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Adapting Health Interventions for Local Fit when Scaling-up: A Realist Review Protocol

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45 **DISCLAIMER:** The authors put forward the views expressed in the submitted article are our
46 own and not an official position of the institution or funder.
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53 **KEYWORDS:** Scale-up, adaptation, fidelity, realist synthesis, realist review
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ABSTRACT:

Introduction: Scaling-up is essential to ensure universal access of effective health interventions. Scaling-up is a complex process, which occurs across diverse systems and contexts with no one-size-fits-all approach. To date, little attention has been paid to the process of scaling-up in how to make adaptations for local fit. The aim of this research is to develop theory on what actions can be used to make adaptations to health interventions for local fit when scaling-up across diverse contexts that has practical application for implementers involved in scaling-up.

Methods and Analysis: Given the complexity of this subject, a realist review methodology was selected. Specifically, realist review emphasizes an iterative, non-linear process, whereby the review is refined as it progresses. The identification of how the context may activate mechanisms to achieve outcomes is used to generate theories on what works for whom in what circumstances. This protocol will describe the first stage of developing an initial programme theory framework, identifying potential actions, contexts, mechanisms and outcomes that could be used to make adaptations when scaling-up. This protocol will then outline the methods for the further stages of the review which will focus on identifying case examples of scale-up and adaptation in practice. This review is based on Pawson's five stages; (i) clarifying scope and development of a theoretical framework, (ii) developing a search strategy, (iii) selection and appraisal, (iv) data extraction and (v) data synthesis and analysis. With the additional stage of further theory refinement with stakeholders.

Ethics and Dissemination: This review will develop theory on how adaptations can be made when scaling-up. Findings will be disseminated in a peer-reviewed journal and through stakeholder engagement as part of the research process. Ethical approval has been received through Health Policy and Management/Centre for Global Health Research Ethics Committee of Trinity College Dublin.

Abstract Word Count: 298

STRENGTHS AND LIMITATIONS OF THIS STUDY:

- This study addresses a gap in the literature on how to adapt health interventions for local fit when scaling-up health interventions across diverse contexts.

- This study will explore examples of scale-up in practice as part of the review, allowing for learning from what is happening in real world settings and allow the findings to have practical applications for implementers.
- Often realist reviews do not have many details on the specifics of how the data extraction and synthesis will be carried out, therefore a strength of this paper is the detail given on this process including supplemental files with details of the research logbook, the data extraction, and suggested coding and synthesis procedures.
- The use of a realist approach will allow for the exploration of the complexity of scale-up and adaptation, with the involvement of stakeholders to further ensure the findings are useful and have relevance in the field.

INTRODUCTION:

The process of scaling-up an effective health intervention is complex and occurs across diverse systems and contexts^{1 2}. It is estimated that only 14% of healthcare research makes it into real world settings^{3 4}. Therefore, many existing health problems could be addressed through scaling-up of interventions already known to be effective. For example, it is estimated that 85% of childhood deaths could be avoided in low and middle income countries through scale-up of existing health interventions like zinc and oral rehydration therapy treatment⁵. Currently scale-up has been estimated to take 15 years from pilot to national scale⁶. Scale-up is time consuming and challenging due to the complexity of implementing across diverse contexts where the population⁷, finances, resources and capacity⁸ may differ. The result is a growing discussion on the need to provide more evidence for how to address this important research-to-practice gap.

Scale-up, Adaptation and Fidelity

Fidelity has been described by Castro and colleagues⁹ as delivering the programme as intended and tested. However there may often be a need to adapt to the needs of a target population⁹. Adaptation has been seen as an essential process to match community needs, organisation resources and to gain trust and ownership by community¹⁰. Recent frameworks have supported the local development of adaptations when scaling-up, by actions such as use of quality improvement methodology^{2 11}. Fidelity can often be seen as a top-down (researcher, intervention developer) driven approach and adaptation has been viewed as more of a community driven

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3 bottom-up approach (frontline service providers, communities, individuals)¹². However, when
4 looking at fidelity it is impossible to ignore potential necessary adaptations for local needs, and
5 when looking at adaptation to ignore how to maintain fidelity to the original intervention. With
6 both adaptation and fidelity proposed as necessary when scaling-up across diverse populations
7 and delivery systems⁷. In considering fidelity it is proposed that any adaptations retain the
8 underlying intervention theory and that the essential components or active ingredients remain
9 intact, with any changes made to match the unique features of the setting^{10 12 13}. This opinion was
10 shared by Aarons and colleagues⁷ in relation to scale-up and Chambers and colleagues¹¹ in
11 relation to sustainability, where identification of theory and essential elements of the
12 intervention can facilitate adaptation outside of these, and assist in avoiding a “voltage drop”¹¹,
13 or the tendency for effectiveness to taper with ongoing implementation.
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24 **The Need for Adaptation when Scaling-up**

25 Within complex systems, such as healthcare, applying a single approach in all settings is
26 unlikely to be effective, as it does not take into account the complex contextual environment
27 within which the intervention takes place¹⁴. Therefore, adaptations are important in terms of
28 ensuring that the intervention content, context, and/or delivery strategy fits with local needs
29 across scale-up sites¹⁵. A tradeoff may need to occur between increasing scale and adapting to
30 maintain local values, local relevance, quality and sustainability¹⁶. Additionally, and given that
31 contexts are continually changing over time, allowing for adaptations with contextual changes is
32 needed to ensure sustainability of interventions¹¹. Specifically, adaptation has the potential to
33 enable implementers to match the needs of a more heterogeneous population; to simplify a
34 complex intervention; to focus on a specific problem or to expand to address multiple problems;
35 to increase ownership of an intervention; to adjust to a lack of available resources or
36 requirements made by agencies or funders; allow for additional applications of an intervention
37 and/or address a lack of knowledge of the intervention¹⁰. It is important to note that adaptations
38 may be intended or unintended^{15 17}, and may be positive or negative¹⁸. Holliday and colleagues¹⁸
39 put forward in the design and testing of an educational intervention, that adaptations can be on a
40 spectrum from acceptable to unacceptable, and avoidable to unavoidable. Thus, some
41 adaptations may be unavoidable for local fit, however are acceptable as they maintain the
42 intervention theory and essential components. While others may be unacceptable as they change
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3 the underlying theory and essential components, or avoidable in that they may not necessarily
4 need to be adapted within that setting.
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8 Although adaptation has been highlighted as a key contributing factor in addressing feasibility
9 and/or acceptability for local settings when scaling-up^{7 11}, adaptation is rarely documented as
10 part of the scale-up process^{1 19 20}. Often efforts to achieve scale-up can focus on the replication of
11 the originally tested pilot or feasibility study. Replication however, does not account for the
12 diverse social, political, and cultural contexts across scale-up sites. This results in a need for
13 more tailored approaches²¹. The need to adapt interventions for local settings has been put
14 forward across the health spectrum from maternal and child health²², malaria prevention²³,
15 HIV²⁴⁻²⁶, to mental health²⁷. Unfortunately, little guidance is currently available on how to
16 complete local adaptation, adding to the difficulty in achieving and reporting of scale-up of
17 health interventions with local fit^{1 28}.
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27 **Adaptations in Practice**

28 Despite its absence of documentation, adaptation has been discovered as naturally and
29 commonly occurring in the practice of scaling-up²⁹. For example, within 44 preventive
30 interventions in a Substance Abuse and Mental Health Services (SAMHSA) national database in
31 the USA, over half of these had been adapted, suggesting that adaptation is more common than
32 not⁹. A study by Moore and colleagues²⁹ looked at the adaptation of evidence-based programmes
33 in Pennsylvania for reducing delinquency and violence. Out of ten evidence-based programmes
34 with over 200 replications across the state, 44% reported making adaptations. It has also been
35 recognised that informal on-the-job adaptations are often made by professionals working in, and
36 deeply embedded in the context and who therefore may understand the nuances³⁰. However, this
37 informal on-the-job approach to adaptation is rarely discussed, documented or evaluated,
38 resulting in a dearth of information on how adaptation may impact the intervention in the longer
39 term.
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51 **Guidance for Adaptation and Scale-Up**

52 Within the implementation and scale-up literature there are many models and frameworks
53 mentioning the need for adaptations, for example the AIDED and ExpandNet process
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3 frameworks^{1 31}. Despite growing recognition of the importance of adapting across diverse local
4 settings, along with evidence that adaptations are occurring in practice^{9 29 30}, there is minimal
5 guidance on what specific actions (for example transferring decision making to local level,
6 generation and use of local data or engagement of the community) can be used to achieve
7 adaptations when scaling-up, and even less guidance on *how*, *why* and *when* to choose one
8 method over another across different contexts. Moreover, while there is some guidance available
9 for implementers on adaptations, these guidelines are not specific to scale-up, and most existing
10 guidance on adaptation are based in the field of substance abuse prevention and HIV behaviour
11 change interventions^{10 17 32-35}. Additionally, these are largely designed for high-income country
12 contexts and some of this guidance requires highly skilled, and resource heavy processes.
13 Additionally some guidance suggests involving the original intervention developers, and at times
14 promoting redesign and testing of the intervention³⁴ which may not be feasible at multiple
15 diverse sites when scaling-up. Previous scale-up and sustainability frameworks have promoted
16 adaptation for local fit^{7 11}, however there is a need for more guidance on how to achieve this. A
17 previous review explored the process at scale-up of complex interventions³⁶, however did not
18 specifically address adaptations for local fit when scaling-up. Therefore, while acknowledging
19 the importance of adaptation for local fit there is minimal guidance for implementers on what
20 actions can be used to achieve adaptations when scaling-up, by what mechanisms these may
21 work and how the context may influence this. Therefore, there is a need to build on current
22 knowledge of scale-up.
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40 **Aims and objectives**

41 The aim of this research is to develop theory on what actions can be used to make adaptations to
42 health interventions for local fit when scaling-up across diverse contexts that has practical
43 application for implementers involved in scaling-up.
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48 Objectives:

- 49 ➤ Identify what adaptations are being made in practice when scaling-up health interventions
50 for local fit.
- 51 ➤ Uncover what actions are used to achieve adaptations when scaling-up health interventions
52 for local fit.
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- Discover by what mechanisms do these actions work to achieve adaptations when scaling-up health interventions for local fit.
- Identify what contextual factors influence whether these actions work and whether mechanisms are elicited in different settings.
- To put forward theories on what actions can be used to make adaptations when scaling-up, by what mechanisms do these actions work, and what contextual factors may influence whether these mechanisms would be elicited.

METHODS AND ANALYSIS:

Realist Review Methodology

Realist review is a methodology for evidence synthesis that uses a theory driven interpretive approach to explain findings^{37 38}. It aims to provide an explanation of what works, for whom and why, in what circumstances³⁹. It allows for exploration of the complexity of a topic with a focus on theory generation that may be applicable in the setting under study, but also applicable in wider settings through development of theory of “middle-range”^{37 40}. Realist review methodology allows for inclusion of a wide body of evidence including grey literature sources⁴¹. It supports stakeholder involvement throughout the stages of the review to inform the scope of the review, to develop and refine theory³⁸ and/or assist in dissemination⁴² of findings.

Realist review focuses on causation, with identification of where an intervention or action under certain contextual conditions (C), may trigger a mechanism (M), to achieve a given outcome (O)^{37 43}. It completes this through development of context-mechanism-outcome configurations (CMOCs)³⁹, which are central to the analysis and theory building process with mechanisms often seen as the integral link between the context and the outcome⁴⁰. They can uncover the “why” a given outcome may have occurred. Dalkin and colleagues⁴³ conceptualised mechanisms as either resources or reasoning. They put forward that resources are introduced in a context, which trigger a response or reasoning, which results in an outcome. However, mechanisms may only activate in specific contextual conditions with the context as acting like a dimmer switch⁴³. Within optimal contextual conditions mechanisms are triggered or “fire”, and with sub-optimal conditions mechanisms may fire to a lesser degree or not at all⁴³. It is also acknowledged that

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3 actions may influence and change the context, which in turn may influence whether and how a
4 mechanism fires.
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8 In the current research, we view actions that were carried out to achieve adaptations when
9 scaling-up (for example generation of evidence or participation of stakeholders), as a mechanism
10 in the form of a resource. These actions, under the optimal contextual conditions, may trigger a
11 mechanism in the form of reasoning or response (for example awareness or commitment), which
12 in turn may generate the outcome of interest (for example local ownership of the intervention).
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18 Demi-regularities (semi-predictable patterns occurring in the CMOCs) can further assist in
19 explanation of the findings. Abductive reasoning can be used to support this, which Jagosh and
20 colleagues⁴⁴ described as the “iterative process of examining evidence and developing hunches
21 or ideas about the causal factors linked to that evidence” p5. Abductive reasoning could be
22 discussed as explaining a finding from both the seen and unseen, and drawing from theoretical
23 perspectives to provide possible explanations for an outcome^{45 46}. This can involve
24 recontextualizing or redescribing explanations based on interpretations⁴⁵. Retroduction can also
25 then be used to situate the findings and put forward what causal pathways and conditions may
26 need to be present for the phenomenon of interest to occur⁴⁵.
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36 A realist review methodology was chosen as appropriate to address the study objectives for four
37 reasons. Firstly, within scale-up research, realist review methodology allows for in-depth
38 consideration of how actions can be influenced by contextual factors (e.g. resource availability,
39 level of perceived need for intervention in a local setting etc.) to trigger mechanisms (e.g. trust,
40 commitment, awareness) to generate desired outcomes (e.g. local ownership, feasible and
41 acceptable adaptations of a health intervention) leading to successful scale-up and local fit.
42 Second, realist review methodology was chosen as it recognises the use of multiple evidence
43 sources, which was considered particularly important for scaling-up. While not prioritised on a
44 traditional hierarchy of evidence, grey literature reports may contain valuable information on the
45 scale-up process. Third, stakeholder involvement can also assist in validation and refinement of
46 theory⁴⁷ and it has been put forward by Brennan and colleagues³⁸ that involvement of
47 stakeholders can provide a “reality check” as to whether the findings are consistent with
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3 experience and knowledge from practice. Involvement of stakeholders with experience in
4 adaption and scale-up through research and practice, may assist in ensuring the findings are
5 practical and of utility to implementers in the field. Finally, realist review methodology has been
6 previously used to explore the process of scaling-up complex healthcare interventions³⁶. This
7 allowed for an in-depth analysis of how complex health interventions were scaled-up across
8 three case studies, identifying active mechanisms that were needed to achieve scale-up, and
9 suggesting how the context may have influenced the scale-up across these cases.
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18 **Stages of the Realist Review**

19 This protocol is based on the five stages of realist review by Pawson and colleagues³⁷, with the
20 addition of a further stage of stakeholder involvement for theory refinement, which has been put
21 forward by previous reviews^{38 48} (figure 1). These stages are not necessarily carried out in a
22 linear process as the stages are iterative and may overlap and inform each other as learning on
23 the topic progresses and theory refinement takes place.
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30 **Figure 1. (see legend at end of manuscript)**

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33 Stage one of this review has been completed to clarify the scope of the review and develop the
34 initial theoretical framework. This protocol paper will briefly describe this first stage process
35 and how findings were used to develop the protocol for the following stages 2-6 which are to be
36 carried out.
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42 **Stage 1. Clarifying the Scope of the Review and Developing a Theoretical Framework**

43 According to Pawson and colleagues³⁷, a realist review begins with clarifying the scope of the
44 review and the elicitation of initial rough theories in the form of an initial programme theory
45 (IPT). The IPT can provide a map of the areas to be investigated and gives a structure for data
46 synthesis³⁶. These can be further refined, tested and added to as the synthesis progresses⁴⁰.
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52 **Developing the IPT Framework**

53 For this research, an IPT framework was developed which was a theoretical framework to guide
54 the review. This will be refined as the review progresses in future stages. Further versions of this
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3 will lead to the development of a theoretical framework to guide the findings. Purposeful and
4 iterative searching was undertaken for this first stage of the realist review³⁶. An initial scoping
5 search was undertaken for scale-up and adaptation in healthcare to get an overview of the
6 available literature in the field. There was a large volume returned with many articles discussing
7 the need to adapt for local fit, however without giving guidance for how, why or when to
8 complete this when scaling-up. As a result, a decision was made to particularly focus on
9 guidance and frameworks relating to scale-up, adaptation and fidelity to prioritize identification
10 of what actions could be taken (for example create opportunities for learning, giving guidance to
11 sites etc.) to make adaptations when scaling-up. Guidance and frameworks were identified from
12 the initial scoping search results, in addition to use of reference lists, in particular of recent
13 reviews in the field of implementation and scale-up by Milat et al⁴⁹, Subramanian et al⁵⁰, Nilsen
14 et al⁵¹, and also use of the ExpandNet bibliography. This was complimented by input from the
15 review team (with backgrounds in global health and health systems), and two further experts (in
16 the fields of fidelity and of implementation research) to highlight and direct to any further
17 relevant literature (figure 2). The frameworks included can be seen in supplemental file 1.
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31 **Figure 2. (see legend at end of manuscript)**
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34 The format of the IPT framework to guide this review was informed by Willis and colleagues³⁶
35 realist review, which focused on the process of scale-up of complex interventions, identifying in
36 their initial IPT framework actions, contexts and outcomes. After analysis and synthesis of three
37 case studies they further identified what mechanisms were triggered to achieve scale-up of
38 complex interventions and what contexts influenced this. In light of this method, this study
39 developed an IPT framework focusing on what potential actions, contexts, mechanisms, distal
40 outcomes and proximal outcomes may be of relevance to scale-up and adaptation. A particular
41 focus of this IPT framework was the identification of potential actions (e.g. definition of roles,
42 use of feedback loops etc.), and how these can achieve the outcome of adaptation for local fit.
43 This IPT framework will provide a theoretical map for further exploration in the following
44 stages of the review.
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3 A challenge of developing an IPT framework in a realist review is finding a level of abstraction
4 that allows the recognition of demi-regularities among the detail and variation in the evidence,
5 whilst being specific enough to answer the review question³⁶. The IPT framework went through
6 revisions aiming to keep the actions, contexts, mechanisms and outcomes that were deemed
7 most relevant to adaptation and scale-up, rather than those relating to scale-up in general.
8 Decision making was recorded in the research logbook (see supplemental file 2 for an example
9 from the research logbook). Causation between the potential actions, contexts, mechanisms and
10 outcomes were not made at this stage and will be added iteratively as the review progresses and
11 scope is refined. The contexts were placed under headings adapted from the socio-ecological
12 model⁵² to aid organisation. The IPT framework can be seen in figure 3 (please see supplemental
13 file 1 for the guidance and frameworks identified which informed this).
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24 **Figure 3. (see legend at end of manuscript)**

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27 The IPT framework will assist in; (i) initial coding of actions, contexts, mechanisms and
28 outcomes for data extraction in stage 4, and will inform a codebook for reviewers (while also
29 allowing for new actions, contexts, mechanisms and outcomes to emerge), (ii) providing an
30 initial framework for the synthesis to assist in organisation of the CMOCs and demi-regularities
31 in stage 5 (see figure 1 for outline of stages). As mentioned, coding and synthesis of findings
32 will be guided by this IPT framework, however new actions, contexts, mechanisms and
33 outcomes will be identified from the data and added to this as they emerge. Thus, this review
34 will add to and refine the framework as the stages progress.
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43 **Clarifying the Scope of the Review**

44 As learning progressed it was noted that much guidance and frameworks in the implementation
45 and scale-up literature in health may be untested and largely theoretical in nature. Therefore, the
46 scope of the review was refined to include specific examples of scale-up and adaptation in
47 practice. A focus was placed on the process of scale-up in identifying what actions were used to
48 inform adaptations when scaling-up in real-world settings, and to discover by what mechanisms
49 did these work, and how the context may have influenced this. Decision making while clarifying
50 the scope of the review was documented in the research logbook (see example in supplemental
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3 file 2). The scope of this review may be further refined in an iterative process as the review
4 progresses and will be documented.
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8 The remaining section presents the protocol for stages 2-6, detailing the methods that will be
9 used throughout the remainder of the realist review. An overview of the stages and details can
10 also be seen in figure 4.
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14 15 16 **Stage 2. Search strategy**

17 Stage 2 will involve a search for examples of scale-up and adaptation in practice. Scoping and
18 pilot searches were completed and a librarian was consulted to help inform the selection of
19 databases and search-terms. A systematic search will be completed using the concept headings
20 of; scale-up and context (contextualize, adapt, tailor, redesign etc.). Search terms will be adapted
21 for each database and suggested search terms can be seen in supplemental file 3. Search
22 databases will include: PubMed, CINAHL, Global Indicus Medicus (World Health Organization
23 library including both academic and grey literature), SCOPUS, EMBASE, and Psychinfo. For
24 further grey literature searching, Social Care Institute for excellence (SCIE), Open Grey and
25 GreyLit will be used. Searching of reference lists from identified papers will be carried out along
26 with forward citation searching using Google Scholar. Additionally, the corresponding author
27 from the articles selected will be contacted to identify other articles on their scale-up example
28 that could be relevant to answering the research question.
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45 Further rounds of searches may be completed in later stages of the review in keeping with the
46 iterative nature of realist reviews⁴⁷. This may be to search for further evidence or wider theories
47 that may explain findings and assist in theory refinement. The need for searches, search terms
48 and strategies will be identified as the review progresses. These will be documented in the
49 research logbook, as they occur.
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Stage 3. Study Selection, Criteria and Procedures

Inclusion Criteria

All articles and sources obtained from stage two will subsequently undergo further review for inclusion based on three criteria. To be retained for further review sources must describe; (i) an example of scale-up of a healthcare intervention(s) in practice, (ii) adaptations that were made for health intervention(s) to fit local settings, and (iii) discuss in detail actions for adapting health intervention(s) at scale. For this study, scale-up is defined as a purposeful expansion of a health intervention to a wider population^{1 53}. This could involve expanding geographically or to a wider population within the same setting. Both scale-up at national and sub-national levels will be included once the intervention was being purposefully expanded to a new wider population group in practice. A health intervention will be defined as per the international classification of health interventions⁵⁴ as “an act performed for, with or on behalf of a person or population to assess, improve, maintain, promote or modify health, functioning or health conditions” (paragraph 1). For this study, it will be limited to interventions where the health intervention is aimed at individuals. Adaptations will be defined as deliberate and/or unintended changes to the intervention content, context or training and delivery¹⁵. For inclusion in this study, adaptations need to have occurred during scale-up to adapt for local contexts, and actions used (for example local decision making). Articles discussing the adaptations without describing what actions were used to adapt the intervention will also be excluded. Studies where the adaptations occurred during the RCT or pilot stage, and the same intervention was rolled out nationally (or sub-nationally) without further adaptations to the content, context or delivery, will be excluded. Both positive and negative adaptations may be included. Please see supplemental file 3 for more details.

