group will have a representative at the local reference panel, and their input is expected to enhance the quality of the review process and the refining of the ‘programme theory’. Importantly, the advisory team will play a critical role in supporting the dissemination of the review findings to policymakers and other knowledge users31.

Dissemination
The results that will emerge from the RRR will potentially be useful to policymakers and other key stakeholders, including NGOs and groups working to involve men in women’s SRH programmes in SSA. The findings will also be presented to key policymakers, and relevant stakeholders and the aforementioned advisory group will be instrumental in enabling this process. We will also draft publications that will be submitted to high-impact, peer-reviewed journals, and the findings will be presented at academic conferences. We envision to present the results at the Africa Health Agenda International Conference. Also, an infographic will be developed based on the review findings and disseminated via social media platforms, for example, twitter, using various hashtags.

Study status
Formation of the expert panel is complete. The searching of the literature has not commenced.

Discussion
The planned RRR will synthesise and generate evidence on the contextual factors and mechanisms that enhance or hinder male involvement in women’s SRH programmes. The findings will potentially have relevance to programmes that involve men, either as partners or spouses, or even key decision-makers. The RRR will provide knowledge synthesis within a short period, and to ensure that the evidence generated is relevant and suitable for the knowledge users, local reference panels and expert panels will guide the RRR. Involving these groups in the process not only facilitates the efficiency of identifying essential materials to include in the review, but has the potential to produce sufficiently robust findings which can inform current practice39. We expect the review will have a political impact, influencing the development of national policy frameworks on male involvement in countries of SSA where such frameworks are lacking. The programme theories emerging from this work also have the potential to be adapted to the other contexts, for example, Ireland and the UK where there is a growing population from SSA.

Data availability
No data is associated with this article.

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Thank you for the opportunity to review the manuscript focused on a rapid realist review protocol for assessment of contextual factors and mechanisms of male involvement in SRH services in sub-Saharan Africa. The study protocol is clear and provides background to the approach of Dr. Mwendwa and colleagues. There are some key areas for clarification:

1. In the abstract, background, and discussion sections, the authors discuss sexual and reproductive health programs at a very general level. However, in the Methods section, there is specificity around targeting "strategies to address the practice of female genital mutilation/cutting (FGM/C)." Again, in the "Synthesizing the evidence" section, the authors focus on anti-FGM/C experts to join the review panel. If the focus of the review and target audience for the findings is around FGM/C, then I would recommend including that throughout the study protocol paper. Further, that would modify the search terms/groupings for your search strategy.

2. I agree with Dr. Mukumbang's comment that more information around data analysis would be beneficial, especially for others to replicate this approach.

3. Finally, as with all program implementation, there is the intention of a program approach, fidelity to the program approach or implementation plan, and then the success/failure of the program. Will the authors include programs that succeeded and failed with male involvement in SRH? It would be helpful to understand programs that failed as the contextual factors and mechanisms may have been important to the implementation.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes
Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** I am a maternal and newborn health epidemiologist focused on design, testing and implementation of evidence-based interventions to improve quality of care and health outcomes.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

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**Author Response 02 Feb 2021**

Purity Mwendwa, University College Dublin, Dublin, Ireland

**Comments/queries 1**
In the abstract, background, and discussion sections, the authors discuss sexual and reproductive health programs at a very general level. However, in the Methods section, there is specificity around targeting "strategies to address the practice of female genital mutilation/cutting (FGM/C)." Again, in the "Synthesising the evidence" section, the authors focus on anti-FGM/C experts to join the review panel. If the focus of the review and target audience for the findings is around FGM/C, then I would recommend including that throughout the study protocol paper. Further, that would modify the search terms/groupings for your search strategy.

**Response**
The protocol has been amended throughout to reflect sexual and reproductive health programs more generally as opposed to making reference to female genital mutilation/cutting (FGM/C) programmes more specifically. The following changes have been effected as follows; **Methods, paragraph 4**
Potential local reference groups will include key stakeholders in the Ministry of Health, Kenya at the national and county levels. Representatives will also be drawn from community-based organisations addressing SRH, community health workers and opinion leaders.

**Comments/queries 2**
I agree with Dr. Mukumbang's comment that more information around data analysis would be beneficial, especially for others to replicate this approach.

**Response**
This is now added to the section ‘**Analysing and Synthesising the evidence** paragraph 1’
Data analysis will incorporate both inductive and deductive approaches (The RAMESES II Project, 2017) and we will adopt Gilmore et al (2019) approach in analysing and synthesising evidence. The Nvivo software will be used to support the management and analysis of the
data.