As scale-up occurs over a long-time period, with an estimated 15 years to reach national scale, no time limit will be placed on evidence⁶. Keeping the time-period open allows for documents published at the beginning of scale-up projects to also be captured in the search. Searches will be carried out in English. Languages will be limited to those spoken by the review team; English, Spanish, Portuguese, and French.

Study Appraisal: Relevance and Rigour

As realist philosophy does not exclude evidence based on type of study, RAMESES guidelines will be applied to assess the relevance and rigour of the studies⁴⁰. As discussed by Pawson⁴¹, useful information can arise from studies which may not be prioritised on a traditional hierarchy of evidence. Each retained evidence or document will be assessed in terms of its relevance to the research question and whether it is rigorous enough to hold value to theory building, testing or refinement. Any exclusions based on these criteria will be documented in the research logbook.

Procedures

Title and abstract screening will be completed. Following this two reviewers will complete full text screening independently, with a third reviewer available to resolve any conflicts should they arise. Depending on the number of documents with examples of scale-up returned, further refinement of the scope of the review may be decided by the review team. This will be documented in the research logbook. For further searches as they arise in an iterative fashion, selection criteria will be decided by the review team and will be based on the ability of studies to further refine theory.

Stage 4. Data extraction

The following data will be extracted from the scale-up examples identified in stage 3; (i) what adaptations were made, (ii) what actions were used to make these adaptations, and (iii) the contexts, mechanisms and outcomes that relate to these actions (in the form of CMOCs). A data extraction form and codebook will be developed from the IPT framework to guide data extraction for each scale-up example (see supplemental files 4 and 5 for draft versions, noting that these will be refined as the review progresses). Where multiple documents relate to the same example of scale-up, these will be combined into one data extraction form for that case example, and the supporting quotes referenced as to which document it originated from.

(i) Adaptations

It has previously been identified that adaptations are often poorly reported in research^{15 30 55 56}.

While some adaptations may reflect small, surface-level changes, others may reflect large deep

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3 structural adaptations. To systematically capture the type of adaptations made, Stirman and
4 colleagues¹⁵ taxonomy of modifications will be used to assist categorisation of adaptations,
5 including what type of adaptations were made, who made them and at what level.
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10 11 (ii) Actions

12 A description of what action(s) was/were carried out to achieve the adaptation(s) will be
13 extracted from the examples to the data extraction form. These may relate to the potential actions
14 identified in the IPT framework and resultant codebook, or may reflect new actions emerging
15 from the data. Any new actions will be categorised and added to the codebook as they emerge
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21 (iii) CMOCs relating to the Actions

22 Contexts, mechanisms and outcomes relating to the actions and adaptations will be extracted.
23 While some CMOCs may relate to the potential actions, contexts, mechanisms and outcomes
24 identified in the IPT framework and resultant codebook, others may reflect new CMOCs
25 emerging from the data. Quotes and descriptions will be taken from the text to support these
26 CMOCs. Abductive reasoning will also be applied for any inferred contexts or mechanisms and
27 the reasoning stated on the data extraction form^{36 44}.
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35 Once the above steps are completed for each case example, an example will be presented to
36 members of the Irish Realist Researcher Group for feedback on the coding procedures to inform
37 refinements of the codebook as needed (supplemental files 4 and 5). Following this, the
38 completed data extraction forms for each case will be reviewed again by the first reviewer using
39 the updated coding procedures. A second reviewer will then take a random sample of 10% of the
40 scale-up case examples for extraction following the same coding procedures using a data
41 extraction form for these case examples. The reviewers will then discuss and compare the
42 CMOCs extracted and reach agreement, if differences occur. Following this, the remaining data
43 extraction forms for all case examples will be reviewed by the second reviewer and agreement
44 reached between reviewers on the CMOCs, including any inferred contexts or mechanisms and
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3 reasoning for the same. A third reviewer will be available for input or to resolve any
4 discrepancies between the first and second reviewer.
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8 9 **Stage 5. Data Synthesis**

10 The findings from each example of scale-up will then be synthesized across cases. The data
11 extraction forms from each case example will be uploaded and coded in NVivo, using the IPT
12 framework and resultant codebook to guide initial codes. New codes will be added or refined as
13 they emerge, thus adding to the theoretical framework as the synthesis progresses.
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20 The type of adaptations made will be synthesized across cases to give a picture of what
21 adaptations are happening in practice. Then the actions used to achieve adaptations will be
22 synthesized. Following this, the CMOCs will be synthesized across cases to look for demi-
23 regularities to assist in theory building of causation by refinement of what actions are used to
24 make adaptations, by what mechanisms to they work, and what contextual factors may influence
25 this. This will be completed in NVivo, with use of the theoretical framework and resultant
26 codebook, with new codes added as they emerge. Demi-regularities with patterns of causal links
27 will be sought, along with variations in the CMOCs. The following conceptual tools may be
28 used as needed to assist in theory refinement^{40 57}; (i) juxtaposing, where evidence from one
29 setting may aid explanation of outcomes from another, (ii) reconciliation, where differences are
30 identified to explain findings which may contradict each other, (iii) adjudication between
31 studies, (iv) consolidation for example by building multiple explanations, and (iv) situating by
32 identifying what may happen in one setting compared to another. Reasoning will be documented
33 in a research logbook.
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51 Abductive reasoning⁴⁴ and retroduction⁴⁵ will be used to guide the review to interpret and
52 explain the findings and put forward contextual conditions that may need to be present for the
53 outcomes to occur. As part of this process, wider substantive theory will be searched for to assist
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3 in explanation of the findings and for further theory refinement⁴⁰. This will lead to the
4 development of theory relating to how adaptations can be made when scaling-up.
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8 9 **Stage 6. Stakeholder Involvement**

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11 Finally, stakeholders with experience of adaptation and scale-up in both research and practice
12 internationally will be sought and contacted to assist in theory refinement. Initial stakeholders
13 will be identified and contacted by the research team. Stakeholders will also be asked to identify
14 further persons in their field of expertise. Initial review findings will be presented to
15 stakeholders and their opinions sought, based on their practical knowledge and expertise³⁸. The
16 resultant theories may be further refined based on learning from this process⁵⁸. This stage may
17 inform further searches as needed in an iterative fashion. A summary of the stages and proposed
18 actions for this realist review can be found in figure 4 below.
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30 **Figure 4. (see legend at end of manuscript)**

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33 The above stages will be carried out as per realist review methodology in an iterative fashion,
34 allowing for refinement of theory and the scope of the review and subsequent searches as
35 learning progresses. Any iterations to the above protocol will be captured in the research
36 logbook and reported in the final dissemination of the research. The above stages set out to
37 achieve the study's objectives of discovering what actions can be used to achieve adaptations
38 when scaling-up health interventions for local fit, by what mechanisms do these actions work,
39 and what contextual factors may influence this. It is hoped this approach will provide practical
40 and useful findings for implementers in the field of scale-up.
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51 **ETHICS AND DISSEMINATION**

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3 Ethical approval for this study was received from the Health Policy and Management and Centre
4 for Global Health Research Ethics Committee of Trinity College Dublin, Ireland in March 2017.
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6 The dissemination of the findings of this review will follow the RAMESES reporting
7 guidelines⁵⁹. The results of this review will be used to put forward theory to explain what and
8 how actions can be used to influence and achieve adaptations when scaling up for local fit. Use
9 of a realist review methodology, with the stages outlined above, allows for an exploration of the
10 complexity of the process of scale-up across diverse contexts, and the identification of the
11 contextual factors that may influence actions, and by what mechanisms these may work. By
12 including stakeholders with experience in the field of adaptation and scale-up, it is hoped this
13 will add to theory development and refinement, and will help ensure that findings have practical
14 utility for implementers. The findings of this study will be published in a peer-reviewed journal,
15 through conference presentations and dissemination through stakeholder involvement in theory
16 refinement. The review will also be published as a PhD thesis, available through Trinity College
17 Dublin library.
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35 **AUTHORS CONTRIBUTIONS:**

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37 JP is lead reviewer completing this study as part of a PhD. JP developed the general study
38 concept and outline. JP completed the literature review and development of the IPT framework
39 and led the iterations. JP developed the search strategy, and methods for selection, appraisal,
40 extraction, synthesis, and stakeholder involvement. BG contributed to IPT framework
41 refinement, the methods for data extraction and coding processes using NVivo, and the methods
42 for synthesizing across cases. FV contributed to the general study concept and design, clarifying
43 the scope of the review and refinement of the IPT framework. ET contributed as an expert in
44 fidelity in stage one and assisted in refinement of the IPT framework. ET contributed to the
45 methods of the search strategy and methods of the data extraction and synthesis stages, including
46 the role of second reviewer. HM contributed to conceptual study design, and clarifying the scope
47 of the review by refinement of research question and IPT framework. EM contributed to
48 conceptual study design, refinement of research question and IPT framework, the search
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3 strategy, refinement of the data extraction form, and contributed to the method of involvement of
4 stakeholders for theory refinement. JP wrote the first draft of the paper, which was reviewed and
5 contributed by all other authors. All authors approved the final version.
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12 review.
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22 training.
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28 **COMPETING INTERESTS STATEMENT:**

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30 The authors declare there are no competing interests.
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34 **Legend for Figures**

35
36 **Figure 1.** Overview of stages of the realist review. Based on Pawson and colleagues³⁷. Adapted
37 from Groot and colleagues⁶⁰ and Molnar and colleagues⁶¹. These stages are non-linear and will
38 be carried out in an iterative fashion with theory refinement occurring throughout.
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43 **Figure 2.** Development of the IPT Framework
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47 **Figure 3.** IPT Framework. Potential actions, contexts, mechanisms and outcomes identified
48 from stage one for further exploration in future phases.
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52 **Figure 4.** Summary of stages and proposed actions for the realist review.
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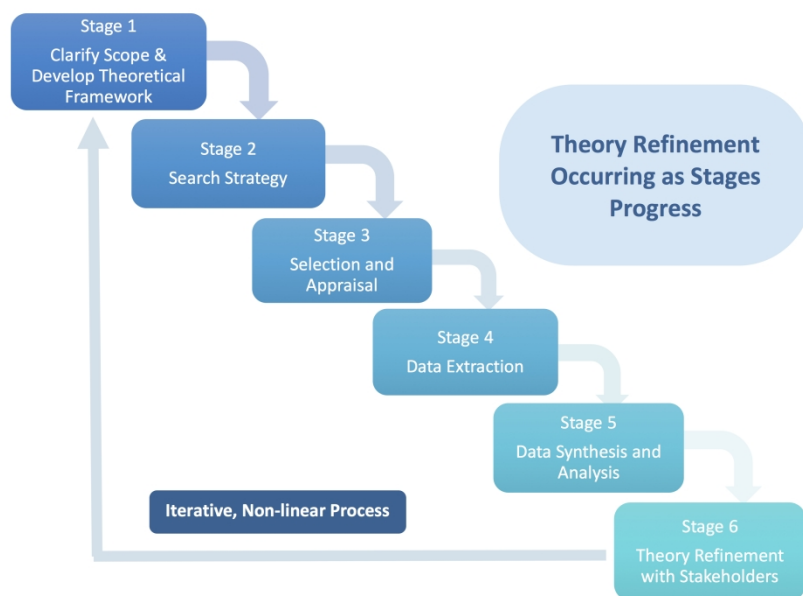


Figure 1. Overview of stages of the realist review. Based on Pawson and colleagues. Adapted from Groot and colleagues and Molnar and colleagues. These stages are non-linear and will be carried out in an iterative fashion with theory refinement occurring throughout.

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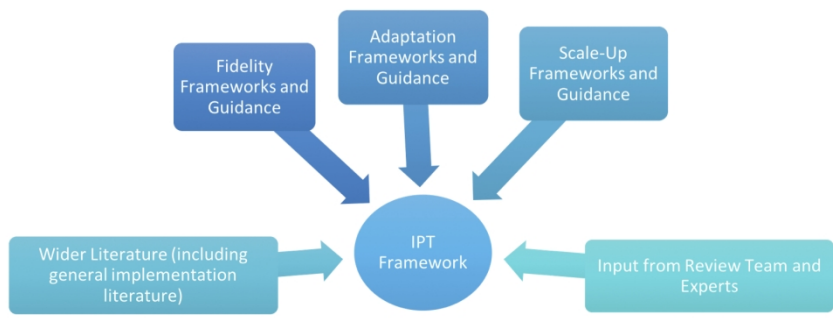


Figure 2. Development of the IPT Framework

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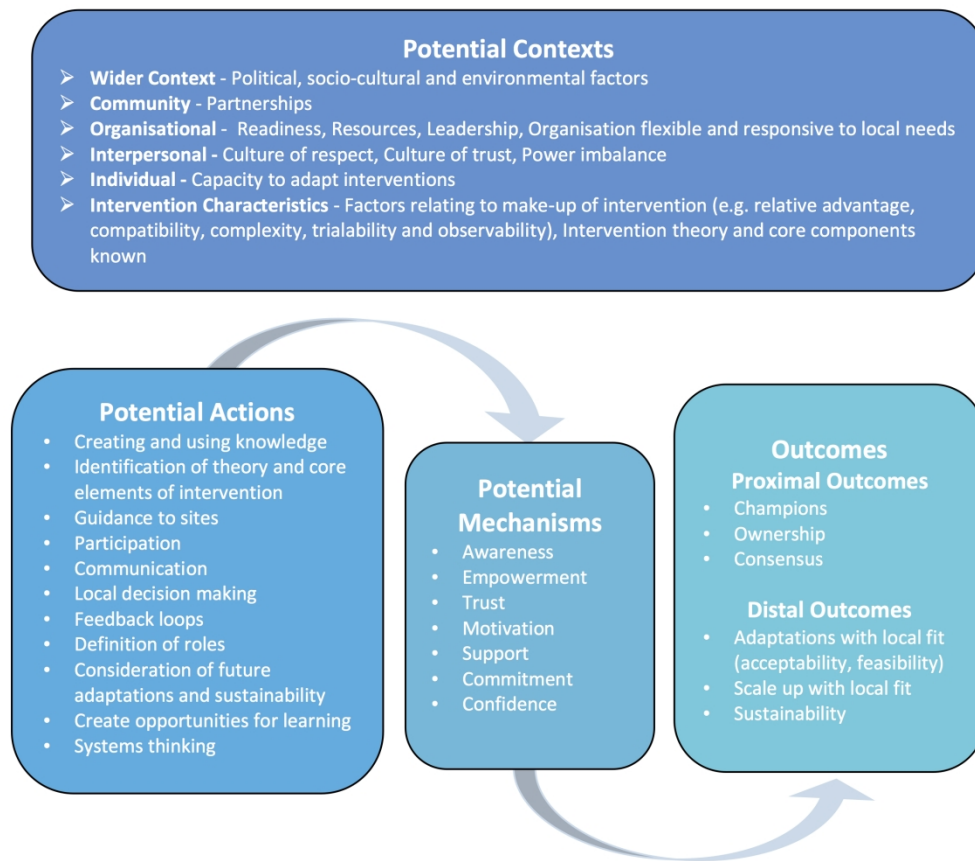


Figure 3. IPT Framework. Potential actions, contexts, mechanisms and outcomes identified from stage one for further exploration in future phases.

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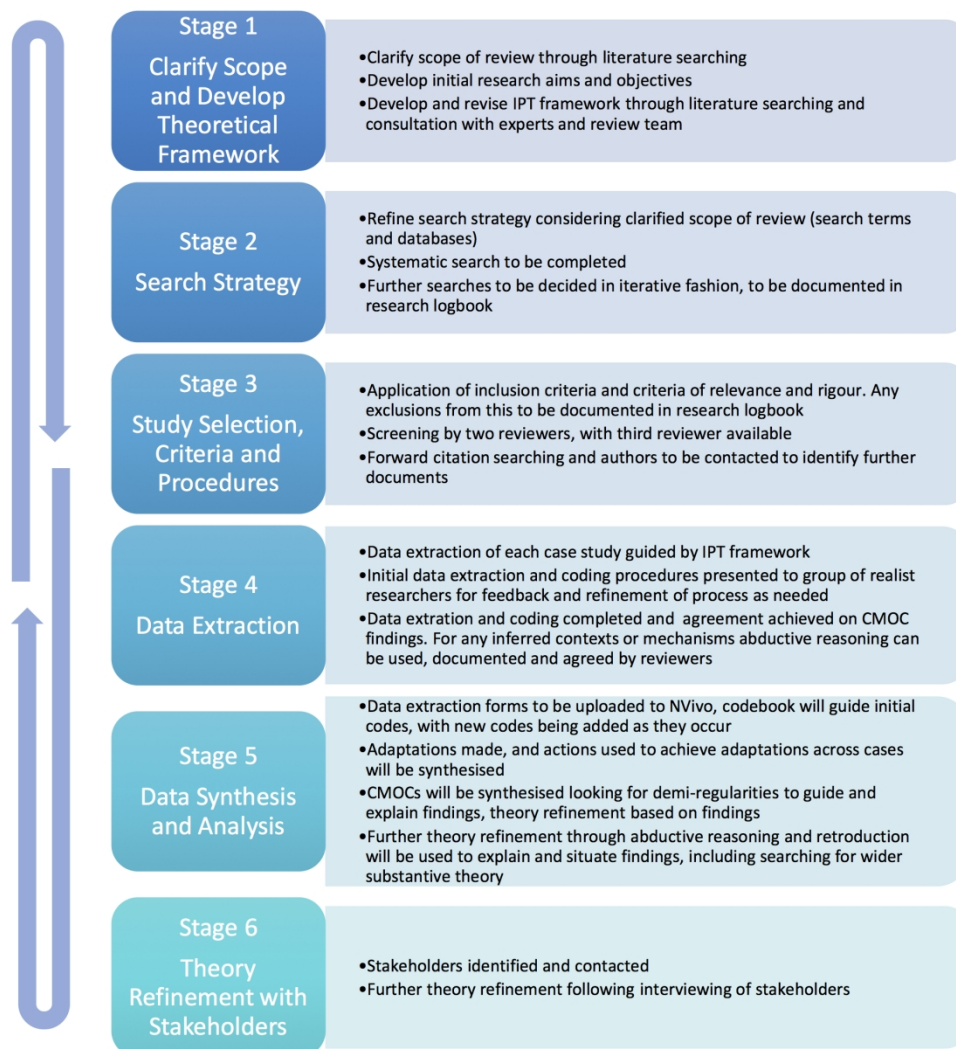


Figure 4. Summary of stages and proposed actions for the realist review.

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Supplemental File 1. Guidance and frameworks identified which assisted in IPT development

Guidance and Frameworks Identified	
Scale-Up	<p>Scale-up frameworks are categorised into; determinant frameworks, process models and evaluative frameworks (depending on their primary focus) as per Nilsen ¹;</p> <p>Determinant frameworks</p> <ul style="list-style-type: none"> • Scaling up health service innovations: a framework for action, ExpandNet^{2,3} • Dynamic Sustainability Framework (DSF)⁴ • A framework for understanding the constraints of scaling up⁵ • Scaling up; A proposed framework for success⁶ • The non-adoption, abandonment, scale-up, spread, and sustainability (NASSS) for patient facing health and care technologies⁷ • The learning process approach⁸ • Conceptual framework for priority setting in health⁹ <p>Process Models</p> <ul style="list-style-type: none"> • Scaling up Management (SUM) Framework¹⁰, updated by¹¹ • Practical guidance for scaling up health service innovations, ExpandNet¹² • Nine steps for delivering a scale up strategy, ExpandNet¹³ • Beginning with the end in mind, ExpandNet¹⁴ • SEED Scale¹⁵ • A guide to scaling up population health interventions¹⁶ • IHI framework for going to full scale¹⁷ • A guide to fostering change to scale up effective health services¹⁸ • AIDED model for dissemination, diffusion and scale up of family health innovations in LICs¹⁹ • Program assessment guide for scaling up nutrition interventions²⁰ • Scaling up breastfeeding²¹ • MuSCL framework²² <p>Evaluative Frameworks</p> <ul style="list-style-type: none"> • Scaling out²³ <p>Not specific to scale-up but highlighted to be of relevance to implementation and adapting for local context were;</p> <ul style="list-style-type: none"> • Consolidated Framework For Implementation Research (CFIR)^{24,25} • Promoting Action on Research Implementation (PARIHS) Framework²⁶ • Integrated i-PARIHS Framework²⁷ • Knowledge to action framework²⁸ • Implementation Research (IR) Toolkit²⁹ • Taxonomy of implementation outcomes³⁰ • RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) Framework^{31,32} • Methods to Improve the Selection and Tailoring of Implementation Strategies³³

Adaptation	<ul style="list-style-type: none"> • Elements to consider in cultural programme adaptation³⁴ • Finding the balance program fidelity and adaptation in substance abuse prevention³⁵ • Key principles for adapting research based interventions in HIV³⁶ • Intervention mapping to adapt an effective HIV, sexually transmitted disease, and pregnancy prevention programs³⁷ • ADAPT MAP draft guidance for adapting HIV interventions³⁸ • ADAPT-ITT model for adapting EBI for HIV³⁹ • Replicating effective programs (REP) framework⁴⁰ • ADAPTE guidelines⁴¹
Fidelity (including Intervention Development and Testing)	<ul style="list-style-type: none"> • Bauman's parameters for consideration in intervention development⁴² • The conceptual framework for adaptive interventions⁴³ • NIH Behaviour Change Consortium (BCC) fidelity concepts⁴⁴ • Comprehensive intervention fidelity guide⁴⁵ • Carroll's conceptual framework for implementation fidelity⁴⁶ • Hasson's modified conceptual framework for implementation fidelity⁴⁷ • The modified Carroll's fidelity framework⁴⁸ • Fidelity variation concepts from ASSIST RCT⁴⁹ • Figuring out fidelity⁵⁰ • Contextualised Interventions⁵¹ • Medical Research Council (MRC) guidance for process evaluations⁵² • The conceptual model for translating evidence based Interventions into community Settings⁵³ • Template for Intervention Description and Replication (TIDieR) guidance⁵⁴ • RE-AIM framework^{31 32}
Some examples from the wider literature (including general implementation literature and theories)	<p>Some examples of wider literature used to also inform IPT Framework (please note this is not comprehensive and all wider literature is referenced in the full research logbook available on request);</p> <ul style="list-style-type: none"> • Mechanisms for scale-up by Willis and colleagues⁵⁵ and large system transformation in healthcare by Best and colleagues⁵⁶ • Barriers and facilitators to scale-up, Norton and Mittman⁵⁷ • Diffusions of innovation theory, Rogers⁵⁸ • Complex adaptive systems theory, Paina and colleagues⁵⁹

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Supplemental File 2. Examples from Research Logbook for Recording Decision Making

1. Example from Research Logbook of Decision Making for Clarifying Scope of Review

Source: Fidelity, adaptation and scale-up literature from stage 1	Thought process, decision making	Clarified Scope
Adaptation guidance and frameworks mainly from high income country contexts, with a focus on HIV and substance abuse prevention. Many contain a resource heavy and highly skilled process, with some involving research institutional partnerships and intervention developers.	These may not be feasible at scale, need to learn from what is happening in practice during scale-up and adaptations.	Decision to focus on examples of scale-up in practice for stage two.
Despite recognition of the need to adapt, there is a lack of clear guidance in scale-up literature and frameworks on what actions to take when adapting for local fit.	Unable to refine question to a specific action or actions for adapting when scaling-up. Decision to keep scope of review broad at this stage to capture any actions that were reported in the examples in practice. This allows for the benefit of identifying what any and all actions that are being used in practice when scaling-up. The scope of the review could be further refined after discovery of this.	Decision to keep scope of review broad at this stage to capture <u>any actions</u> that were reported when adapting during scale up in the examples.

2. Example from Research Logbook of Decision Making for IPT framework

Source: Wider Literature Search (including general implementation literature)	Thought process, decision making	Inclusion in IPT Framework
<ul style="list-style-type: none"> Funding and power imbalance, funding available for specific evidence based Interventions¹, choosing intervention based on funding² Power dynamics influencing whether people could meaningfully participate (e.g. male dominance)³ Scale free networks, power imbalance and influence⁴ 	<p>Power dynamics came up in the general implementation literature in addition to the within the scale-up frameworks.</p> <p>This was discussed in relation to funders and a potential top down power imbalance leading to selection of certain interventions or adaptations based on available funding. It was also discussed in relation to being able to meaningfully participate being limited by power dynamics within a community. Complex adaptive systems theory also speaks of scale free networks which could relate to certain people within networks being particularly influential or powerful.</p>	As a result, “power imbalance” was included in the IPT under contexts.

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Supplemental File 3. Suggested Search Terms and Databases, Inclusion Criteria for Stage Two.

Suggested Search Terms and Databases for Stage Two.

Database	Search Terms
Pubmed	(context[Title/Abstract] OR contextualization[Title/abstract] OR contextualization[Title/abstract] OR contextualise[Title/Abstract] OR contextualize[Title/Abstract] OR Culture[Mesh] OR Adapt[Title/Abstract] OR redesign[Title/Abstract] OR re-design[Title/Abstract] OR tailor[title/abstract] OR tailoring[title/abstract] OR "Community Health Planning"[Mesh]) AND ("scaling up"[Title/Abstract] OR "scale up"[Title/Abstract] OR "scale-up"[Title/Abstract] OR "scaling-up"[Title/Abstract])
Cinahl	("scale up" OR "scaling up" OR "scale-up" OR "scaling-up") AND (Context OR contextualise OR contextualize OR contextualisation OR contextualization OR Culture (MM) OR Adapt OR Design OR redesign OR re-design OR Tailor OR tailoring OR tailored)
Global Indicus Medicus	"scale-up" OR "scaling-up" OR "scale up" OR "scaling up" excluding medline (as will have already been searched). Includes; WHOLIS, IMSEAR (SEARO), LILACS, WPRIM, IMEMR, AIM.
SCOPUS	((TITLE-ABS-KEY ("scale up") OR TITLE-ABS-KEY ("scaling up") OR TITLE-ABS-KEY ("scale-up") OR TITLE-ABS-KEY ("scaling up"))) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal OR mult OR arts OR busi OR deci OR econ OR psyc OR soci)) AND ((TITLE (context) OR TITLE-ABS-KEY (contextualise) OR TITLE-ABS-KEY(contextualize) OR TITLE-ABS-KEY (contextualisation) OR TITLE-ABS-KEY(contextualization) OR TITLE-ABS-KEY (adapt) OR TITLE (design) OR TITLE-ABS-KEY (redesign) OR TITLE-ABS-KEY (re-design) OR TITLE-ABS-KEY (tailor) OR TITLE-ABS-KEY (tailored) OR TITLE-ABS-KEY (tailoring)) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal OR mult OR arts OR busi OR deci OR econ OR psyc OR soci))
Web of Science	("scale up" OR "scaling up" OR "scale-up" OR "scaling-up") Refined by: TOPIC: (*context* OR adapt OR redesign OR *tailor*) Social sciences arts and humanities (no science technology).
EMBASE	'scale up' OR 'scaling up' OR 'scale-up' OR 'scaling-up' AND (context OR contextualise OR contextualize OR contextualisation OR contextualization OR adapt OR redesign OR 're design' OR tailor OR tailoring) AND [embase]/lim
Psycinfo	((Context OR contextualise OR contextualize OR contextualisation OR contextualization OR Adapt OR Design OR redesign OR re-design OR Tailor OR tailoring OR tailored OR AND (Context OR contextualise OR contextualize OR contextualisation OR contextualization OR Culture (MM) OR Adapt OR Design OR redesign OR re-design OR Tailor OR tailoring OR tailored OR MJ Culture)) AND ("scale up" OR "scaling up" OR "scale-up" OR "scaling-up"))
Grey Lit	"Scale up" OR "scaling up" OR "scale-up" OR "scaling-up"
Social Care Online (SCIE)	"Scale up" OR "scaling up" OR "scale-up" OR "scaling-up"
Open Grey	("Scale up" OR "scaling up" OR "scale-up" OR "scaling-up" OR "scale-up") AND health

Suggested Inclusion and Exclusion Criteria for Stage 2

In order to be incorporated in this phase of the synthesis the evidence needed to meet the following three inclusion criteria;

1. Be a case example of scale up of a healthcare intervention(s)

Scale up was defined as a purposeful expansion of a health intervention to a wider population^{1,2}. This could involve expanding geographically or to a wider population within the same setting. Both scale up at national and sub-national levels were included once the intervention was being purposefully expanded to a new wider population group. If an article or study was not based on a real-world case example but put forward guidance, framework or aspirational steps these were excluded.

A health intervention was defined as “an act performed for, with or on behalf of a person or population to assess, improve, maintain, promote or modify health, functioning or health conditions”³. For this study, it was limited it to interventions where the direct target was the individual. An example of this would be provision of nutritional supplements, vaccines or medication (e.g. vitamin A, polio vaccine etc.) and/or educational or behaviour change interventions directly delivered to the individual (e.g. breastfeeding education, safe sex promotion etc.). If the primary intervention was capacity building of HRH which may have future impacts on health this was considered indirect and not included. As scale up often occurs as a package of interventions, case examples of this were included if a specific direct health intervention was identified as a primary part of this package. Where case studies were general service delivery for example provision of mental health services at scale but did not specify a specific health intervention these were excluded.

2. Adaptations were made for health intervention(s) to fit local settings

Adaptations were defined as “deliberate and/or unintended changes to the intervention content, context or training and delivery”. For inclusion in this study these adaptations need to have occurred during scale up to adapt for local contexts. If the adaptations occurred during the RCT or pilot stage and the same intervention was rolled out nationally (or sub-nationally) without further adaptations to the content, context or delivery these were excluded.

3. Discusses in detail action(s) for modifying health intervention(s) at scale

Actions used to make adaptations needed to be explained in detail. In detail meant to give sufficient information to be relevant to answering the research question(s) using criteria of relevance and rigour below. If the article discussed the adaptation without discussing what process was used it was excluded.

Time limit: No time limit will be placed on evidence as it was noted that scale-up occurs over a long time period with an estimated 15 years to reach national scale ⁴.

Language: Searches will be carried out in English. Languages will be limited to those spoken by the review team; English, Spanish, Portuguese and French.

Relevance and Rigour

As realist philosophy does not exclude evidence based on type of study, the criteria of relevance and rigour will be used for further appraisal as per RAMESES guidance⁵. For exploring examples of scale-up and adaptation in practice it was felt that evidence may come from a variety of sources including grey literature. Therefore, the relevance of the piece of evidence to the research question and whether the evidence or document was rigorous enough to hold value to theory building, testing or refinement will be analysed. Any exclusions and reasoning from these criteria of relevance and rigour will be recorded in a research logbook.

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3 **Supplemental File 4. Draft Data Extraction Form (to be further refined as needed)**
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5 **Scale-up example (location, intervention):**

6 **References of articles/documents included:**

7 **Details of Intervention:**

8 **Topic (e.g. nutrition, HIV):**

9 **Study Type(s):**

10 **Summary (short description of case example of scale-up):**
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13 **1. Adaptations** (Please see codebook for further descriptions as needed)

14 **What adaptations were made and to what elements?** (give details where discussed)

15 **(i) Content** (e.g. changes to intervention procedure, materials or delivery):
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18 **(ii) Context** (e.g. changing the delivery channel, format, setting, personnel, population):
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20 **(iii) Training/Evaluation** (e.g. longer/shorter training, style of training etc.):
21

22 **At what level was the adaptation made?** (where discussed, refer to codebook as needed)
23

24 **Who made decision to adapt?** (where discussed, refer to codebook as needed)
25

26 **Why decision to adapt?** (where discussed)
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28

29 **2. Actions**

30 **Actions for Adaptations** (please list with short descriptions of what was carried out, refer to
31 codebook as needed):
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33

34 **3. Context-Mechanism-Outcomes (CMOCs)**

35 Please provide details of CMOCs identified below relating to actions for adaptations, please provide
36 quotes to support and any reasoning for any inferred contexts or mechanisms, refer to codebook as
37 needed.
38
39

40 **CMOC 1.**

41 Action (mechanism resource):

42 Context:

43 Mechanism (reasoning or response):

44 Outcome:

45 CMOC:

46 Supporting quotes or reasoning:
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48

49 **CMOC 2.**

50 Action (mechanism resource):

51 Context:

52 Mechanism (reasoning or response):

53 Outcome:

54 CMOC:

55 Supporting quotes or reasoning:
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58 **Please add as many as needed below e.g. CMOC 3, CMOC 4**
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Supplemental File 5. Draft Data Extraction Guidance and Sample Codebook (to be further refined as per protocol)

Adaptations definition and coding (based on Stirman and colleagues taxonomy of modifications¹)	
<p>Notes: Headings and description for the taxonomy of modifications below. If any of these are not stated to mark as such on the data extraction form.</p> <ul style="list-style-type: none"> • Firstly, to identify and briefly state what adaptation was made and whether it was to the content, context of training/evaluation. If the adaptation was to the content, this can be further classified under the 12 suggested headings if applicable. If not to mark as “other” • Secondly to identify where stated at what level the adaptation was made (e.g. at individual recipient level or community level) using the seven suggested headings or the other category • Thirdly to capture who made the decision to adapt where stated • Finally, if the reason was given for why adaptation was needed 	
Adaptations	Deliberate and/or unintended changes to the intervention content, context or training and delivery
Adaptations to Content	<p>Changes to intervention procedure, materials or delivery.</p> <p>These can be further classified as (note as many as apply on data extraction form);</p> <ol style="list-style-type: none"> 1. Tailoring, tweaking, refining - minor change, leaves all major principles in place e.g. modifying language 2. Adding elements - consistent with fundamentals of intervention 3. Removing elements - e.g. those that are culturally not appropriate 4. Shortening, condensing (pacing/timing) - shorter amount of time or no of sessions 5. Lengthening, extending (pacing/timing) 6. Substituting elements - a module or activity is replaced with another (e.g. condom application replaced with abstinence talk) 7. Re-ordering elements 8. Integrating another approach - intervention used as starting point but other techniques added 9. Integrating prevention into another approach - starting with another approach, but intervention added in 10. Repeating elements 11. Loosening structure - flexibility with programme/process e.g. opening and closing, layout can be different 12. Departing from the intervention (drift) - Intervention no longer used in given situations <p>Other (Give details)</p>
Adaptations to Context	Changing the delivery channel, format, setting, personnel, population etc.
Adaptations to Training/Evaluation	Longer/shorter training, style of training etc.
At what level was the adaptation made	<p>This can be classified as (please note as many as apply on data extraction form);</p> <ol style="list-style-type: none"> 1. Individual recipient e.g. changed for a person's needed e.g. literacy, hearing, physicality

	<p>2. Cohort level - for individuals grouped within a setting</p> <p>3. Population level - Intervention modified for cultural, ethnic, social groups</p> <p>4. Provider/facilitator level - modified for all of a certain practitioners clients</p> <p>5. Unit level - modified for all in that unit e.g. clinic, department</p> <p>6. Hospital/Organization level - entire organisation</p> <p>7. Networks/Community Level - entire networks or systems (e.g. all hospitals, facilities)</p> <p>Other (Give details)</p>
Who made decision to adapt	Please state where present (e.g. individual practitioner, team, non-programme staff, administration, programme developer, researcher, coalition of stakeholders, other)
Why decision to adapt	Please state where present (e.g. feasibility, acceptability)

Definitions of Actions, Contexts, Mechanisms, Outcomes and CMOCs	
Actions	<p>Mechanisms are often seen as the integral link between the context and the outcome². They uncover the “why” a given outcome may have occurred. Dalkin and colleagues³ conceptualised mechanisms as either resources or reasoning. They put forward that resources are introduced in a context, which trigger a response, which results in an outcome.</p> <p>For this research, we viewed actions used to make adaptations when scaling-up as a mechanism in the form of a resource. Actions can be acts, processes or interventions used to make, guide or support adaptations when scaling up. For example, generation of evidence which informs adaptations or participation of stakeholders. These under the right contextual conditions may fire a mechanism in the form or reasoning or response, for example awareness or commitment, which in turn may generate the outcome of interest.</p> <p>Actions may be captured twice.</p> <ul style="list-style-type: none"> • Firstly, to identify what actions were used and give a brief description (heading 2 in data extraction form). Please do not limit to actions only in the IPT and allow new actions to emerge from the data also. • Secondly, if there is a CMOC associated with that action it will be captured under the CMOC heading below (heading 3 on data extraction form). Note not all actions may have CMOCs related to them.
Contexts	<p>Contexts relate to conditions that affect mechanisms and therefore outcomes. A context can act like a dimmer switch for the triggering of mechanism to varying degrees³. Pawson and Tilley⁴ note context “<i>may not only relate to place but also to systems of interpersonal and social relationships, and even to biology, technology, economic conditions</i>”^{p8}.</p>

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Mechanisms	For this research actions were seen as a “resource”, and resulting mechanisms were the “reasoning” or response. For coding as a mechanism, it would be a response to a given action. Mechanisms in the form of reasoning are often hidden and unseen, for example awareness or commitment.
Outcomes	Outcomes can be intended or unintended consequences from actions or interventions in given context. They can be positive or negative. For this research outcomes can be proximal or distal. With distal outcomes relating to the overall aim for example adaptations with local fit or sustainability as reported by the evidence, and proximal outcomes relating to those that may occur prior to this for example ownership of intervention or consensus for adaptations.
CMOC	Context-mechanism-outcome-configuration. This is the combination of the action, context, mechanism and outcome together. This may be presented as a narrative sentence which describes the CMO combination. For example, when XX is carried out in the context of XX, this caused a response of XX which led to outcome XX.

Potential Actions, Contexts, Mechanism and Outcomes identified from the IPT framework below		
Notes: Please do not limit data extraction to these codes, allow new codes to emerge as they appear in the data, or more detailed codes and categorization of below as needed.		
Additionally, what is categorised as an action, context, mechanism or outcome in one instance may be categorised under another heading in another CMOC depending on the configuration. For example, ownership may be an outcome in one CMOC and a context in another. Please categorize under whichever heading is appropriate for the CMOC. Reasoning can be documented as needed.		
Potential Actions	Creating and using knowledge	The creation of knowledge e.g. through evaluation, local knowledge, continual assessment mechanisms and/or the use of existing knowledge e.g. local data, real time data, routine data, evidence for intervention
	Identification of theory and core elements of intervention	The identification of theory or core elements/components of the intervention. This could involve purposeful selection of an intervention where these are known or seeking out this information for the selected intervention
	Guidance to sites	Providing guidance to local sites on intervention theory or core elements, or on how to adapt intervention
	Participation	Participation / engagement of; service users, providers, community, local organisational or government HR. This could be through various activities for example; consultations, partnerships, CBPR, local decision making
	Communication	Communication between individuals or at organisational levels
	Local decision making	Involvement of; local service users, providers, community, local organisational or government HR for decision making for adaptations. Autonomy given to local level for adaptations

	Feedback loops	Feedback loops or mechanisms in place to guide decision making for adaptations this could involve monitoring and evaluation at time points, planned consultations etc.
	Definition of roles	The transparent clarification and definition of roles and responsibilities for adaptation during scale-up
	Consideration of future adaptations and sustainability	Consideration of future adaptations and sustainability and actions planned to allow for this. This includes recognition of contexts changing overtime and actions planned to allow for this
	Create opportunities for learning	Creating opportunities for learning is purposeful activities that could assist in learning for implementers, organisational staff, the community or service users. It could relate to building capacity to complete adaptations, or learning of the context, adaptations or strategies used to address local fit. This could be formal e.g. through learning networks, or informal e.g. arranged through social networks
	Systems thinking	Systems thinking applies to an in-depth consideration of the complex links, relationships, inter-dependencies within a system. This may be difficult to capture however if an example reports use of systems thinking or describes this process it can be included as this
	Further actions to be added as identified	
Potential Contexts	Wider context	
	Political, socio-cultural and environmental factors	This is a broad heading that can capture elements of the wider system e.g. political, economic, environment that influence whether a mechanism fires. This heading will be added to and refined and learning progresses
	Community	
	Partnerships	This could be between community and an organisation. This could include the nature of the partnerships in terms of history and trust for example
	Organisational	
	Readiness	Where the organisation (or community) are ready for intervention and implementation, for example with resources, capacity in place, community sensitized to intervention, buy in for intervention exists etc. This could also capture a lack of readiness or rushing to scale
	Resources	Resources or lack of resources such as; financial, logistical or human resource availability
	Leadership	This could relate to strong leadership, or a lack of leadership which may influence adaptation and scale-up
	Organisation flexible and responsiveness to local needs	Organisation flexible and responsiveness to local needs. This could relate to where the organisation is open to receiving and acting on feedback
	Interpersonal Relationships	

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	Culture of respect	Culture of respect between individuals, or within an organisation. This could include placing value on the knowledge and opinions of those in the local setting
	Culture of trust	Culture of trust between individuals, or within an organisation. This could also relate to a history or relationship of trust built over time.
	Power imbalance	Power imbalance between individuals or organisations. This could relate to a power imbalance within a community setting limiting individual’s participation, or could relate to top-down/bottom-up power imbalance between funders and an organisation, or between different levels of the health system
	Individual	
	Capacity to adapt interventions	Capacity to carry out actions needed to adapt and/or implement interventions
	Intervention characteristics	
	Factors relating to make up of the intervention	For example; relative advantage, compatibility, complexity, trialability and observability. This could also include whether the intervention was simple or complex
	Intervention theory and core components known	Theory and core components of intervention known and available to sites
	Further contexts to be added as identified	
Potential Mechanisms	Awareness	“Knowledge or perception of a situation or fact” ⁵ . This could relate to the local context, the need to adapt, the intervention itself or the scale-up or adaptation process
	Empowerment	The process of becoming more powerful or confident in the ability to do something ⁵ . This can include authority or power given to someone to do something
	Trust	“Firm belief in the reliability, truth, or ability of someone or something” ⁵ . Trust could relate to the intervention itself, the scale-up or adaptation process or trust between actors e.g. service users, organisation, implementers etc.
	Motivation	Intrinsic or extrinsic motivation towards the intervention, its adaptation or scale-up. Motivation is an internal process that may cause a desire or willingness ⁵ towards something this is not seen, however relating actions could be
	Support	This may capture support from an individual, community or organisation. They may approve of or encourage the intervention, the adaptation or scale-up process. This may also capture the concept of buy-in
	Commitment	“The state or quality of being dedicated to a cause, activity, etc.” ⁵ . This could relate to a commitment to the problem (e.g. addressing the health problem), the intervention, adaptation or scale-up process. This differs from support as it relates to dedication or engagement and so it is more active than support alone

	Confidence	“The feeling or belief that one can have faith in or rely on someone or something.” ⁵ . Confidence relates more to self-assurance ⁶ or certainty in an ability of oneself or others. This could be confidence in the ability to adapt or implement the intervention, in the intervention itself or of other people’s ability to complete actions or goals for scale-up
	Further mechanisms to be added as identified	
Outcomes (Proximal)	Champions	Champions who support, encourage, commit to or drive the intervention and/or scale-up or adaptation process
	Ownership	A feeling or sense of ownership of the intervention and/or scale-up or adaptation process by an individual, community or organisation
	Consensus	Shared agreement or vision on the intervention, adaptation or elements of scale-up process
Outcomes (Distal)	Adaptations with local fit (acceptability, feasibility)	Adaptations made which are acceptable and/or feasible in local settings. This could be demonstrated by demand for intervention by service users, or where Interventions match local needs and resources
	Scale up with local fit	Intervention is scaled-up across sites with local fit where intervention is acceptable and/or feasible
	Sustainability	Intervention is continued to be delivered at sites or the outcome of the intervention is sustained at sites over a time. This intervention may be continually adapted and does not need to remain the same
	Further outcomes to be added as identified	

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Adapting Health Interventions for Local Fit when Scaling-up: A Realist Review Protocol

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3 **TITLE:** Adapting Health Interventions for Local Fit when Scaling-up: A Realist Review
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45 **DISCLAIMER:** The authors put forward the views expressed in the submitted article are our
46 own and not an official position of the institution or funder.
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53 **KEYWORDS:** Scale-up, adaptation, fidelity, realist synthesis, realist review
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ABSTRACT:

Introduction: Scaling-up is essential to ensure universal access of effective health interventions. Scaling-up is a complex process, which occurs across diverse systems and contexts with no one-size-fits-all approach. To date, little attention has been paid to the process of scaling-up in how to make adaptations for local fit. The aim of this research is to develop theory on what actions can be used to make adaptations to health interventions for local fit when scaling-up across diverse contexts that has practical application for implementers involved in scaling-up.