**Comments/queries 3**
Finally, as with all program implementation, there is the intention of a program approach, fidelity to the program approach or implementation plan, and then the success/failure of the program. Will the authors include programs that succeeded and failed with male involvement in SRH? It would be helpful to understand programs that failed as the contextual factors and mechanisms may have been important to the implementation.

**Response**
The authors note that, while this would be an important aspect to include in the review, it is often difficult to identify literature in relation to failed interventions.

**Competing Interests:** No competing interests were disclosed.
interventions operate, or why they fall short, in particular environments and conditions. This statement is not entirely accurate. The epistemology of realist research is to provide mechanism-based causality explanations of social phenomena. Explaining how programmes or interventions work is the specific focus of realist evaluation, which is the focus of Pawson and Tilley.

"Accordingly, because observations on their own cannot explain causal linkages between variables, it becomes necessary to demonstrate why relationships occur and to show what it is that leads to specific outcomes." I found this sentence confusing in the sense that I am not sure how it links the sentences before and after it. In other words, I am not sure how it establishes the realist evaluation's stance. It would have been important for the authors to establish why the notions of context, mechanisms and outcomes are central to realist evaluation.

"In realist reviews (RR), the Context + (plus) Mechanism = Outcome (CMO) links form the fundamental principles." There seem to be some omissions in the above sentence. Consider replacing the word "links" with "heuristic tool".

"In RRRs, the emphasis tends to be on the links between the interventions and outcomes,..." I am not sure what this means. RRRs are informed by the realist evaluation principles. Based on this notion, the statement highlight seems confusing to me.

An explanation of what programme theories are will be useful.

"For the proposed study, we adopt the RRR methodology..." The first part of this sentence is redundant. Consider deleting. For the second part, it should be written as "We will adopt..."

"As this review will inform the development of strategies to tackle the..." I am not so sure of the certainty that the authors display in this sentence but I will propose some modesty. Findings from this review can inform the development..."

How is the initial programme theory going to the developed?

Because there are various interventions that the authors are considering to implore, I would propose that they should consider using the intervention-context-actor-mechanism-outcome (ICAMO) heuristic tool towards their theory development. I have added a citation that illustrates the (ICAMO) heuristic tool and how useful it could be in review.

There is no mention of how the data will be analysed. The process of data analyses should have been described as this is critical in how the initial programme theory translates to the refined programme theory and the linking or the CMO components towards theory development.

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Is the rationale for, and objectives of, the study clearly described?
Yes
Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** I am a Health Policy and Systems Researcher in sub-Saharan Africa specialised in realist-informed methodologies.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

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**Author Response 02 Feb 2021**

**Purity Mwendwa**, University College Dublin, Dublin, Ireland

**Comments/Queries 1**
The authors write: "This has been attributed majorly to socio-economic and health system factors such as poverty, low literacy levels and limited health, human and physical infrastructure. Male involvement in women's SRH has been recommended as a critical strategy for the improvement of health outcomes for this cohort. It is relevant to realising the global sustainable development goals 3 and 53, 5." I found it had to link male involvement as part of relevant interventions to improve SRH outcomes for women based on the socio-economic and health systems factors identified. I would be more inclined to male involvement to be related to socio-cultural barriers.

**Response**
We have amended the paragraph in the introduction as follows;
...This has been attributed to socioeconomic and health system factors (Girum,2017) as well as social-cultural barriers which preclude male involvement in women's health (Ganle and Dery, 2017).

**Comments/Queries 2**
The authors write: "However, systematic reviews fail to demonstrate how programmes work in diverse settings and within different populations information that would be critical for informing policy decisions." I think that equally important especially in realist perspectives is to capture why other programs fail to work.

**Response**
We have amended the paragraph in the introduction 4th paragraph as follows; However, systematic reviews fail to demonstrate how programmes work in diverse settings and within different populations (Davies,2006) information that would be critical for informing policy decisions. Incorporating realist perspectives helps to elucidate why
programmes work or fail to work in specific contexts.

**Comments/Queries 3**
The authors write: "...the realist philosophy whose premise is to ascertain how programmes or interventions operate, or why they fall short, in particular environments and conditions. This statement is not entirely accurate. The epistemology of realist research is to provide mechanism-based causality explanations of social phenomena. Explaining how programmes or interventions work is the specific focus of realist evaluation, which is the focus of Pawson and Tilley.