Methods and Analysis: Given the complexity of this subject, a realist review methodology was selected. Specifically, realist review emphasizes an iterative, non-linear process, whereby the review is refined as it progresses. The identification of how the context may activate mechanisms to achieve outcomes is used to generate theories on what works for whom in what circumstances. This protocol will describe the first completed stage of development of an initial programme theory framework which identified potential actions, contexts, mechanisms and outcomes that could be used to make adaptations when scaling-up. It will then outline the methods for future stages of the review which will focus on identifying case examples of scale-up and adaptation in practice. This review is based on Pawson's five stages; (i) clarifying scope and development of a theoretical framework, (ii) developing a search strategy, (iii) selection and appraisal, (iv) data extraction and (v) data synthesis and analysis. With the additional stage of further theory refinement with stakeholders.

Ethics and Dissemination: This review will develop theory on how adaptations can be made when scaling-up. Findings will be disseminated in a peer-reviewed journal and through stakeholder engagement as part of the research process. Ethical approval has been received through Health Policy and Management/Centre for Global Health Research Ethics Committee of Trinity College Dublin.

Abstract Word Count: 299

STRENGTHS AND LIMITATIONS OF THIS STUDY:

- The use of a realist review approach will allow for the exploration of the complexity of scale-up and adaptation in practice.

- We present an initial programme theory framework which identifies potential actions, contexts, mechanisms and outcomes that may influence scale-up and adaptation which is based on peer-reviewed literature and frameworks in the fields of fidelity, adaptation and scale-up.
- This protocol provides a detailed account of proposed methods for a realist review, including the supplemental files of a research logbook, coding and synthesis procedures, which may assist future researchers in options for approaches that can be taken and for addressing the issue of decision making and transparency for realist reviews.
- This study will utilise the inclusion of stakeholders for theory refinement in the later stages of the review, ensuring practicality of findings and dissemination through the review process.
- The scope of this review is ambitious within the time-frame, however in keeping with realist reviews this may be further refined throughout the stages in light of findings from the literature or by stakeholder consultation.

INTRODUCTION:

The process of scaling-up an effective health intervention is complex and occurs across diverse systems and contexts^{1 2}. It is estimated that only 14% of healthcare research makes it into real world settings^{3 4}. Therefore, many existing health problems could be addressed through scaling-up of interventions already known to be effective. For example, it is estimated that 85% of childhood deaths could be avoided in low and middle income countries through scale-up of existing health interventions like zinc and oral rehydration therapy treatment⁵. Currently scale-up has been estimated to take 15 years from pilot to national scale⁶. Scale-up is time consuming and challenging due to the complexity of implementing across diverse contexts where the population⁷, finances, resources and capacity⁸ may differ. The result is a growing discussion on the need to provide more evidence for how to address this important research-to-practice gap.

Scale-up, Adaptation and Fidelity

Scale-up can be defined as a purposeful expansion of a health intervention to a wider population^{1 9}. This could involve expanding geographically, or to a wider population within the same setting. Adaptations can be defined as deliberate and/or unintended changes to the intervention content,

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3 context or training and delivery¹⁰. As per the international classification of health interventions¹¹
4 , a health intervention can be defined as “*an act performed for, with or on behalf of a person or*
5 *population to assess, improve, maintain, promote or modify health, functioning or health*
6 *conditions*” (paragraph 1). When scaling-up it can be necessary to adapt for local contexts as
7 needs and resources may differ between scale-up sites^{7 12}. Adaptation has been seen as an
8 essential process to match community needs, organisation resources and to gain trust and
9 ownership by community¹³. By addressing and adapting for local fit, it can assist in successful
10 implementation and sustainability of an intervention¹². However, with adaptations there is also a
11 need to ensure fidelity to the intervention theory and essential components to ensure the
12 effectiveness of an intervention is not reduced or lost⁷.

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15 Fidelity has been described by Castro and colleagues¹⁴ as delivering the programme as intended
16 and tested, however they also noted there may often be a need to adapt to the target population¹⁴.
17 Fidelity can often be seen as a top-down (researcher, intervention developer) driven approach
18 and adaptation has been viewed as more of a community driven bottom-up approach (frontline
19 service providers, communities, individuals)¹⁵. However, when looking at fidelity it is
20 impossible to ignore potential necessary adaptations for local needs, and when looking at
21 adaptation to ignore how to maintain fidelity to the original intervention. With both proposed as
22 necessary when scaling-up across diverse populations and delivery systems⁷. In considering
23 fidelity it is suggested that any adaptations retain the underlying intervention theory and that the
24 essential components or active ingredients remain intact, with any changes made to match the
25 unique features of the setting^{13 15 16}. This opinion was shared by Aarons and colleagues⁷ in
26 relation to scale-up, and Chambers and colleagues¹² in relation to sustainability, where
27 identification of theory and essential elements of the intervention can facilitate adaptation
28 outside of these, and assist in avoiding a “voltage drop”¹², or the tendency for effectiveness to
29 taper with ongoing implementation.

30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 **The Need for Adaptation when Scaling-up**

51 Within complex systems, such as healthcare, applying a single approach in all settings is
52 unlikely to be effective, as it does not take into account the complex contextual environment
53 within which the intervention takes place¹⁷. Therefore, adaptations are important in terms of
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3 ensuring that the intervention content, context, and/or delivery strategy fits with local needs
4 across scale-up sites¹⁰. A tradeoff may need to occur between increasing scale and adapting to
5 maintain local values, local relevance, quality and sustainability¹⁸. Additionally, and given that
6 contexts are continually changing over time, allowing for adaptations with contextual changes is
7 needed to ensure sustainability of interventions¹². Specifically, adaptation has the potential to
8 enable implementers to match the needs of a more heterogeneous population; to simplify a
9 complex intervention; to focus on a specific problem or to expand to address multiple problems;
10 to increase ownership of an intervention; to adjust to a lack of available resources or
11 requirements made by agencies or funders; allow for additional applications of an intervention
12 and/or address a lack of knowledge of the intervention¹³. It is important to note that adaptations
13 may be intended or unintended^{10 19}, and may be positive or negative²⁰. With positive adaptations
14 supporting implementation and achieving desired clinical outcomes, while negative adaptations
15 could potential hinder or reduce these. Holliday and colleagues²⁰ put forward in the design and
16 testing of an educational intervention, that adaptations can be on a spectrum from acceptable to
17 unacceptable, and avoidable to unavoidable. Thus, some adaptations may be unavoidable for
18 local fit, however are acceptable as they maintain the intervention theory and essential
19 components. While others may be unacceptable as they change the underlying theory and
20 essential components, or avoidable in that they may not necessarily need to be adapted within
21 that setting.
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38 Although adaptation has been highlighted as a key contributing factor in addressing feasibility
39 and/or acceptability for local settings when scaling-up^{7 12}, adaptation is rarely documented as
40 part of the scale-up process^{1 21 22}. Often efforts to achieve scale-up can focus on the replication of
41 the originally tested pilot or feasibility study. Replication however, does not account for the
42 diverse social, political, and cultural contexts across scale-up sites. This results in a need for
43 more tailored approaches²³. There is a need to understand how an intervention may work in a
44 given context to allow for selection of approaches that are most likely to be effective in that
45 setting, thus avoiding interventions being deemed potentially ineffective and not achieving
46 scale-up²⁴. The need to adapt interventions for local settings has been put forward across the
47 health spectrum from maternal and child health²⁵, malaria prevention²⁶, HIV²⁷⁻²⁹, to mental
48 health³⁰. While some recent frameworks have supported the local development of adaptations
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3 when scaling-up, and suggested actions such as use of quality improvement methodology^{2 12}.
4 Unfortunately, there still remains minimal guidance on how to complete local adaptation, adding
5 to the difficulty in achieving and reporting of scale-up of health interventions with local fit^{1 31}.
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10 **Adaptations in Practice**

11 Despite its absence of documentation, adaptation has been discovered as naturally and
12 commonly occurring in the practice of scaling-up³². For example, within 44 preventive
13 interventions in a Substance Abuse and Mental Health Services (SAMHSA) national database in
14 the USA, over half of these had been adapted, suggesting that adaptation is more common than
15 not¹⁴. A study by Moore and colleagues³² looked at the adaptation of evidence-based
16 programmes in Pennsylvania for reducing delinquency and violence. Out of ten evidence-based
17 programmes with over 200 replications across the state, 44% reported making adaptations. It has
18 also been recognised that informal on-the-job adaptations are often made by professionals
19 working in, and deeply embedded in the context and who therefore may understand the
20 nuances³³. However, this informal on-the-job approach to adaptation is rarely discussed,
21 documented or evaluated, resulting in a dearth of information on how adaptation may impact the
22 intervention in the longer term.
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34 **Guidance for Adaptation and Scale-Up**

35 Within the implementation and scale-up literature there are many models and frameworks
36 mentioning the need for adaptations, for example the AIDED and ExpandNet process
37 frameworks^{1 34}. Despite growing recognition of the importance of adapting across diverse local
38 settings, along with evidence that adaptations are occurring in practice^{14 32 33}, there is minimal
39 guidance on what and how specific actions (for example transferring decision making to local
40 level, generation and use of local data or engagement of the community) can be used to achieve
41 adaptations when scaling-up, and even less guidance on *how*, *why* and *when* to choose one
42 method over another across different contexts. Moreover, while there is some guidance available
43 for implementers on adaptations, these guidelines are not specific to scale-up, and most existing
44 guidance on adaptation are based in the field of substance abuse prevention and HIV behaviour
45 change interventions^{13 19 35-38}. These were largely designed for high-income country contexts and
46 some of this guidance requires highly skilled, and resource heavy processes. Additionally some
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3 guidance suggests involving the original intervention developers, and at times promoting
4 redesign and testing of the intervention³⁷ which may not be feasible at multiple diverse sites
5 when scaling-up. Previous scale-up and sustainability frameworks have promoted adaptation for
6 local fit^{7 12}, however there is a need for more guidance on how to achieve this. A previous
7 review explored the process at scale-up of complex interventions³⁹, however did not specifically
8 address adaptations for local fit when scaling-up. Therefore, while acknowledging the
9 importance of adaptation for local fit there is minimal guidance for implementers on what
10 actions can be used to achieve adaptations when scaling-up, by what mechanisms these may
11 work and how the context may influence this. Therefore, there is a need to build on current
12 knowledge of scale-up.
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22 **Research Questions**

23 What are the actions that can be used to guide adaptations when scaling-up healthcare
24 interventions?
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26 How do these actions work (i.e. by what mechanisms, and in what contexts)?
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30 **Aims and Objectives**

31 The aim of this research is to develop theory on what and how actions can be used in different
32 contexts to make adaptations to health interventions for local fit when scaling-up across diverse
33 contexts that has practical application for implementers involved in scaling-up.
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39 Objectives:

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41 ➤ Identify what adaptations are being made in practice when scaling-up health interventions
42 for local fit.
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44 ➤ Identify what actions are used to achieve adaptations when scaling-up health interventions
45 for local fit.
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47 ➤ Discover how these actions work by uncovering what mechanisms are triggered, in what
48 contexts, to achieve adaptations when scaling-up health interventions for local fit.
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50 ➤ To put forward theories on what actions can be used, and how these actions may work to
51 achieve adaptations when scaling-up health interventions for local fit, by identifying demi-
52 regularities within the uncovered contexts and mechanisms.
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METHODS AND ANALYSIS:

Realist Review Methodology

Realist review is a methodology for evidence synthesis that uses a theory driven interpretive approach to explain findings^{40 41}. It aims to provide an explanation of what works, for whom and why, in what circumstances⁴². It allows for exploration of the complexity of a topic with a focus on theory generation that may be applicable in the setting under study, but also applicable in wider settings through development of theory of “middle-range”^{40 43}. Realist review methodology allows for inclusion of a wide body of evidence including grey literature sources⁴⁴. It supports stakeholder involvement throughout the stages of the review to inform the scope of the review, to develop and refine theory⁴¹ and/or assist in dissemination⁴⁵ of findings.

Realist review focuses on causation, with identification of where an intervention or action under certain contextual conditions (C), may trigger a mechanism (M), to achieve a given outcome (O)^{40 46}. It completes this through development of context-mechanism-outcome configurations (CMOCs)⁴², which are central to the analysis and theory building process with mechanisms often seen as the integral link between the context and the outcome⁴³. They can uncover the “why” a given outcome may have occurred. Dalkin and colleagues⁴⁶ conceptualised mechanisms as either resources or reasoning. They put forward that a mechanism can be a resource which can be introduced in a context, which can trigger a mechanism in the form of response or reasoning, resulting in an outcome. However, mechanisms may only activate in specific contextual conditions with the context as acting like a dimmer switch⁴⁶. Within optimal contextual conditions mechanisms are triggered or “fire”, and with sub-optimal conditions mechanisms may fire to a lesser degree or not at all⁴⁶. It is also acknowledged that actions may influence and change the context, which in turn may influence whether and how a mechanism fires.

In the current research, we view actions that were carried out to achieve adaptations when scaling-up (for example generation of evidence or participation of stakeholders), as a mechanism in the form of a resource. These actions, under the optimal contextual conditions, may trigger a mechanism in the form of reasoning or response (for example awareness or commitment), which in turn may generate outcomes. For this research outcomes can be proximal or distal. With distal

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3 outcomes relating to the overall aim for example adaptations with local fit or sustainability as
4 reported by the evidence, and proximal outcomes relating to those that may occur prior to this,
5 for example local ownership of the intervention or consensus for adaptations.
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10 Demi-regularities (semi-predictable patterns occurring in the CMOCs) can further assist in
11 explanation of the findings. Abductive reasoning can be used, which Jagosh and colleagues⁴⁷
12 described as the “*iterative process of examining evidence and developing hunches or ideas about*
13 *the causal factors linked to that evidence*” p5. Abductive reasoning could be discussed as
14 explaining a finding from both the seen and unseen, and drawing from theoretical perspectives to
15 provide possible explanations for an outcome^{48 49}. This can involve recontextualizing or
16 redesccribing explanations based on interpretations⁴⁸. Retroduction can also then be used to
17 situate the findings and put forward what causal pathways and conditions may need to be present
18 for the phenomenon of interest to occur⁴⁸.
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27 A realist review methodology was chosen as appropriate to address the study objectives for four
28 reasons. Firstly, within scale-up research, realist review methodology allows for in-depth
29 consideration of how actions can be influenced by contextual factors (e.g. resource availability,
30 level of perceived need for intervention in a local setting etc.) to trigger mechanisms (e.g. trust,
31 commitment, awareness) to generate desired outcomes (e.g. local ownership, feasible and
32 acceptable adaptations of a health intervention) leading to successful scale-up and local fit.
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34 Second, realist review methodology was chosen as it recognises the use of multiple evidence
35 sources, which was considered particularly important for scaling-up. While not prioritised on a
36 traditional hierarchy of evidence, grey literature reports may contain valuable information on the
37 scale-up process. Third, stakeholder involvement can also assist in validation and refinement of
38 theory⁵⁰ and it has been put forward by Brennan and colleagues⁴¹ that involvement of
39 stakeholders can provide a “reality check” as to whether the findings are consistent with
40 experience and knowledge from practice. Involvement of stakeholders with experience in
41 adaptation and scale-up through research and practice, may assist in ensuring the findings are
42 practical and of utility to implementers in the field. Finally, realist review methodology has been
43 previously successfully used to explore the process of scaling-up complex healthcare
44 interventions³⁹. This allowed for an in-depth analysis of how complex health interventions were
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3 scaled-up across three case studies, identifying active mechanisms that were needed to achieve
4 scale-up, and suggesting how the context may have influenced the scale-up across these cases.
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8 9 **Stages of the Realist Review**

10 This protocol is based on the five stages of realist review by Pawson and colleagues⁴⁰, with the
11 addition of a further stage of stakeholder involvement for theory refinement, which has been put
12 forward by previous reviews^{41 51} (please see figure 1, adapted from Molnar and colleagues⁵² and
13 Groot and colleagues⁵³). These stages are not necessarily carried out in a linear process as the
14 stages are iterative and may overlap and inform each other as learning on the topic progresses
15 and theory refinement takes place.
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23 **Figure 1. (see legend at end of manuscript)**

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26 Stage one of this review has been completed to clarify the scope of the review and develop the
27 initial theoretical framework. This protocol paper will briefly describe this first stage process
28 and how findings were used to develop the protocol for the following stages 2-6 which are to be
29 carried out from June 2018 to March 2019.
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35 **Stage 1. Clarifying the Scope of the Review and Developing a Theoretical Framework**

36 According to Pawson and colleagues⁴⁰, a realist review begins with clarifying the scope of the
37 review and the elicitation of initial rough theories in the form of an initial programme theory
38 (IPT). The IPT can provide a map of the areas to be investigated and gives a structure for data
39 synthesis³⁹. These can be further refined, tested and added to as the synthesis progresses⁴³.
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45 **Developing the IPT Framework**

46 For this research, an IPT framework was developed which was a theoretical framework to guide
47 the review. This will be refined as the review progresses in future stages. The methodology and
48 format of the IPT framework to guide this review was informed by Willis and colleagues³⁹
49 realist review, which focused on the process of scale-up of complex interventions, identifying in
50 their initial IPT framework actions, contexts and outcomes. After analysis and synthesis of three
51 case studies they further identified what mechanisms were triggered to achieve scale-up of
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3 complex interventions and what contexts influenced this. Therefore, the Willis and colleagues³⁹
4 realist review provided an appropriate guide to inform the methodology for the IPT development
5 for this review. In light of this method, this study developed an IPT framework focusing on what
6 potential actions, contexts, mechanisms, distal outcomes and proximal outcomes may be of
7 relevance to scale-up and adaptation. A particular focus of this IPT framework was the
8 identification of potential actions (e.g. definition of roles, use of feedback loops etc.), and how
9 these can achieve the outcome of adaptation for local fit. This IPT framework will provide a
10 theoretical map for further exploration in the following stages of the review.
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19 Purposeful and iterative searching was undertaken for this first stage of the realist review to
20 inform the content of this IPT framework³⁹. An initial scoping search was undertaken for scale-
21 up and adaptation in healthcare to get an overview of the available literature in the field. There
22 was a large volume returned with many articles discussing the need to adapt for local fit,
23 however without giving guidance for how, why or when to complete this when scaling-up. As a
24 result, a decision was made to particularly focus on guidance and frameworks relating to scale-
25 up, adaptation and fidelity to prioritize identification of what actions could be taken (for example
26 create opportunities for learning, giving guidance to sites etc.) to make adaptations when
27 scaling-up. Guidance and frameworks were identified from the initial scoping search results, in
28 addition to use of reference lists, in particular of recent reviews in the field of implementation
29 and scale-up by Milat et al⁵⁴, Subramanian et al⁵⁵, Nilsen et al⁵⁶, and also use of the ExpandNet
30 bibliography. This was complimented by input from the review team (with backgrounds in
31 global health and health systems), and two further experts (in the fields of fidelity and of
32 implementation research) to highlight and direct to any further relevant literature (figure 2). The
33 frameworks included can be seen in supplemental file 1.
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46 **Figure 2. (see legend at end of manuscript)**
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50 A challenge of developing an IPT framework in a realist review is finding a level of abstraction
51 that allows the recognition of demi-regularities among the detail and variation in the evidence,
52 whilst being specific enough to answer the review question³⁹. The IPT framework went through
53 revisions aiming to keep the actions, contexts, mechanisms and outcomes that were deemed
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3 most relevant to adaptation and scale-up, rather than those relating to scale-up in general.
4 Decision making was recorded in the research logbook (see supplemental file 2 for an example
5 from the research logbook). Causation between the potential actions, contexts, mechanisms and
6 outcomes were not made at this stage and will be added iteratively as the review progresses and
7 scope is refined. The contexts were placed under headings adapted from the socio-ecological
8 model⁵⁷ to aid organisation. The IPT framework can be seen in figure 3 (please see supplemental
9 file 1 for the guidance and frameworks identified which informed this).

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17 **Figure 3. (see legend at end of manuscript)**

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20 The IPT framework will assist in; (i) initial coding of actions, contexts, mechanisms and
21 outcomes for data extraction in stage 4, and will inform a codebook for reviewers (while also
22 allowing for new actions, contexts, mechanisms and outcomes to emerge), (ii) providing an
23 initial framework for the synthesis to assist in organisation of the CMOCs and demi-regularities
24 in stage 5 (see figure 1 for outline of stages). As mentioned, coding and synthesis of findings
25 will be guided by this IPT framework, however new actions, contexts, mechanisms and
26 outcomes will be identified from the data and added to this as they emerge. Thus, this review
27 will add to and refine the framework as the stages progress.

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36 **Clarifying the Scope of the Review**

37 As learning progressed it was noted that much guidance and frameworks in the implementation
38 and scale-up literature in healthcare may be untested and largely theoretical in nature. Therefore,
39 the scope of the review was refined to include specific examples of scale-up and adaptation in
40 practice. Decision making while clarifying the scope of the review was documented in the
41 research logbook (see example in supplemental file 2). The scope of this review may be further
42 refined in an iterative process as the review progresses and will be documented in the research
43 logbook for transparency.

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51 The remaining section presents the protocol for stages 2-6 detailing the methods that will be
52 used throughout the remainder of the realist review which will be carried out from June 2018 to
53 March 2019. An overview of the stages and details can also be seen in figure 4.

Stage 2. Search strategy

Stage 2 will involve a search for examples of scale-up and adaptation in practice. Scoping and pilot searches were completed throughout stage one and a librarian was consulted to help inform the selection of databases and concept headings for use in stage 2. A systematic search will be completed using the concept headings of; scale-up, context (contextualize, adapt, tailor, redesign etc.) and healthcare. Search terms will be adapted for each database. Search databases will include: PubMed, CINAHL, Global Indicus Medicus (World Health Organization library including both academic and grey literature), SCOPUS, EMBASE, and Psychinfo. For further grey literature searching, Social Care Institute for excellence (SCIE), Open Grey and GreyLit will be used. Searching of reference lists from identified papers will be carried out along with forward citation searching using Google Scholar. Additionally, the corresponding author from the articles selected will be contacted to identify other articles on their scale-up example that could be relevant to answering the research question.

Further rounds of searches may be completed in later stages of the review in keeping with the iterative nature of realist reviews⁵⁰. This may be to search for further evidence or wider theories that may explain findings and assist in theory refinement. The need for searches, search terms and strategies will be identified as the review progresses. These will be documented in the research logbook, as they occur.

Stage 3. Study Selection, Criteria and Procedures

Inclusion Criteria

All articles and sources obtained from stage two will subsequently undergo further review for inclusion based on three criteria. To be retained for further review sources must describe; (i) an example of scale-up of a healthcare intervention(s) in practice, (ii) adaptations that were made for health intervention(s) to fit local settings, and (iii) discuss in detail actions for adapting

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3 health intervention(s) at scale. Both scale-up at national and sub-national levels will be included
4 once the intervention was being purposefully expanded to a new wider population group in
5 practice. For inclusion in this study, adaptations will need to have occurred during scale-up to
6 adapt for local contexts, and actions used (for example local decision making) have been
7 documented in detail. Articles discussing the adaptations without describing what actions were
8 used to adapt the intervention will also be excluded. Studies where the adaptations occurred
9 during the RCT or pilot stage, and the same intervention was rolled out nationally (or sub-
10 nationally) without further adaptations to the content, context or delivery, will be excluded. Both
11 positive and negative adaptations may be included. Please see supplemental file 3 for more
12 details.
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22 As scale-up occurs over a long-time period, with an estimated 15 years to reach national scale,
23 no time limit will be placed on evidence⁶. Keeping the time-period open allows for documents
24 published at the beginning of scale-up projects to also be captured in the search. Searches will be
25 carried out in English. Languages will be limited to those spoken by the review team; English,
26 Spanish, Portuguese, and French.
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32 Study Appraisal: Relevance and Rigour

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34 As realist philosophy does not exclude evidence based on type of study, RAMESES guidelines
35 will be applied to assess the relevance and rigour of the studies⁴³. As discussed by Pawson⁴⁴,
36 useful information can arise from studies which may not be prioritised on a traditional hierarchy
37 of evidence. Each retained evidence or document will be assessed in terms of its relevance to the
38 research question and whether it is rigorous enough to hold value to theory building, testing or
39 refinement. Any exclusions based on these criteria will be documented in the research logbook.
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46 Procedures

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48 Title and abstract screening will be completed. Following this two reviewers will complete full
49 text screening independently, with a third reviewer available to resolve any conflicts should they
50 arise. Depending on the number of documents with examples of scale-up returned, further
51 refinement of the scope of the review may be decided by the review team. This will be
52 documented in the research logbook. For further searches as they arise in an iterative fashion,
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3 selection criteria will be decided by the review team and will be based on the ability of studies to
4 further refine theory.
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9 **Stage 4. Data extraction**

10 The following data will be extracted from the scale-up examples identified in stage 3; (i) what
11 adaptations were made, (ii) what actions were used to make these adaptations, and (iii) the
12 contexts, mechanisms and outcomes that relate to these actions (in the form of CMOCs). A data
13 extraction form and codebook will be developed from the IPT framework to guide data
14 extraction for each scale-up example (see supplemental files 4 and 5 for draft versions, noting
15 that these will be refined as the review progresses). Where multiple documents relate to the same
16 example of scale-up, these will be combined into one data extraction form for that case example,
17 and the supporting quotes referenced as to which document it originated from.
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26 (i) Adaptations

27 It has previously been identified that adaptations are often poorly reported in research^{10 33 58 59}.
28 While some adaptations may reflect small, surface-level changes, others may reflect large deep
29 structural adaptations. To systematically capture the type of adaptations made, Stirman and
30 colleagues¹⁰ taxonomy of modifications will be used to assist categorisation of adaptations,
31 including what type of adaptations were made, who made them and at what level.
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39 (ii) Actions

40 A description of what action(s) was/were carried out to achieve the adaptation(s) will be
41 extracted from the examples to the data extraction form. These may relate to the potential actions
42 identified in the IPT framework and resultant codebook, or may reflect new actions emerging
43 from the data. Any new actions will be categorised and added to the codebook as they emerge.
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49 (iii) CMOCs relating to the Actions

50 Contexts, mechanisms and outcome configurations (CMOCs) relating to the actions and
51 adaptations will be extracted from each case example. Note that a case example may contain
52 multiple sources (i.e. a peer reviewed article and a national report on the same scale-up) or just
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3 one source. While some CMOCs may relate to the potential actions, contexts, mechanisms and
4 outcomes identified in the IPT framework and resultant codebook, others may reflect new
5 CMOCs emerging from the data. Quotes and descriptions will be taken from the text to support
6 these CMOCs. Abductive reasoning will also be applied for any inferred contexts or
7 mechanisms and the reasoning stated on the data extraction form^{39 47}.
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13 Once the above steps are completed for each case example, an example will be presented to
14 members of the Irish Realist Researcher Group for feedback on the coding procedures to inform
15 refinements of the methods and codebook as needed (supplemental files 4 and 5). This is a group
16 of 8-10 researchers with experience in realist methods. Following this, the completed data
17 extraction forms for each case will be reviewed again by the first reviewer using the updated
18 coding procedures. A second reviewer will then take a random sample of 10% of the scale-up
19 case examples for extraction following the same coding procedures using a data extraction form
20 for these case examples. The reviewers will then discuss and compare the CMOCs extracted and
21 reach agreement, if differences occur. Following this, the remaining data extraction forms for all
22 case examples will be reviewed by the second reviewer and agreement reached between
23 reviewers on the CMOCs, including any inferred contexts or mechanisms and reasoning for the
24 same. A third reviewer will be available for input or to resolve any discrepancies between the
25 first and second reviewer.
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42 **Stage 5. Data Synthesis**

43 The findings from each example of scale-up will then be synthesized across cases. The data
44 extraction forms from each case example will be uploaded and coded in NVivo, using the IPT
45 framework and resultant codebook to guide initial codes. New codes will be added or refined as
46 they emerge, thus adding to the theoretical framework as the synthesis progresses.
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54 The type of adaptations made will be synthesized across cases to give a picture of what
55 adaptations are happening in practice. Then the actions used to achieve adaptations will be
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3 synthesized. To explore how these actions achieved adaptations, the CMOCs identified from
4 each case example will be coded in NVivo to look for demi-regularities occurring across the
5 different case examples. Therefore some, but not all, of the CMOCs from each case example
6 may be identified based on whether demi-regularities were seen and if they add value to theory
7 building and refinement at this stage. These results will be synthesized to make further sense of
8 the findings and refine the theory. The following conceptual tools may be used as needed to
9 assist in this theory refinement^{43 60}; (i) juxtaposing, where evidence from one setting may aid
10 explanation of outcomes from another, (ii) reconciliation, where differences are identified to
11 explain findings which may contradict each other, (iii) adjudication between studies, (iv)
12 consolidation for example by building multiple explanations, and (iv) situating by identifying
13 what may happen in one setting compared to another. Reasoning will be documented in a
14 research logbook.
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26 Abductive reasoning⁴⁷ and retroduction⁴⁸ will be used to guide the review to interpret and
27 explain the findings and put forward contextual conditions that may need to be present for the
28 outcomes to occur. As part of this process, wider substantive theory will be searched for to assist
29 in explanation of the findings and for further theory refinement⁴³. This will lead to the
30 development of theory relating to how adaptations can be made when scaling-up.
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38 **Stage 6. Stakeholder Involvement**

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40 Finally, stakeholders with experience of adaptation and scale-up in both research and practice
41 internationally will be sought and contacted to assist in theory refinement. Initial stakeholders
42 will be identified and contacted by the research team. Stakeholders will also be asked to identify
43 further persons in their field of expertise. Initial review findings will be presented to
44 stakeholders and their opinions sought, based on their practical knowledge and expertise⁴¹. The
45 resultant theories may be further refined based on learning from this process⁶¹. This involvement
46 of stakeholders with experience in adaptation and scale-up through research and practice, may
47 assist in ensuring the findings are useful in practice for implementers in the field. The
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3 involvement of stakeholders will allow for initial dissemination of the research findings. This
4 stage may inform further searches as needed in an iterative fashion.
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8 9 **Patient and Public Involvement**

10 Members of the public and patients were not involved in the development of this protocol.
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13 14 **Figure 4. (see legend at end of manuscript)**

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18 A summary of the stages and proposed actions for this realist review can be found in figure 4
19 below. The above stages will be carried out as per realist review methodology in an iterative
20 fashion, allowing for refinement of theory and the scope of the review and subsequent searches
21 as learning progresses. Any iterations to the above protocol will be captured in the research
22 logbook and reported in the final dissemination of the research. The above stages set out to
23 achieve the study's objectives of discovering what actions can be used to achieve adaptations
24 when scaling-up health interventions for local fit, by what mechanisms do these actions work,
25 and what contextual factors may influence this. It is hoped this approach will provide practical
26 and useful findings for implementers in the field of scale-up.
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39 **ETHICS AND DISSEMINATION**

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41 Ethical approval for this study was received from the Health Policy and Management and Centre
42 for Global Health Research Ethics Committee of Trinity College Dublin, Ireland in March 2017.
43 The dissemination of the findings of this review will follow the RAMESES reporting
44 guidelines⁶². The results of this review will be used to put forward theory to explain what and
45 how actions can be used to influence and achieve adaptations when scaling up for local fit. Use
46 of a realist review methodology, with the stages outlined above, allows for an exploration of the
47 complexity of the process of scale-up across diverse contexts, and the identification of the
48 contextual factors that may influence actions, and by what mechanisms these may work. By
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3 including stakeholders with experience in the field of adaptation and scale-up, it is hoped this
4 will add to theory development and refinement, and will help ensure that findings have practical
5 utility for implementers. The findings of this study will be published in a peer-reviewed journal,
6 through conference presentations and dissemination through stakeholder involvement in theory
7 refinement. The review will also be published as a PhD thesis, available through Trinity College
8 Dublin library.
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18 **AUTHORS CONTRIBUTIONS:**

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20 JP is lead reviewer completing this study as part of a PhD. JP developed the general study
21 concept and outline. JP completed the literature review and development of the IPT framework
22 and led the iterations. JP developed the search strategy, and methods for selection, appraisal,
23 extraction, synthesis, and stakeholder involvement. BG contributed to IPT framework
24 refinement, the methods for data extraction and coding processes using NVivo, and the methods
25 for synthesizing across cases. FV contributed to the general study concept and design, clarifying
26 the scope of the review and refinement of the IPT framework. ET contributed as an expert in
27 fidelity in stage one and assisted in refinement of the IPT framework. ET contributed to the
28 methods of the search strategy and methods of the data extraction and synthesis stages, including
29 the role of second reviewer. HM contributed to conceptual study design, and clarifying the scope
30 of the review by refinement of research question and IPT framework. EM contributed to
31 conceptual study design, refinement of research question and IPT framework, the search
32 strategy, refinement of the data extraction form, and contributed to the method of involvement of
33 stakeholders for theory refinement. JP wrote the first draft of the paper, which was reviewed and
34 contributed by all other authors. All authors approved the final version.
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50 Centre for Global Health, Trinity College Dublin for lending her expertise to stage one of this
51 review.
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COMPETING INTERESTS STATEMENT:

The authors declare there are no competing interests.

Legend for Figures

Figure 1. Overview of stages of the realist review. Based on Pawson and colleagues⁴⁰. Adapted from Molnar and colleagues⁵² and Groot and colleagues⁵³. These stages are non-linear and will be carried out in an iterative fashion with theory refinement occurring throughout.

Figure 2. Development of the IPT Framework

Figure 3. IPT Framework. Potential actions, contexts, mechanisms and outcomes identified from stage one for further exploration in future phases.

Figure 4. Summary of stages and proposed actions for the realist review.

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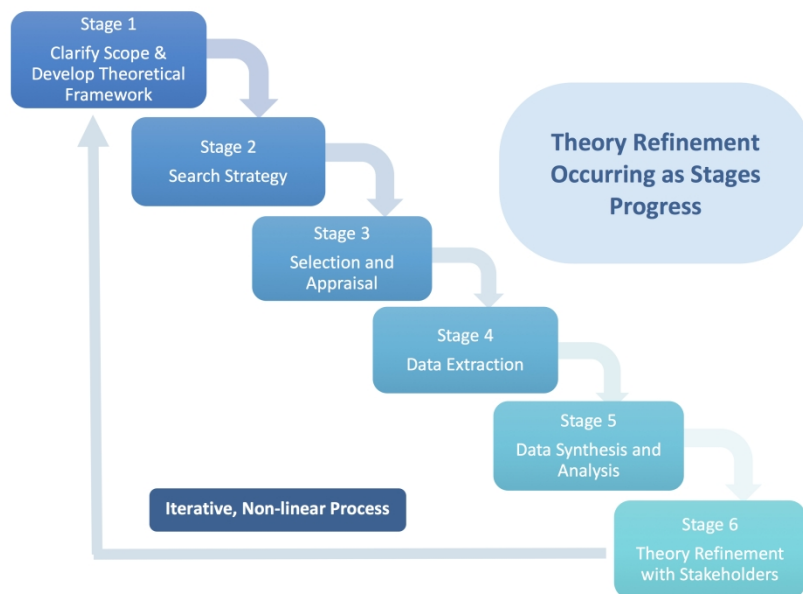


Figure 1. Overview of stages of the realist review. Based on Pawson and colleagues⁴⁰. Adapted from Molnar and colleagues⁵² and Groot and colleagues⁵³. These stages are non-linear and will be carried out in an iterative fashion with theory refinement occurring throughout.

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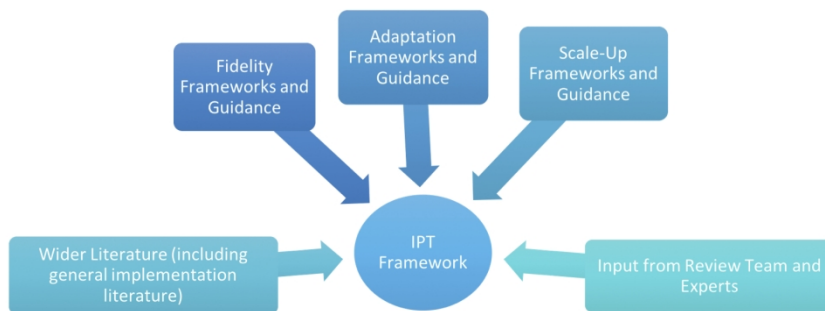


Figure 2. Development of the IPT Framework

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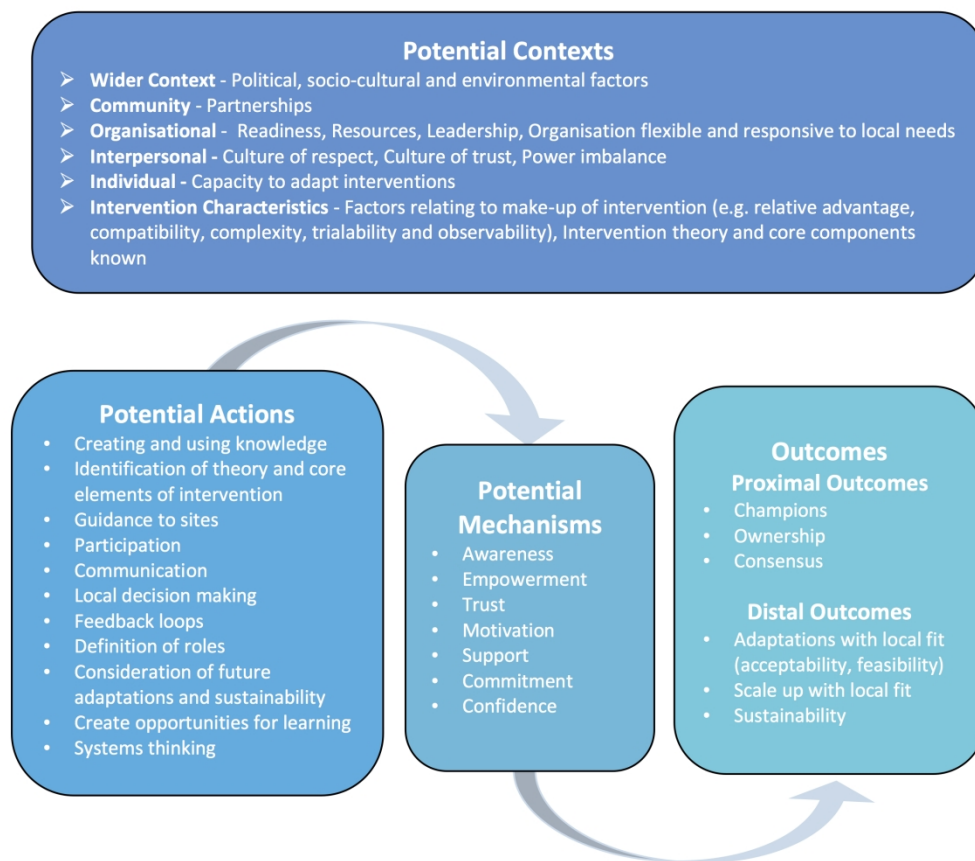


Figure 3. IPT Framework. Potential actions, contexts, mechanisms and outcomes identified from stage one for further exploration in future phases.

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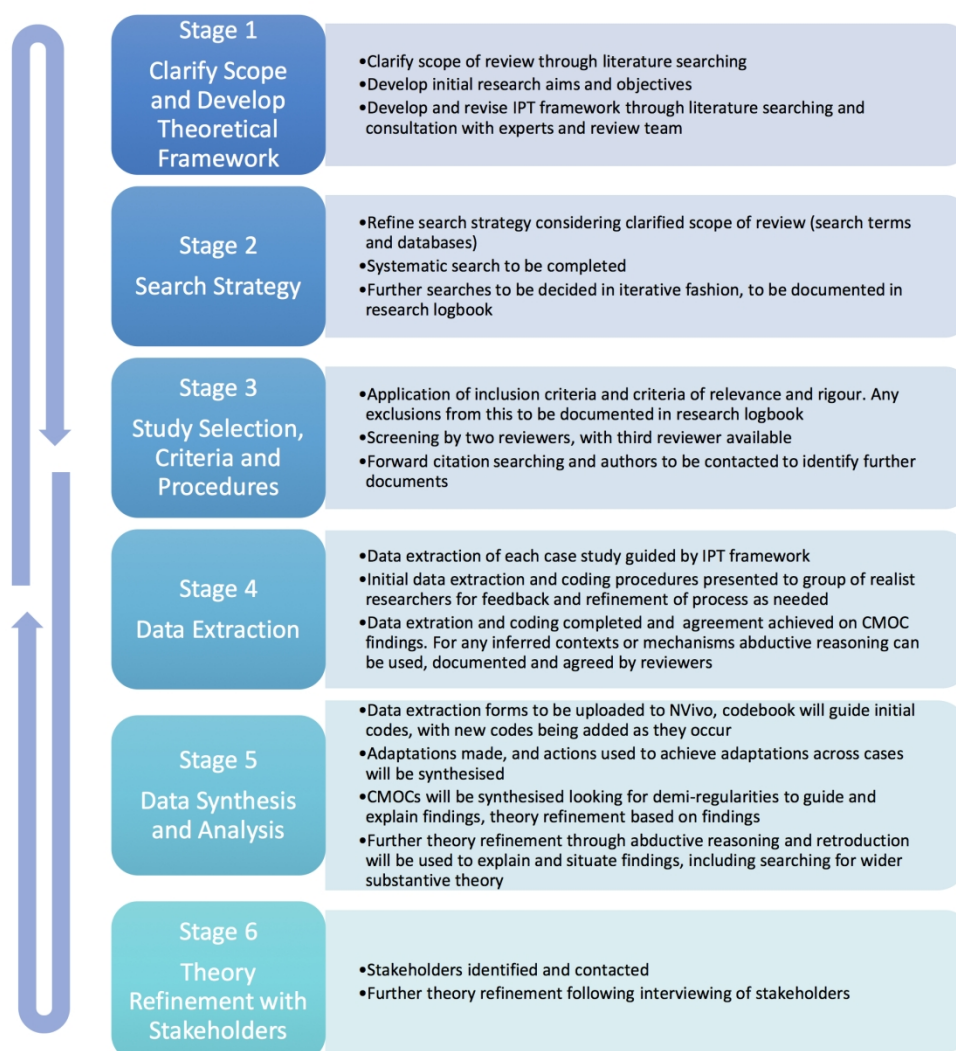


Figure 4. Summary of stages and proposed actions for the realist review.