**Response**
We have corrected this in the introduction, 5th paragraph as follows:
According to Pawson and Tilley, realist research aims to provide explanations that clarify how interventions or programmes operate in specific contexts (Pawson & Tilley, 1997).

**Comments/Queries 4**
"Accordingly, because observations on their own cannot explain causal linkages between variables, it becomes necessary to demonstrate why relationships occur and to show what it is that leads to specific outcomes. I found this sentence confusing in the sense that I am not sure how it links the sentences before and after it. In other words, I am not sure how it establishes the realist evaluation's stance. It would have been important for the authors to establish why the notions of context, mechanisms and outcomes are central to realist evaluation.

**Response**
This paragraph as been restructured and the following sentence included: **Introduction paragraph 6**
...The different components (CMO) are not static or linked in linear ways but dynamic and hence it is important to understand the dynamic interplay of the linkages between context, processes and outcomes.

**Comments/Queries 5**
"In realist reviews (RR), the Context + (plus) Mechanism = Outcome (CMO) heuristic tool form the fundamental principles. There seem to be some omissions in the above sentence. Consider replacing the word "links" with "heuristic tool".

**Response**
The terms ‘heuristic tool’ have been added to this sentence
In realist reviews (RR), the Context + (plus) Mechanism = Outcome (CMO) heuristic tool forms the fundamental principles.

**Comments/Queries 6**
"In RRRs, the emphasis tends to be on the links between the interventions and outcomes,..." I am not sure what this means. RRRs are informed by the realist evaluation principles. Based on this notion, the statement highlight seems confusing to me.

**Response**
This sentence has been omitted altogether

**Comments/Queries 7**
An explanation of what programme theories are will be useful.
Response

This has been included under the section ‘search strategy’ paragraph 2
Programme theories are statements that help to clarify how programmes or interventions are presumed to work (Davidoff, Dixon-Woods, Leviton, & Michie, 2015). In realist evaluation, they form the units of analysis and serve to connect the (CMO) configurations (Wong et al, 2013; Pawson and Tilley, 1997) and become refined through testing.

Comments/Queries 8
"For the proposed study, we adopt the RRR methodology..." The first part of this sentence is redundant. Consider deleting. For the second part, it should be written as "We will adopt..."
Response
This has now been amended within the methods section, paragraph 1, the first sentence to read;
“We will adopt the RRR methodology...”

Comments/Queries 9
"As this review will inform the development of strategies to tackle the..." I am not so sure of the certainty that the authors display in this sentence but I will propose some modesty. Findings from this review can inform the development..."
Response
We have amended this in the Methods, paragraph 3 as follows;
Findings from this review can inform the development of strategies to promote men’s involvement in women’s SRH programmes in SSA.

Comments/Queries 10
How is the initial programme theory going to the developed?
We have added the following paragraph under the section ‘search strategy’ paragraph 2 as follows;
Response
The initial programme theory will be developed based on a review of the literature and refined through expert panel and reference groups consultations to specify how men’s involvement in women’s SRH programmes could improve access and utilisation of services to improve women’s SRH.

Comments/Queries 11
Because there are various interventions that the authors are considering to implore, I would propose that they should consider using the intervention-context-actor-mechanism-outcome (ICAMO) heuristic tool towards their theory development. I have added a citation that illustrates the (ICAMO) heuristic tool and how useful it could be.
Response
We have taken this suggestion on board and amended this paragraph in the Methods, paragraph 3 as follows;
In realist reviews (RR), the context-mechanism-outcome (CMO) heuristic tool forms the fundamental principles (22) (Pawson, 1997). For the current study, however, we use the expanded heuristic tool, intervention-context-actor-mechanism-outcome (ICAMO) proposed by (Marchal, Kegels, & Van Belle, 2018) and (Mukumbang, Marchal, Van Belle, & van Wyk, 2018) that includes two additional components- ‘Intervention’ and ‘Actors’ based.
on the premise that interventions would need to be taken up by the Actors if they are to succeed.

**Comments/Queries 12**
There is no mention of how the data will be analysed. The process of data analyses should have been described as this is critical in how the initial programme theory translates to the refined programme theory and the linking or the CMO components towards theory development.

**Response**
This is now added to the section ‘Analysing and Synthesising the evidence’ paragraph 1 as follows;
Data analysis will incorporate both inductive and deductive approaches (The RAMESES II Project, 2017) and we will adopt Gilmore et al (2019) approach in analysing and synthesising evidence. The Nvivo software will be used to support the management and analysis of the data.

**Competing Interests:** No competing interests were disclosed.