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Supplemental File 1. Guidance and frameworks identified which assisted in IPT development

Guidance and Frameworks Identified	
Scale-Up	<p>Scale-up frameworks are categorised into; determinant frameworks, process models and evaluative frameworks (depending on their primary focus) as per Nilsen ¹;</p> <p>Determinant frameworks</p> <ul style="list-style-type: none"> • Scaling up health service innovations: a framework for action, ExpandNet^{2,3} • Dynamic Sustainability Framework (DSF)⁴ • A framework for understanding the constraints of scaling up⁵ • Scaling up; A proposed framework for success⁶ • The non-adoption, abandonment, scale-up, spread, and sustainability (NASSS) for patient facing health and care technologies⁷ • The learning process approach⁸ • Conceptual framework for priority setting in health⁹ <p>Process Models</p> <ul style="list-style-type: none"> • Scaling up Management (SUM) Framework¹⁰, updated by¹¹ • Practical guidance for scaling up health service innovations, ExpandNet¹² • Nine steps for delivering a scale up strategy, ExpandNet¹³ • Beginning with the end in mind, ExpandNet¹⁴ • SEED Scale¹⁵ • A guide to scaling up population health interventions¹⁶ • IHI framework for going to full scale¹⁷ • A guide to fostering change to scale up effective health services¹⁸ • AIDED model for dissemination, diffusion and scale up of family health innovations in LICs¹⁹ • Program assessment guide for scaling up nutrition interventions²⁰ • Scaling up breastfeeding²¹ • MuSCLE framework²² <p>Evaluative Frameworks</p> <ul style="list-style-type: none"> • Scaling out²³ <p>Not specific to scale-up but highlighted to be of relevance to implementation and adapting for local context were;</p> <ul style="list-style-type: none"> • Consolidated Framework For Implementation Research (CFIR)^{24,25} • Promoting Action on Research Implementation (PARIHS) Framework²⁶ • Integrated i-PARIHS Framework²⁷ • Knowledge to action framework²⁸ • Implementation Research (IR) Toolkit²⁹ • Taxonomy of implementation outcomes³⁰ • RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) Framework^{31,32} • Methods to Improve the Selection and Tailoring of Implementation Strategies³³

Adaptation	<ul style="list-style-type: none"> • Elements to consider in cultural programme adaptation³⁴ • Finding the balance program fidelity and adaptation in substance abuse prevention³⁵ • Key principles for adapting research based interventions in HIV³⁶ • Intervention mapping to adapt an effective HIV, sexually transmitted disease, and pregnancy prevention programs³⁷ • ADAPT MAP draft guidance for adapting HIV interventions³⁸ • ADAPT-ITT model for adapting EBI for HIV³⁹ • Replicating effective programs (REP) framework⁴⁰ • ADAPTE guidelines⁴¹
Fidelity (including Intervention Development and Testing)	<ul style="list-style-type: none"> • Bauman's parameters for consideration in intervention development⁴² • The conceptual framework for adaptive interventions⁴³ • NIH Behaviour Change Consortium (BCC) fidelity concepts⁴⁴ • Comprehensive intervention fidelity guide⁴⁵ • Carroll's conceptual framework for implementation fidelity⁴⁶ • Hasson's modified conceptual framework for implementation fidelity⁴⁷ • The modified Carroll's fidelity framework⁴⁸ • Fidelity variation concepts from ASSIST RCT⁴⁹ • Figuring out fidelity⁵⁰ • Contextualised Interventions⁵¹ • Medical Research Council (MRC) guidance for process evaluations⁵² • The conceptual model for translating evidence based Interventions into community Settings⁵³ • Template for Intervention Description and Replication (TIDieR) guidance⁵⁴ • RE-AIM framework^{31 32}
Some examples from the wider literature (including general implementation literature and theories)	<p>Some examples of wider literature used to also inform IPT Framework (please note this is not comprehensive and all wider literature is referenced in the full research logbook available on request);</p> <ul style="list-style-type: none"> • Mechanisms for scale-up by Willis and colleagues⁵⁵ and large system transformation in healthcare by Best and colleagues⁵⁶ • Barriers and facilitators to scale-up, Norton and Mittman⁵⁷ • Diffusions of innovation theory, Rogers⁵⁸ • Complex adaptive systems theory, Paina and colleagues⁵⁹

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Supplemental File 2. Examples from Research Logbook for Recording Decision Making

1. Example from Research Logbook of Decision Making for Clarifying Scope of Review

Source: Fidelity, adaptation and scale-up literature from stage 1	Thought process, decision making	Clarified Scope
Adaptation guidance and frameworks mainly from high income country contexts, with a focus on HIV and substance abuse prevention. Many contain a resource heavy and highly skilled process, with some involving research institutional partnerships and intervention developers.	These may not be feasible at scale, need to learn from what is happening in practice during scale-up and adaptations.	Decision to focus on examples of scale-up in practice for stage two.
Despite recognition of the need to adapt, there is a lack of clear guidance in scale-up literature and frameworks on what actions to take when adapting for local fit.	Unable to refine question to a specific action or actions for adapting when scaling-up. Decision to keep scope of review broad at this stage to capture any actions that were reported in the examples in practice. This allows for the benefit of identifying what any and all actions that are being used in practice when scaling-up. The scope of the review could be further refined after discovery of this.	Decision to keep scope of review broad at this stage to capture <u>any actions</u> that were reported when adapting during scale up in the examples.

2. Example from Research Logbook of Decision Making for IPT framework

Source: Wider Literature Search (including general implementation literature)	Thought process, decision making	Inclusion in IPT Framework
<ul style="list-style-type: none"> • Funding and power imbalance, funding available for specific evidence based Interventions¹, choosing intervention based on funding² • Power dynamics influencing whether people could meaningfully participate (e.g. male dominance)³ • Scale free networks, power imbalance and influence⁴ 	<p>Power dynamics came up in the general implementation literature in addition to the within the scale-up frameworks.</p> <p>This was discussed in relation to funders and a potential top down power imbalance leading to selection of certain interventions or adaptations based on available funding. It was also discussed in relation to being able to meaningfully participate being limited by power dynamics within a community. Complex adaptive systems theory also speaks of scale free networks which could relate to certain people within networks being particularly influential or powerful.</p>	As a result, “ power imbalance ” was included in the IPT under contexts.

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Supplemental File 3. Suggested Concept Headings and Databases & Inclusion Criteria for Stage Two.

Suggested Concept Headings for Search Stage Two

1. Scale-up
2. Context (contextualize, adapt, tailor, redesign etc.)
3. Health (may also be used as a concept to further refine depending on the database)

MeSh headings, controlled vocabulary and keywords will be identified for each database as appropriate for stage two.

Suggested Databases

- Pubmed
- Cinahl
- Global Indicus Medicus
- SCOPUS
- Web of Science
- EMBASE
- Psycinfo
- Grey Lit
- Social Care Online (SCIE)
- Open Grey

For identified articles:

- Google scholar will be used for forward citation searching
- The corresponding author from the articles selected will be contacted to identify other articles on their scale-up example that could be relevant to answering the research question.

Suggested Inclusion and Exclusion Criteria for Stage 2

In order to be incorporated in this phase of the synthesis the evidence will need to meet the following three inclusion criteria;

1. Be a case example of scale up of a healthcare intervention(s)

Scale up is defined as a purposeful expansion of a health intervention to a wider population^{1 2}. This could involve expanding geographically or to a wider population within the same setting. Both scale up at national and sub-national levels will be included once the intervention was being purposefully expanded to a new wider population group. If an article or study is not based on a real-world case example but puts forward guidance, framework or aspirational steps these will be excluded.

A health intervention is defined as “an act performed for, with or on behalf of a person or population to assess, improve, maintain, promote or modify health, functioning or health conditions”³. For this study, it will be limited it to interventions where the direct target was the individual. An example of this would be provision of nutritional supplements, vaccines or medication (e.g. vitamin A, polio vaccine etc.) and/or educational or behaviour change interventions directly delivered to the individual (e.g. breastfeeding education, safe sex promotion etc.). If the primary intervention is capacity building of HRH which may have future impacts on health this was considered indirect and not included. As scale-up often occurs as a

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3 package of interventions, case examples of this will be included if a specific direct health
4 intervention was identified as a primary part of this package. Where case studies were general
5 service delivery for example provision of mental health services at scale but did not specify a
6 specific health intervention these will be excluded.
7

8 9 **2. Adaptations were made for health intervention(s) to fit local settings**

10 **Adaptations** will be defined as “deliberate and/or unintended changes to the intervention
11 content, context or training and delivery”. For inclusion in this study these adaptations will need
12 to have occurred during scale-up to adapt for local contexts. If the adaptations occurred during
13 the RCT or pilot stage and the same intervention was rolled out nationally (or sub-nationally)
14 without further adaptations to the content, context or delivery these will be excluded.
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16 17 **3. Discusses in detail action(s) for modifying health intervention(s) at scale**

18 **Actions** used to make adaptations will need to be explained in detail. In detail meaning to give
19 sufficient information to be relevant to answering the research question(s) using criteria of
20 relevance and rigour below. If the article discussed the adaptation without discussing what
21 process was used it was excluded.
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23

24 **Time limit:** No time limit will be placed on evidence as it was noted that scale-up occurs over a long
25 time period with an estimated 15 years to reach national scale⁴.
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28 **Language:** Searches will be carried out in English. Languages will be limited to those spoken by the
29 review team; English, Spanish, Portuguese and French.
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32 **Relevance and Rigour**

33 As realist philosophy does not exclude evidence based on type of study, the criteria of relevance and
34 rigour will be used for further appraisal as per RAMESES guidance⁵. For exploring examples of scale-
35 up and adaptation in practice it was felt that evidence may come from a variety of sources including
36 grey literature. Therefore, the relevance of the piece of evidence to the research question and
37 whether the evidence or document was rigorous enough to hold value to theory building, testing or
38 refinement will be decided. Any exclusions and reasoning from these criteria of relevance and rigour
39 will be recorded for transparency in the research logbook.
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3 **Supplemental File 4. Draft Data Extraction Form (to be further refined as needed)**
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5 **Scale-up example (location, intervention):**

6 **References of articles/documents included:**

7 **Details of Intervention:**

8 **Topic (e.g. nutrition, HIV):**

9 **Study Type(s):**

10 **Summary (short description of case example of scale-up):**
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13 **1. Adaptations** (Please see codebook for further descriptions as needed)

14 **What adaptations were made and to what elements?** (give details where discussed)

15 **(i) Content** (e.g. changes to intervention procedure, materials or delivery):
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18 **(ii) Context** (e.g. changing the delivery channel, format, setting, personnel, population):
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20 **(iii) Training/Evaluation** (e.g. longer/shorter training, style of training etc.):
21

22 **At what level was the adaptation made?** (where discussed, refer to codebook as needed)
23

24 **Who made decision to adapt?** (where discussed, refer to codebook as needed)
25

26 **Why decision to adapt?** (where discussed)
27
28

29 **2. Actions**

30 **Actions for Adaptations** (please list with short descriptions of what was carried out, refer to
31 codebook as needed):
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33

34 **3. Context-Mechanism-Outcomes (CMOCs)**

35 Please provide details of CMOCs identified below relating to actions for adaptations, please provide
36 quotes to support and any reasoning for any inferred contexts or mechanisms, refer to codebook as
37 needed.
38
39

40 **CMOC 1.**

41 Action (mechanism resource):

42 Context:

43 Mechanism (reasoning or response):

44 Outcome:

45 CMOC:

46 Supporting quotes or reasoning:
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49 **CMOC 2.**

50 Action (mechanism resource):

51 Context:

52 Mechanism (reasoning or response):

53 Outcome:

54 CMOC:

55 Supporting quotes or reasoning:
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58 **Please add as many as needed below e.g. CMOC 3, CMOC 4**
59
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Supplemental File 5. Draft Data Extraction Guidance and Sample Codebook (to be further refined as per protocol)

Adaptations definition and coding (based on Stirman and colleagues taxonomy of modifications¹)	
<p>Notes: Headings and description for the taxonomy of modifications below. If any of these are not stated to mark as such on the data extraction form.</p> <ul style="list-style-type: none"> • Firstly, to identify and briefly state what adaptation was made and whether it was to the content, context of training/evaluation. If the adaptation was to the content, this can be further classified under the 12 suggested headings if applicable. If not to mark as “other” • Secondly to identify where stated at what level the adaptation was made (e.g. at individual recipient level or community level) using the seven suggested headings or the other category • Thirdly to capture who made the decision to adapt where stated • Finally, if the reason was given for why adaptation was needed 	
Adaptations	Deliberate and/or unintended changes to the intervention content, context or training and delivery
Adaptations to Content	<p>Changes to intervention procedure, materials or delivery.</p> <p>These can be further classified as (note as many as apply on data extraction form);</p> <ol style="list-style-type: none"> 1. Tailoring, tweaking, refining - minor change, leaves all major principles in place e.g. modifying language 2. Adding elements - consistent with fundamentals of intervention 3. Removing elements - e.g. those that are culturally not appropriate 4. Shortening, condensing (pacing/timing) - shorter amount of time or no of sessions 5. Lengthening, extending (pacing/timing) 6. Substituting elements - a module or activity is replaced with another (e.g. condom application replaced with abstinence talk) 7. Re-ordering elements 8. Integrating another approach - intervention used as starting point but other techniques added 9. Integrating prevention into another approach - starting with another approach, but intervention added in 10. Repeating elements 11. Loosening structure - flexibility with programme/process e.g. opening and closing, layout can be different 12. Departing from the intervention (drift) - Intervention no longer used in given situations <p>Other (Give details)</p>
Adaptations to Context	Changing the delivery channel, format, setting, personnel, population etc.
Adaptations to Training/Evaluation	Longer/shorter training, style of training etc.
At what level was the adaptation made	<p>This can be classified as (please note as many as apply on data extraction form);</p> <ol style="list-style-type: none"> 1. Individual recipient e.g. changed for a person's needed e.g. literacy, hearing, physicality

	<p>2. Cohort level - for individuals grouped within a setting</p> <p>3. Population level - Intervention modified for cultural, ethnic, social groups</p> <p>4. Provider/facilitator level - modified for all of a certain practitioners clients</p> <p>5. Unit level - modified for all in that unit e.g. clinic, department</p> <p>6. Hospital/Organization level - entire organisation</p> <p>7. Networks/Community Level - entire networks or systems (e.g. all hospitals, facilities)</p> <p>Other (Give details)</p>
Who made decision to adapt	Please state where present (e.g. individual practitioner, team, non-programme staff, administration, programme developer, researcher, coalition of stakeholders, other)
Why decision to adapt	Please state where present (e.g. feasibility, acceptability)

Definitions of Actions, Contexts, Mechanisms, Outcomes and CMOCs	
Actions	<p>Mechanisms are often seen as the integral link between the context and the outcome². They uncover the “why” a given outcome may have occurred. Dalkin and colleagues³ conceptualised mechanisms as either resources or reasoning. They put forward that resources are introduced in a context, which trigger a response, which results in an outcome.</p> <p>For this research, we viewed actions used to make adaptations when scaling-up as a mechanism in the form of a resource. Actions can be acts, processes or interventions used to make, guide or support adaptations when scaling up. For example, generation of evidence which informs adaptations or participation of stakeholders. These under the right contextual conditions may fire a mechanism in the form or reasoning or response, for example awareness or commitment, which in turn may generate the outcome of interest.</p> <p>Actions may be captured twice.</p> <ul style="list-style-type: none"> • Firstly, to identify what actions were used and give a brief description (heading 2 in data extraction form). Please do not limit to actions only in the IPT and allow new actions to emerge from the data also. • Secondly, if there is a CMOC associated with that action it will be captured under the CMOC heading below (heading 3 on data extraction form). Note not all actions may have CMOCs related to them.
Contexts	<p>Contexts relate to conditions that affect mechanisms and therefore outcomes. A context can act like a dimmer switch for the triggering of mechanism to varying degrees³. Pawson and Tilley⁴ note context “<i>may not only relate to place but also to systems of interpersonal and social relationships, and even to biology, technology, economic conditions</i>”^{p8}.</p>

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Mechanisms	For this research actions were seen as a “resource”, and resulting mechanisms were the “reasoning” or response. For coding as a mechanism, it would be a response to a given action. Mechanisms in the form of reasoning are often hidden and unseen, for example awareness or commitment.
Outcomes	Outcomes can be intended or unintended consequences from actions or interventions in given context. They can be positive or negative. For this research outcomes can be proximal or distal. With distal outcomes relating to the overall aim for example adaptations with local fit or sustainability as reported by the evidence, and proximal outcomes relating to those that may occur prior to this for example ownership of intervention or consensus for adaptations.
CMOC	Context-mechanism-outcome-configuration. This is the combination of the action, context, mechanism and outcome together. This may be presented as a narrative sentence which describes the CMO combination. For example, when XX is carried out in the context of XX, this caused a response of XX which led to outcome XX.

Potential Actions, Contexts, Mechanism and Outcomes identified from the IPT framework below		
Notes: Please do not limit data extraction to these codes, allow new codes to emerge as they appear in the data, or more detailed codes and categorization of below as needed.		
Additionally, what is categorised as an action, context, mechanism or outcome in one instance may be categorised under another heading in another CMOC depending on the configuration. For example, ownership may be an outcome in one CMOC and a context in another. Please categorize under whichever heading is appropriate for the CMOC. Reasoning can be documented as needed.		
Potential Actions	Creating and using knowledge	The creation of knowledge e.g. through evaluation, local knowledge, continual assessment mechanisms and/or the use of existing knowledge e.g. local data, real time data, routine data, evidence for intervention
	Identification of theory and core elements of intervention	The identification of theory or core elements/components of the intervention. This could involve purposeful selection of an intervention where these are known or seeking out this information for the selected intervention
	Guidance to sites	Providing guidance to local sites on intervention theory or core elements, or on how to adapt intervention
	Participation	Participation / engagement of; service users, providers, community, local organisational or government HR. This could be through various activities for example; consultations, partnerships, CBPR, local decision making
	Communication	Communication between individuals or at organisational levels
	Local decision making	Involvement of; local service users, providers, community, local organisational or government HR for decision making for adaptations. Autonomy given to local level for adaptations

	Feedback loops	Feedback loops or mechanisms in place to guide decision making for adaptations this could involve monitoring and evaluation at time points, planned consultations etc.
	Definition of roles	The transparent clarification and definition of roles and responsibilities for adaptation during scale-up
	Consideration of future adaptations and sustainability	Consideration of future adaptations and sustainability and actions planned to allow for this. This includes recognition of contexts changing overtime and actions planned to allow for this
	Create opportunities for learning	Creating opportunities for learning is purposeful activities that could assist in learning for implementers, organisational staff, the community or service users. It could relate to building capacity to complete adaptations, or learning of the context, adaptations or strategies used to address local fit. This could be formal e.g. through learning networks, or informal e.g. arranged through social networks
	Systems thinking	Systems thinking applies to an in-depth consideration of the complex links, relationships, inter-dependencies within a system. This may be difficult to capture however if an example reports use of systems thinking or describes this process it can be included as this
	Further actions to be added as identified	
Potential Contexts	Wider context	
	Political, socio-cultural and environmental factors	This is a broad heading that can capture elements of the wider system e.g. political, economic, environment that influence whether a mechanism fires. This heading will be added to and refined and learning progresses
	Community	
	Partnerships	This could be between community and an organisation. This could include the nature of the partnerships in terms of history and trust for example
	Organisational	
	Readiness	Where the organisation (or community) are ready for intervention and implementation, for example with resources, capacity in place, community sensitized to intervention, buy in for intervention exists etc. This could also capture a lack of readiness or rushing to scale
	Resources	Resources or lack of resources such as; financial, logistical or human resource availability
	Leadership	This could relate to strong leadership, or a lack of leadership which may influence adaptation and scale-up
	Organisation flexible and responsiveness to local needs	Organisation flexible and responsiveness to local needs. This could relate to where the organisation is open to receiving and acting on feedback
Interpersonal Relationships		

	Culture of respect	Culture of respect between individuals, or within an organisation. This could include placing value on the knowledge and opinions of those in the local setting
	Culture of trust	Culture of trust between individuals, or within an organisation. This could also relate to a history or relationship of trust built over time.
	Power imbalance	Power imbalance between individuals or organisations. This could relate to a power imbalance within a community setting limiting individual's participation, or could relate to top-down/bottom-up power imbalance between funders and an organisation, or between different levels of the health system
	Individual	
	Capacity to adapt interventions	Capacity to carry out actions needed to adapt and/or implement interventions
	Intervention characteristics	
	Factors relating to make up of the intervention	For example; relative advantage, compatibility, complexity, trialability and observability. This could also include whether the intervention was simple or complex
	Intervention theory and core components known	Theory and core components of intervention known and available to sites
	Further contexts to be added as identified	
Potential Mechanisms	Awareness	"Knowledge or perception of a situation or fact" ⁵ . This could relate to the local context, the need to adapt, the intervention itself or the scale-up or adaptation process
	Empowerment	The process of becoming more powerful or confident in the ability to do something ⁵ . This can include authority or power given to someone to do something
	Trust	"Firm belief in the reliability, truth, or ability of someone or something" ⁵ . Trust could relate to the intervention itself, the scale-up or adaptation process or trust between actors e.g. service users, organisation, implementers etc.
	Motivation	Intrinsic or extrinsic motivation towards the intervention, its adaptation or scale-up. Motivation is an internal process that may cause a desire or willingness ⁵ towards something this is not seen, however relating actions could be
	Support	This may capture support from an individual, community or organisation. They may approve of or encourage the intervention, the adaptation or scale-up process. This may also capture the concept of buy-in
	Commitment	"The state or quality of being dedicated to a cause, activity, etc." ⁵ . This could relate to a commitment to the problem (e.g. addressing the health problem), the intervention, adaptation or scale-up process. This differs from support as it relates to dedication or engagement and so it is more active than support alone

	Confidence	“The feeling or belief that one can have faith in or rely on someone or something.” ⁵ . Confidence relates more to self-assurance ⁶ or certainty in an ability of oneself or others. This could be confidence in the ability to adapt or implement the intervention, in the intervention itself or of other people’s ability to complete actions or goals for scale-up
	Further mechanisms to be added as identified	
Outcomes (Proximal)	Champions	Champions who support, encourage, commit to or drive the intervention and/or scale-up or adaptation process
	Ownership	A feeling or sense of ownership of the intervention and/or scale-up or adaptation process by an individual, community or organisation
	Consensus	Shared agreement or vision on the intervention, adaptation or elements of scale-up process
Outcomes (Distal)	Adaptations with local fit (acceptability, feasibility)	Adaptations made which are acceptable and/or feasible in local settings. This could be demonstrated by demand for intervention by service users, or where Interventions match local needs and resources
	Scale up with local fit	Intervention is scaled-up across sites with local fit where intervention is acceptable and/or feasible
	Sustainability	Intervention is continued to be delivered at sites or the outcome of the intervention is sustained at sites over a time. This intervention may be continually adapted and does not need to remain the same
	Further outcomes to be added as identified	

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Adapting Health Interventions for Local Fit when Scaling-up: A Realist Review Protocol

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ABSTRACT:

Introduction: Scaling-up is essential to ensure universal access of effective health interventions. Scaling-up is a complex process, which occurs across diverse systems and contexts with no one-size-fits-all approach. To date, little attention has been paid to the process of scaling-up in how to make adaptations for local fit. The aim of this research is to develop theory on what actions can be used to make adaptations to health interventions for local fit when scaling-up across diverse contexts that has practical application for implementers involved in scaling-up.

Methods and Analysis: Given the complexity of this subject, a realist review methodology was selected. Specifically, realist review emphasizes an iterative, non-linear process, whereby the review is refined as it progresses. The identification of how the context may activate mechanisms to achieve outcomes is used to generate theories on what works for whom in what circumstances. This protocol will describe the first completed stage of development of an initial programme theory framework which identified potential actions, contexts, mechanisms and outcomes that could be used to make adaptations when scaling-up. It will then outline the methods for future stages of the review which will focus on identifying case examples of scale-up and adaptation in practice. This realist review consists of six stages; (i) clarifying scope and development of a theoretical framework, (ii) developing a search strategy, (iii) selection and appraisal, (iv) data extraction and (v) data synthesis and analysis and (vi) further theory refinement with stakeholders.

Ethics and Dissemination: This review will develop theory on how adaptations can be made when scaling-up. Findings will be disseminated in a peer-reviewed journal and through stakeholder engagement as part of the research process. Ethical approval has been received through Health Policy and Management/Centre for Global Health Research Ethics Committee of Trinity College Dublin.

Abstract Word Count: 299

STRENGTHS AND LIMITATIONS OF THIS STUDY:

- The use of a realist review approach will allow for the exploration of the complexity of scale-up and adaptation in practice.

- We present an initial programme theory framework which identifies potential actions, contexts, mechanisms and outcomes that may influence scale-up and adaptation which is based on peer-reviewed literature and frameworks in the fields of fidelity, adaptation and scale-up.
- This protocol provides a detailed account of proposed methods for a realist review, including the supplemental files of a research logbook, coding and synthesis procedures, which may assist future researchers in options for approaches that can be taken and for addressing the issue of decision making and transparency for realist reviews.
- This study will utilise the inclusion of stakeholders for theory refinement in the later stages of the review, ensuring practicality of findings and dissemination through the review process.
- The scope of this review is ambitious within the time-frame, however in keeping with realist reviews this may be further refined throughout the stages in light of findings from the literature or by stakeholder consultation.

INTRODUCTION:

The process of scaling-up an effective health intervention is complex and occurs across diverse systems and contexts^{1 2}. It is estimated that only 14% of healthcare research makes it into real world settings^{3 4}. Therefore, many existing health problems could be addressed through scaling-up of interventions already known to be effective. For example, it is estimated that 85% of childhood deaths could be avoided in low and middle income countries through scale-up of existing health interventions like zinc and oral rehydration therapy treatment⁵. Currently scale-up has been estimated to take 15 years from pilot to national scale⁶. Scale-up is time consuming and challenging due to the complexity of implementing across diverse contexts where the population⁷, finances, resources and capacity⁸ may differ. The result is a growing discussion on the need to provide more evidence for how to address this important research-to-practice gap.

Scale-up, Adaptation and Fidelity

Scale-up can be defined as a purposeful expansion of a health intervention to a wider population^{1 9}. This could involve expanding geographically, or to a wider population within the same setting. Adaptations can be defined as deliberate and/or unintended changes to the intervention content,

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3 context or training and delivery¹⁰. As per the international classification of health interventions¹¹
4 , a health intervention can be defined as “*an act performed for, with or on behalf of a person or*
5 *population to assess, improve, maintain, promote or modify health, functioning or health*
6 *conditions*” (paragraph 1). When scaling-up it can be necessary to adapt for local contexts as
7 needs and resources may differ between scale-up sites^{7 12}. Adaptation has been seen as an
8 essential process to match community needs, organisation resources and to gain trust and
9 ownership by community¹³. By addressing and adapting for local fit, it can assist in successful
10 implementation and sustainability of an intervention¹². However, with adaptations there is also a
11 need to ensure fidelity to the intervention theory and essential components to ensure the
12 effectiveness of an intervention is not reduced or lost⁷.

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15 Fidelity has been described by Castro and colleagues¹⁴ as delivering the programme as intended
16 and tested, however they also noted there may often be a need to adapt to the target population¹⁴.
17 Fidelity can often be seen as a top-down (researcher, intervention developer) driven approach
18 and adaptation has been viewed as more of a community driven bottom-up approach (frontline
19 service providers, communities, individuals)¹⁵. However, when looking at fidelity it is
20 impossible to ignore potential necessary adaptations for local needs, and when looking at
21 adaptation to ignore how to maintain fidelity to the original intervention. With both proposed as
22 necessary when scaling-up across diverse populations and delivery systems⁷. In considering
23 fidelity it is suggested that any adaptations retain the underlying intervention theory and that the
24 essential components or active ingredients remain intact, with any changes made to match the
25 unique features of the setting^{13 15 16}. This opinion was shared by Aarons and colleagues⁷ in
26 relation to scale-up, and Chambers and colleagues¹² in relation to sustainability, where
27 identification of theory and essential elements of the intervention can facilitate adaptation
28 outside of these, and assist in avoiding a “voltage drop”¹², or the tendency for effectiveness to
29 taper with ongoing implementation.

30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 **The Need for Adaptation when Scaling-up**

51 Within complex systems, such as healthcare, applying a single approach in all settings is
52 unlikely to be effective, as it does not take into account the complex contextual environment
53 within which the intervention takes place¹⁷. Therefore, adaptations are important in terms of
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3 ensuring that the intervention content, context, and/or delivery strategy fits with local needs
4 across scale-up sites¹⁰. A tradeoff may need to occur between increasing scale and adapting to
5 maintain local values, local relevance, quality and sustainability¹⁸. Additionally, and given that
6 contexts are continually changing over time, allowing for adaptations with contextual changes is
7 needed to ensure sustainability of interventions¹². Specifically, adaptation has the potential to
8 enable implementers to match the needs of a more heterogeneous population; to simplify a
9 complex intervention; to focus on a specific problem or to expand to address multiple problems;
10 to increase ownership of an intervention; to adjust to a lack of available resources or
11 requirements made by agencies or funders; allow for additional applications of an intervention
12 and/or address a lack of knowledge of the intervention¹³. It is important to note that adaptations
13 may be intended or unintended^{10 19}, and may be positive or negative²⁰. With positive adaptations
14 supporting implementation and achieving desired clinical outcomes, while negative adaptations
15 could potential hinder or reduce these. Holliday and colleagues²⁰ put forward in the design and
16 testing of an educational intervention, that adaptations can be on a spectrum from acceptable to
17 unacceptable, and avoidable to unavoidable. Thus, some adaptations may be unavoidable for
18 local fit, however are acceptable as they maintain the intervention theory and essential
19 components. While others may be unacceptable as they change the underlying theory and
20 essential components, or avoidable in that they may not necessarily need to be adapted within
21 that setting.
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38 Although adaptation has been highlighted as a key contributing factor in addressing feasibility
39 and/or acceptability for local settings when scaling-up^{7 12}, adaptation is rarely documented as
40 part of the scale-up process^{1 21 22}. Often efforts to achieve scale-up can focus on the replication of
41 the originally tested pilot or feasibility study. Replication however, does not account for the
42 diverse social, political, and cultural contexts across scale-up sites. This results in a need for
43 more tailored approaches²³. There is a need to understand how an intervention may work in a
44 given context to allow for selection of approaches that are most likely to be effective in that
45 setting, thus avoiding interventions being deemed potentially ineffective and not achieving
46 scale-up²⁴. The need to adapt interventions for local settings has been put forward across the
47 health spectrum from maternal and child health²⁵, malaria prevention²⁶, HIV²⁷⁻²⁹, to mental
48 health³⁰. While some recent frameworks have supported the local development of adaptations
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3 when scaling-up, and suggested actions such as use of quality improvement methodology^{2 12}.
4 Unfortunately, there still remains minimal guidance on how to complete local adaptation, adding
5 to the difficulty in achieving and reporting of scale-up of health interventions with local fit^{1 31}.
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10 **Adaptations in Practice**

11 Despite its absence of documentation, adaptation has been discovered as naturally and
12 commonly occurring in the practice of scaling-up³². For example, within 44 preventive
13 interventions in a Substance Abuse and Mental Health Services (SAMHSA) national database in
14 the USA, over half of these had been adapted, suggesting that adaptation is more common than
15 not¹⁴. A study by Moore and colleagues³² looked at the adaptation of evidence-based
16 programmes in Pennsylvania for reducing delinquency and violence. Out of ten evidence-based
17 programmes with over 200 replications across the state, 44% reported making adaptations. It has
18 also been recognised that informal on-the-job adaptations are often made by professionals
19 working in, and deeply embedded in the context and who therefore may understand the
20 nuances³³. However, this informal on-the-job approach to adaptation is rarely discussed,
21 documented or evaluated, resulting in a dearth of information on how adaptation may impact the
22 intervention in the longer term.
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34 **Guidance for Adaptation and Scale-Up**

35 Within the implementation and scale-up literature there are many models and frameworks
36 mentioning the need for adaptations, for example the AIDED and ExpandNet process
37 frameworks^{1 34}. Despite growing recognition of the importance of adapting across diverse local
38 settings, along with evidence that adaptations are occurring in practice^{14 32 33}, there is minimal
39 guidance on what and how specific actions (for example transferring decision making to local
40 level, generation and use of local data or engagement of the community) can be used to achieve
41 adaptations when scaling-up, and even less guidance on *how*, *why* and *when* to choose one
42 method over another across different contexts. Moreover, while there is some guidance available
43 for implementers on adaptations, these guidelines are not specific to scale-up, and most existing
44 guidance on adaptation are based in the field of substance abuse prevention and HIV behaviour
45 change interventions^{13 19 35-38}. These were largely designed for high-income country contexts and
46 some of this guidance requires highly skilled, and resource heavy processes. Additionally some
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3 guidance suggests involving the original intervention developers, and at times promoting
4 redesign and testing of the intervention³⁷ which may not be feasible at multiple diverse sites
5 when scaling-up. Previous scale-up and sustainability frameworks have promoted adaptation for
6 local fit^{7 12}, however there is a need for more guidance on how to achieve this. A previous
7 review explored the process at scale-up of complex interventions³⁹, however did not specifically
8 address adaptations for local fit when scaling-up. Therefore, while acknowledging the
9 importance of adaptation for local fit there is minimal guidance for implementers on what
10 actions can be used to achieve adaptations when scaling-up, by what mechanisms these may
11 work and how the context may influence this. Therefore, there is a need to build on current
12 knowledge of scale-up.
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22 **Research Questions**

23 What are the actions that can be used to guide adaptations when scaling-up healthcare
24 interventions?
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26 How do these actions work (i.e. by what mechanisms, and in what contexts)?
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30 **Aims and Objectives**

31 The aim of this research is to develop theory on what and how actions can be used in different
32 contexts to make adaptations to health interventions for local fit when scaling-up across diverse
33 contexts that has practical application for implementers involved in scaling-up.
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39 Objectives:

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41 ➤ Identify what adaptations are being made in practice when scaling-up health interventions
42 for local fit.
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44 ➤ Identify what actions are used to achieve adaptations when scaling-up health interventions
45 for local fit.
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47 ➤ Discover how these actions work by uncovering what mechanisms are triggered, in what
48 contexts, to achieve adaptations when scaling-up health interventions for local fit.
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50 ➤ To put forward theories on what actions can be used, and how these actions may work to
51 achieve adaptations when scaling-up health interventions for local fit, by identifying demi-
52 regularities within the uncovered contexts and mechanisms.
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METHODS AND ANALYSIS:

Realist Review Methodology

Realist review is a methodology for evidence synthesis that uses a theory driven interpretive approach to explain findings^{40 41}. It aims to provide an explanation of what works, for whom and why, in what circumstances⁴². It allows for exploration of the complexity of a topic with a focus on theory generation that may be applicable in the setting under study, but also applicable in wider settings through development of theory of “middle-range”^{40 43}. Realist review methodology allows for inclusion of a wide body of evidence including grey literature sources⁴⁴. It supports stakeholder involvement throughout the stages of the review to inform the scope of the review, to develop and refine theory⁴¹ and/or assist in dissemination⁴⁵ of findings.

Realist review focuses on causation, with identification of where an intervention or action under certain contextual conditions (C), may trigger a mechanism (M), to achieve a given outcome (O)^{40 46}. It completes this through development of context-mechanism-outcome configurations (CMOCs)⁴², which are central to the analysis and theory building process with mechanisms often seen as the integral link between the context and the outcome⁴³. They can uncover the “why” a given outcome may have occurred. Dalkin and colleagues⁴⁶ conceptualised mechanisms as either resources or reasoning. They put forward that a mechanism can be a resource which can be introduced in a context, which can trigger a mechanism in the form of response or reasoning, resulting in an outcome. However, mechanisms may only activate in specific contextual conditions with the context as acting like a dimmer switch⁴⁶. Within optimal contextual conditions mechanisms are triggered or “fire”, and with sub-optimal conditions mechanisms may fire to a lesser degree or not at all⁴⁶. It is also acknowledged that actions may influence and change the context, which in turn may influence whether and how a mechanism fires.

In the current research, we view actions that were carried out to achieve adaptations when scaling-up (for example generation of evidence or participation of stakeholders), as a mechanism in the form of a resource. These actions, under the optimal contextual conditions, may trigger a mechanism in the form of reasoning or response (for example awareness or commitment), which in turn may generate outcomes. For this research outcomes can be proximal or distal. With distal

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3 outcomes relating to the overall aim for example adaptations with local fit or sustainability as
4 reported by the evidence, and proximal outcomes relating to those that may occur prior to this,
5 for example local ownership of the intervention or consensus for adaptations.
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10 Demi-regularities (semi-predictable patterns occurring in the CMOCs) can further assist in
11 explanation of the findings. Abductive reasoning can be used, which Jagosh and colleagues⁴⁷
12 described as the “*iterative process of examining evidence and developing hunches or ideas about*
13 *the causal factors linked to that evidence*” p5. Abductive reasoning could be discussed as
14 explaining a finding from both the seen and unseen, and drawing from theoretical perspectives to
15 provide possible explanations for an outcome^{48 49}. This can involve recontextualizing or
16 redesccribing explanations based on interpretations⁴⁸. Retroduction can also then be used to
17 situate the findings and put forward what causal pathways and conditions may need to be present
18 for the phenomenon of interest to occur⁴⁸.
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27 A realist review methodology was chosen as appropriate to address the study objectives for four
28 reasons. Firstly, within scale-up research, realist review methodology allows for in-depth
29 consideration of how actions can be influenced by contextual factors (e.g. resource availability,
30 level of perceived need for intervention in a local setting etc.) to trigger mechanisms (e.g. trust,
31 commitment, awareness) to generate desired outcomes (e.g. local ownership, feasible and
32 acceptable adaptations of a health intervention) leading to successful scale-up and local fit.
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34 Second, realist review methodology was chosen as it recognises the use of multiple evidence
35 sources, which was considered particularly important for scaling-up. While not prioritised on a
36 traditional hierarchy of evidence, grey literature reports may contain valuable information on the
37 scale-up process. Third, stakeholder involvement can also assist in validation and refinement of
38 theory⁵⁰ and it has been put forward by Brennan and colleagues⁴¹ that involvement of
39 stakeholders can provide a “reality check” as to whether the findings are consistent with
40 experience and knowledge from practice. Involvement of stakeholders with experience in
41 adaptation and scale-up through research and practice, may assist in ensuring the findings are
42 practical and of utility to implementers in the field. Finally, realist review methodology has been
43 previously successfully used to explore the process of scaling-up complex healthcare
44 interventions³⁹. This allowed for an in-depth analysis of how complex health interventions were
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3 scaled-up across three case studies, identifying active mechanisms that were needed to achieve
4 scale-up, and suggesting how the context may have influenced the scale-up across these cases.
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8 9 **Stages of the Realist Review**

10 This protocol is based on the five stages of realist review by Pawson and colleagues⁴⁰, with the
11 addition of a further stage of stakeholder involvement for theory refinement, which has been put
12 forward by previous reviews^{41 51} (please see figure 1, adapted from Molnar and colleagues⁵² and
13 Groot and colleagues⁵³). These stages are not necessarily carried out in a linear process as the
14 stages are iterative and may overlap and inform each other as learning on the topic progresses
15 and theory refinement takes place.
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23 **Figure 1. (see legend at end of manuscript)**

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26 Stage one of this review has been completed to clarify the scope of the review and develop the
27 initial theoretical framework. This protocol paper will briefly describe this first stage process
28 and how findings were used to develop the protocol for the following stages 2-6 which are to be
29 carried out from June 2018 to March 2019.
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35 **Stage 1. Clarifying the Scope of the Review and Developing a Theoretical Framework**

36 According to Pawson and colleagues⁴⁰, a realist review begins with clarifying the scope of the
37 review and the elicitation of initial rough theories in the form of an initial programme theory
38 (IPT). The IPT can provide a map of the areas to be investigated and gives a structure for data
39 synthesis³⁹. These can be further refined, tested and added to as the synthesis progresses⁴³.
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45 **Developing the IPT Framework**

46 For this research, an IPT framework was developed which was a theoretical framework to guide
47 the review. This will be refined as the review progresses in future stages. The methodology and
48 format of the IPT framework to guide this review was informed by Willis and colleagues³⁹
49 realist review, which focused on the process of scale-up of complex interventions, identifying in
50 their initial IPT framework actions, contexts and outcomes. After analysis and synthesis of three
51 case studies they further identified what mechanisms were triggered to achieve scale-up of
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3 complex interventions and what contexts influenced this. Therefore, the Willis and colleagues³⁹
4 realist review provided an appropriate guide to inform the methodology for the IPT development
5 for this review. In light of this method, this study developed an IPT framework focusing on what
6 potential actions, contexts, mechanisms, distal outcomes and proximal outcomes may be of
7 relevance to scale-up and adaptation. A particular focus of this IPT framework was the
8 identification of potential actions (e.g. definition of roles, use of feedback loops etc.), and how
9 these can achieve the outcome of adaptation for local fit. This IPT framework will provide a
10 theoretical map for further exploration in the following stages of the review.
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19 Purposeful and iterative searching was undertaken for this first stage of the realist review to
20 inform the content of this IPT framework³⁹. An initial scoping search was undertaken for scale-
21 up and adaptation in healthcare to get an overview of the available literature in the field. There
22 was a large volume returned with many articles discussing the need to adapt for local fit,
23 however without giving guidance for how, why or when to complete this when scaling-up. As a
24 result, a decision was made to particularly focus on guidance and frameworks relating to scale-
25 up, adaptation and fidelity to prioritize identification of what actions could be taken (for example
26 create opportunities for learning, giving guidance to sites etc.) to make adaptations when
27 scaling-up. Guidance and frameworks were identified from the initial scoping search results, in
28 addition to use of reference lists, in particular of recent reviews in the field of implementation
29 and scale-up by Milat et al⁵⁴, Subramanian et al⁵⁵, Nilsen et al⁵⁶, and also use of the ExpandNet
30 bibliography. This was complimented by input from the review team (with backgrounds in
31 global health and health systems), and two further experts (in the fields of fidelity and of
32 implementation research) to highlight and direct to any further relevant literature (figure 2). The
33 frameworks included can be seen in supplemental file 1.
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46 **Figure 2. (see legend at end of manuscript)**
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50 A challenge of developing an IPT framework in a realist review is finding a level of abstraction
51 that allows the recognition of demi-regularities among the detail and variation in the evidence,
52 whilst being specific enough to answer the review question³⁹. The IPT framework went through
53 revisions aiming to keep the actions, contexts, mechanisms and outcomes that were deemed
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3 most relevant to adaptation and scale-up, rather than those relating to scale-up in general.
4 Decision making was recorded in the research logbook (see supplemental file 2 for an example
5 from the research logbook). Causation between the potential actions, contexts, mechanisms and
6 outcomes were not made at this stage and will be added iteratively as the review progresses and
7 scope is refined. The contexts were placed under headings adapted from the socio-ecological
8 model⁵⁷ to aid organisation. The IPT framework can be seen in figure 3 (please see supplemental
9 file 1 for the guidance and frameworks identified which informed this).

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17 **Figure 3. (see legend at end of manuscript)**
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20 The IPT framework will assist in; (i) initial coding of actions, contexts, mechanisms and
21 outcomes for data extraction in stage 4, and will inform a codebook for reviewers (while also
22 allowing for new actions, contexts, mechanisms and outcomes to emerge), (ii) providing an
23 initial framework for the synthesis to assist in organisation of the CMOCs and demi-regularities
24 in stage 5 (see figure 1 for outline of stages). As mentioned, coding and synthesis of findings
25 will be guided by this IPT framework, however new actions, contexts, mechanisms and
26 outcomes will be identified from the data and added to this as they emerge. Thus, this review
27 will add to and refine the framework as the stages progress.
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36 **Clarifying the Scope of the Review**
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38 As learning progressed it was noted that much guidance and frameworks in the implementation
39 and scale-up literature in healthcare may be untested and largely theoretical in nature. Therefore,
40 the scope of the review was refined to include specific examples of scale-up and adaptation in
41 practice. Decision making while clarifying the scope of the review was documented in the
42 research logbook (see example in supplemental file 2). The scope of this review may be further
43 refined in an iterative process as the review progresses, as per realist guidance⁴³, and will be
44 documented in the research logbook for transparency. This iterative focusing of the review may
45 be carried out based on findings from the examples of scale-up in practice and in consultation
46 with stakeholders.
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3 The remaining section presents the protocol for stages 2-6 detailing the methods that will be
4 used throughout the remainder of the realist review which will be carried out from June 2018 to
5 March 2019. An overview of the stages and details can also be seen in figure 4.
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10 11 **Stage 2. Search strategy**

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13 Stage 2 will involve a search for examples of scale-up and adaptation in practice. Scoping and
14 pilot searches were completed throughout stage one and a librarian was consulted to help inform
15 the selection of databases and concept headings for use in stage 2. A systematic search will be
16 completed using the concept headings of; scale-up, context (contextualize, adapt, tailor, redesign
17 etc.) and healthcare. Search terms will be adapted for each database. Search databases will
18 include: PubMed, CINAHL, Global Indicus Medicus (World Health Organization library
19 including both academic and grey literature), SCOPUS, EMBASE, and Psychinfo. For further
20 grey literature searching, Social Care Institute for excellence (SCIE), Open Grey and GreyLit will
21 be used. Searching of reference lists from identified papers will be carried out along with
22 forward citation searching using Google Scholar. Additionally, the corresponding author from
23 the articles selected will be contacted to identify other articles on their scale-up example that
24 could be relevant to answering the research question.
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40 Further rounds of searches may be completed in later stages of the review in keeping with the
41 iterative nature of realist reviews⁵⁰. This may be to search for further evidence or wider theories
42 that may explain findings and assist in theory refinement. The need for searches, search terms
43 and strategies will be identified as the review progresses. These will be documented in the
44 research logbook, as they occur.
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52 **Stage 3. Study Selection, Criteria and Procedures**

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54 Inclusion Criteria
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3 All articles and sources obtained from stage two will subsequently undergo further review for
4 inclusion based on three criteria. To be retained for further review sources must describe; (i) an
5 example of scale-up of a healthcare intervention(s) in practice, (ii) adaptations that were made
6 for health intervention(s) to fit local settings, and (iii) discuss in detail actions for adapting
7 health intervention(s) at scale. Both scale-up at national and sub-national levels will be included
8 once the intervention was being purposefully expanded to a new wider population group in
9 practice. For inclusion in this study, adaptations will need to have occurred during scale-up to
10 adapt for local contexts, and actions used (for example local decision making) have been
11 documented in detail. Articles discussing the adaptations without describing what actions were
12 used to adapt the intervention will also be excluded. Studies where the adaptations occurred
13 during the RCT or pilot stage, and the same intervention was rolled out nationally (or sub-
14 nationally) without further adaptations to the content, context or delivery, will be excluded. Both
15 positive and negative adaptations may be included. Please see supplemental file 3 for more
16 details.
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29 As scale-up occurs over a long-time period, with an estimated 15 years to reach national scale,
30 no time limit will be placed on evidence⁶. Keeping the time-period open allows for documents
31 published at the beginning of scale-up projects to also be captured in the search. Searches will be
32 carried out in English. Languages will be limited to those spoken by the review team; English,
33 Spanish, Portuguese, and French.
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39 Study Appraisal: Relevance and Rigour

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41 As realist philosophy does not exclude evidence based on type of study, RAMESES guidelines
42 will be applied to assess the relevance and rigour of the studies⁴³. As discussed by Pawson⁴⁴,
43 useful information can arise from studies which may not be prioritised on a traditional hierarchy
44 of evidence. Each retained evidence or document will be assessed in terms of its relevance to the
45 research question and whether it is rigorous enough to hold value to theory building, testing or
46 refinement. Any exclusions based on these criteria will be documented in the research logbook.
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53 Procedures

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3 Title and abstract screening will be completed. Following this two reviewers will complete full
4 text screening independently, with a third reviewer available to resolve any conflicts should they
5 arise. Depending on the number of documents with examples of scale-up returned, further
6 refinement of the scope of the review may be decided by the review team. This will be
7 documented in the research logbook. For further searches as they arise in an iterative fashion,
8 selection criteria will be decided by the review team and will be based on the ability of studies to
9 further refine theory.
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18 **Stage 4. Data extraction**

19 The following data will be extracted from the scale-up examples identified in stage 3; (i) what
20 adaptations were made, (ii) what actions were used to make these adaptations, and (iii) the
21 contexts, mechanisms and outcomes that relate to these actions (in the form of CMOCs). A data
22 extraction form and codebook will be developed from the IPT framework to guide data
23 extraction for each scale-up example (see supplemental files 4 and 5 for draft versions, noting
24 that these will be refined as the review progresses). Where multiple documents relate to the same
25 example of scale-up, these will be combined into one data extraction form for that case example,
26 and the supporting quotes referenced as to which document it originated from.
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35 (i) Adaptations

36 It has previously been identified that adaptations are often poorly reported in research^{10 33 58 59}.
37 While some adaptations may reflect small, surface-level changes, others may reflect large deep
38 structural adaptations. To systematically capture the type of adaptations made, Stirman and
39 colleagues¹⁰ taxonomy of modifications will be used to assist categorisation of adaptations,
40 including what type of adaptations were made, who made them and at what level.
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47 (ii) Actions

48 A description of what action(s) was/were carried out to achieve the adaptation(s) will be
49 extracted from the examples to the data extraction form. These may relate to the potential actions
50 identified in the IPT framework and resultant codebook, or may reflect new actions emerging
51 from the data. Any new actions will be categorised and added to the codebook as they emerge.
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5 (iii) CMOCs relating to the Actions

6 Contexts, mechanisms and outcome configurations (CMOCs) relating to the actions and
7 adaptations will be extracted from each case example. Note that a case example may contain
8 multiple sources (i.e. a peer reviewed article and a national report on the same scale-up) or just
9 one source. While some CMOCs may relate to the potential actions, contexts, mechanisms and
10 outcomes identified in the IPT framework and resultant codebook, others may reflect new
11 CMOCs emerging from the data. Quotes and descriptions will be taken from the text to support
12 these CMOCs. Abductive reasoning will also be applied for any inferred contexts or
13 mechanisms and the reasoning stated on the data extraction form^{39 47}.
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22 Once the above steps are completed for each case example, an example will be presented to
23 members of the Irish Realist Researcher Group for feedback on the coding procedures to inform
24 refinements of the methods and codebook as needed (supplemental files 4 and 5). This is a group
25 of 8-10 researchers with experience in realist methods. Following this, the completed data
26 extraction forms for each case will be reviewed again by the first reviewer using the updated
27 coding procedures. A second reviewer will then take a random sample of 10% of the scale-up
28 case examples for extraction following the same coding procedures using a data extraction form
29 for these case examples. The reviewers will then discuss and compare the CMOCs extracted and
30 reach agreement, if differences occur. Following this, the remaining data extraction forms for all
31 case examples will be reviewed by the second reviewer and agreement reached between
32 reviewers on the CMOCs, including any inferred contexts or mechanisms and reasoning for the
33 same. A third reviewer will be available for input or to resolve any discrepancies between the
34 first and second reviewer.
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50 **Stage 5. Data Synthesis**

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52 The findings from each example of scale-up will then be synthesized across cases. The data
53 extraction forms from each case example will be uploaded and coded in NVivo, using the IPT
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3 framework and resultant codebook to guide initial codes. New codes will be added or refined as
4 they emerge, thus adding to the theoretical framework as the synthesis progresses.
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9 The type of adaptations made will be synthesized across cases to give a picture of what
10 adaptations are happening in practice. Then the actions used to achieve adaptations will be
11 synthesized. To explore how these actions achieved adaptations, the CMOCs identified from
12 each case example will be coded in NVivo to look for demi-regularities occurring across the
13 different case examples. Therefore some, but not all, of the CMOCs from each case example
14 may be identified based on whether demi-regularities were seen and if they add value to theory
15 building and refinement at this stage. These results will be synthesized to make further sense of
16 the findings and refine the theory. The following conceptual tools may be used as needed to
17 assist in this theory refinement^{43 60}; (i) juxtaposing, where evidence from one setting may aid
18 explanation of outcomes from another, (ii) reconciliation, where differences are identified to
19 explain findings which may contradict each other, (iii) adjudication between studies, (iv)
20 consolidation for example by building multiple explanations, and (iv) situating by identifying
21 what may happen in one setting compared to another. Reasoning will be documented in a
22 research logbook.
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35 Numerous theories may emerge from the literature. Therefore, further focusing of the review in
36 an iterative fashion may be required. Focusing on particular theories may be guided by demi-
37 regularities occurring across examples. However, it is acknowledged that frequency of
38 occurrence may not necessarily correlate to importance in practice. Therefore, if certain areas are
39 highlighted as particularly critical for successful adaptation by the literature this may also assist
40 focusing of the review. This will be further be guided by stakeholder involvement to give a
41 “reality check”⁴¹, aiming to ensure the review will focus on what is of relevance and importance
42 to those in practice. Decision making for this process will be recorded in the research logbook
43 for transparency.
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52 Abductive reasoning⁴⁷ and retroduction⁴⁸ will be used to guide the review to interpret and
53 explain the findings and put forward contextual conditions that may need to be present for the
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3 outcomes to occur. As part of this process, wider substantive theory will be searched for to assist
4 in explanation of the findings and for further theory refinement⁴³. This will lead to the
5 development of theory relating to how adaptations can be made when scaling-up.
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10 11 **Stage 6. Stakeholder Involvement**

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13 Finally, stakeholders with experience of adaptation and scale-up in both research and practice
14 internationally will be sought and contacted to assist in theory refinement. Initial stakeholders
15 will be identified and contacted by the research team. Stakeholders will also be asked to identify
16 further persons in their field of expertise. Initial review findings will be presented to
17 stakeholders and their opinions sought, based on their practical knowledge and expertise⁴¹. The
18 resultant theories may be further refined and the review focused based on learning from this
19 process⁶¹. This involvement of stakeholders with experience in adaptation and scale-up through
20 research and practice, will assist in focusing the review and its findings, and thus may ensure the
21 findings are useful in practice for implementers in the field. The involvement of stakeholders
22 will allow for initial dissemination of the research findings. This stage may inform further
23 searches through focusing of the review as needed in an iterative fashion.
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38 **Patient and Public Involvement**

39 Members of the public and patients were not involved in the development of this protocol.
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43 **Figure 4. (see legend at end of manuscript)**

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47 A summary of the stages and proposed actions for this realist review can be found in figure 4
48 below. The above stages will be carried out as per realist review methodology in an iterative
49 fashion, allowing for refinement of theory and the scope of the review and subsequent searches
50 as learning progresses. Any iterations to the above protocol will be captured in the research
51 logbook and reported in the final dissemination of the research. The above stages set out to
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3 achieve the study's objectives of discovering what actions can be used to achieve adaptations
4 when scaling-up health interventions for local fit, by what mechanisms do these actions work,
5 and what contextual factors may influence this. It is hoped this approach will provide practical
6 and useful findings for implementers in the field of scale-up.
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11 12 13 **ETHICS AND DISSEMINATION**

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15 Ethical approval for this study was received from the Health Policy and Management and Centre
16 for Global Health Research Ethics Committee of Trinity College Dublin, Ireland in March 2017.
17 The dissemination of the findings of this review will follow the RAMESES reporting
18 guidelines⁶². The results of this review will be used to put forward theory to explain what and
19 how actions can be used to influence and achieve adaptations when scaling up for local fit. Use
20 of a realist review methodology, with the stages outlined above, allows for an exploration of the
21 complexity of the process of scale-up across diverse contexts, and the identification of the
22 contextual factors that may influence actions, and by what mechanisms these may work. By
23 including stakeholders with experience in the field of adaptation and scale-up, it is hoped this
24 will add to theory development and refinement, and will help ensure that findings have practical
25 utility for implementers. The findings of this study will be published in a peer-reviewed journal,
26 through conference presentations and dissemination through stakeholder involvement in theory
27 refinement. The review will also be published as a PhD thesis, available through Trinity College
28 Dublin library.
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47 **AUTHORS CONTRIBUTIONS:**

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49 JP is lead reviewer completing this study as part of a PhD. JP developed the general study
50 concept and outline. JP completed the literature review and development of the IPT framework
51 and led the iterations. JP developed the search strategy, and methods for selection, appraisal,
52 extraction, synthesis, and stakeholder involvement. BG contributed to IPT framework
53 refinement, the methods for data extraction and coding processes using NVivo, and the methods
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3 for synthesizing across cases. FV contributed to the general study concept and design, clarifying
4 the scope of the review and refinement of the IPT framework. ET contributed as an expert in
5 fidelity in stage one and assisted in refinement of the IPT framework. ET contributed to the
6 methods of the search strategy and methods of the data extraction and synthesis stages, including
7 the role of second reviewer. HM contributed to conceptual study design, and clarifying the scope
8 of the review by refinement of research question and IPT framework. EM contributed to
9 conceptual study design, refinement of research question and IPT framework, the search
10 strategy, refinement of the data extraction form, and contributed to the method of involvement of
11 stakeholders for theory refinement. JP wrote the first draft of the paper, which was reviewed and
12 contributed by all other authors. All authors approved the final version.
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24 Centre for Global Health, Trinity College Dublin for lending her expertise to stage one of this
25 review.
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31
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34 training.
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40 **COMPETING INTERESTS STATEMENT:**

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42 The authors declare there are no competing interests.
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46 **Legend for Figures**

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48 **Figure 1.** Overview of stages of the realist review. Based on Pawson and colleagues⁴⁰. Adapted
49 from Molnar and colleagues⁵² and Groot and colleagues⁵³. These stages are non-linear and will
50 be carried out in an iterative fashion with theory refinement occurring throughout.
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55 **Figure 2.** Development of the IPT Framework
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Figure 3. IPT Framework. Potential actions, contexts, mechanisms and outcomes identified from stage one for further exploration in future phases.

Figure 4. Summary of stages and proposed actions for the realist review.

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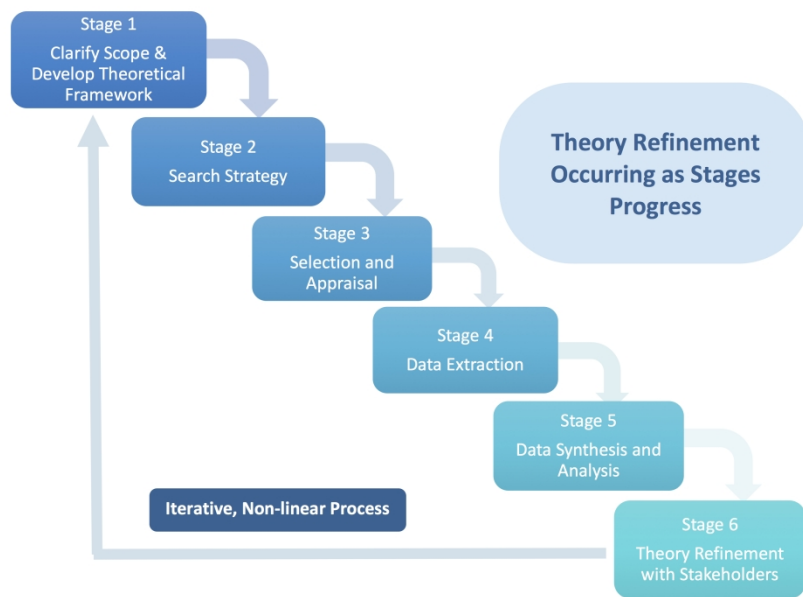


Figure 1. Overview of stages of the realist review. Based on Pawson and colleagues⁴⁰. Adapted from Molnar and colleagues⁵² and Groot and colleagues⁵³. These stages are non-linear and will be carried out in an iterative fashion with theory refinement occurring throughout.

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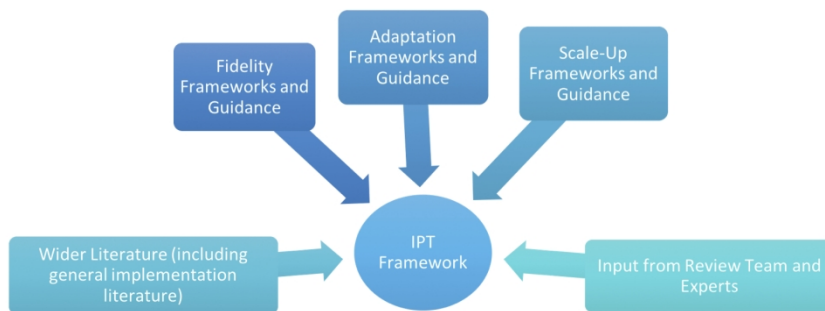


Figure 2. Development of the IPT Framework

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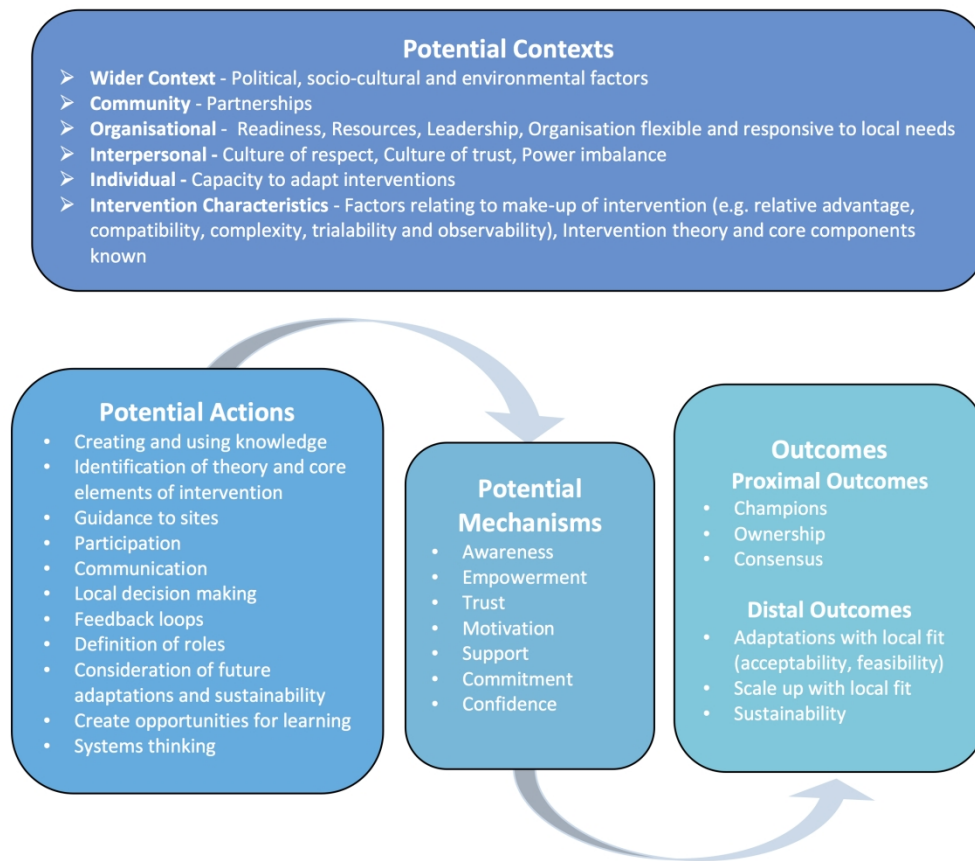


Figure 3. IPT Framework. Potential actions, contexts, mechanisms and outcomes identified from stage one for further exploration in future phases.

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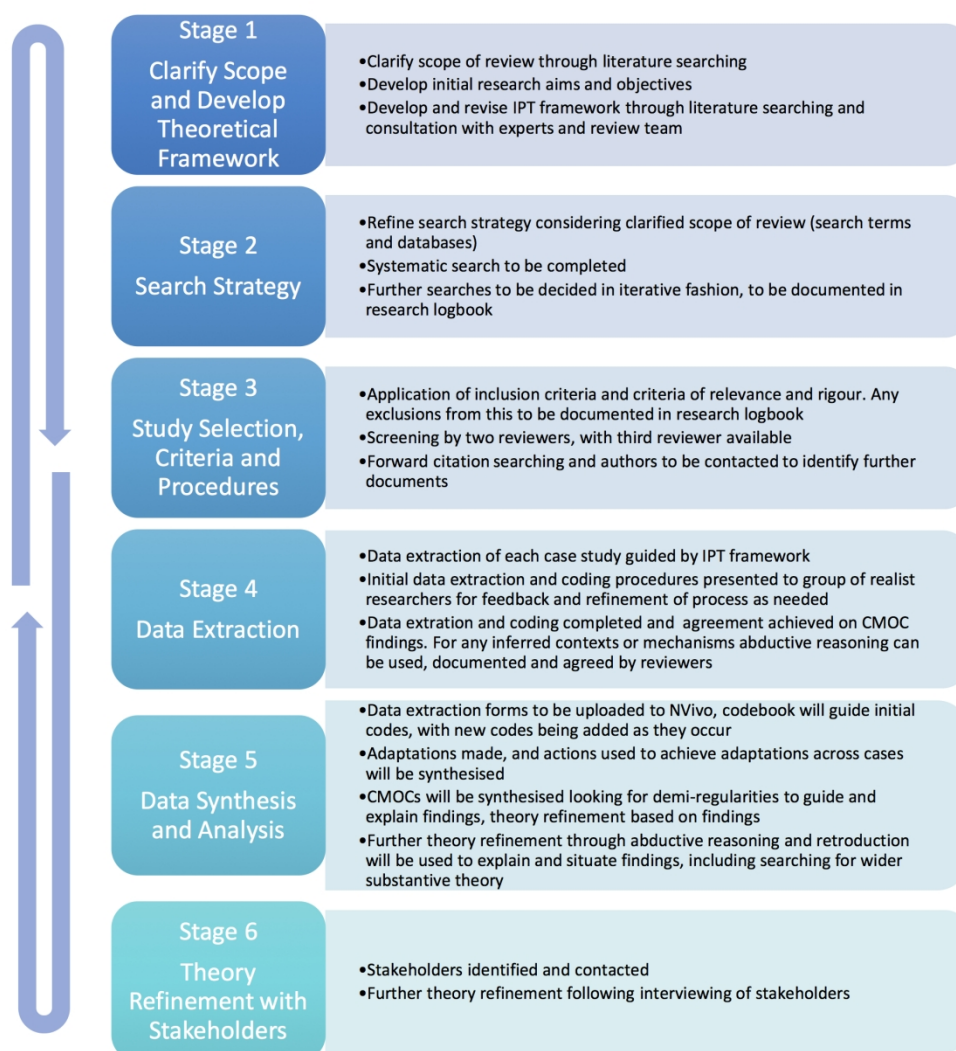


Figure 4. Summary of stages and proposed actions for the realist review.

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Supplemental File 1. Guidance and frameworks identified which assisted in IPT development

Guidance and Frameworks Identified	
Scale-Up	<p>Scale-up frameworks are categorised into; determinant frameworks, process models and evaluative frameworks (depending on their primary focus) as per Nilsen ¹;</p> <p>Determinant frameworks</p> <ul style="list-style-type: none"> • Scaling up health service innovations: a framework for action, ExpandNet^{2,3} • Dynamic Sustainability Framework (DSF)⁴ • A framework for understanding the constraints of scaling up⁵ • Scaling up; A proposed framework for success⁶ • The non-adoption, abandonment, scale-up, spread, and sustainability (NASSS) for patient facing health and care technologies⁷ • The learning process approach⁸ • Conceptual framework for priority setting in health⁹ <p>Process Models</p> <ul style="list-style-type: none"> • Scaling up Management (SUM) Framework¹⁰, updated by¹¹ • Practical guidance for scaling up health service innovations, ExpandNet¹² • Nine steps for delivering a scale up strategy, ExpandNet¹³ • Beginning with the end in mind, ExpandNet¹⁴ • SEED Scale¹⁵ • A guide to scaling up population health interventions¹⁶ • IHI framework for going to full scale¹⁷ • A guide to fostering change to scale up effective health services¹⁸ • AIDED model for dissemination, diffusion and scale up of family health innovations in LICs¹⁹ • Program assessment guide for scaling up nutrition interventions²⁰ • Scaling up breastfeeding²¹ • MuSCLE framework²² <p>Evaluative Frameworks</p> <ul style="list-style-type: none"> • Scaling out²³ <p>Not specific to scale-up but highlighted to be of relevance to implementation and adapting for local context were;</p> <ul style="list-style-type: none"> • Consolidated Framework For Implementation Research (CFIR)^{24,25} • Promoting Action on Research Implementation (PARIHS) Framework²⁶ • Integrated i-PARIHS Framework²⁷ • Knowledge to action framework²⁸ • Implementation Research (IR) Toolkit²⁹ • Taxonomy of implementation outcomes³⁰ • RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) Framework^{31,32} • Methods to Improve the Selection and Tailoring of Implementation Strategies³³

Adaptation	<ul style="list-style-type: none"> • Elements to consider in cultural programme adaptation³⁴ • Finding the balance program fidelity and adaptation in substance abuse prevention³⁵ • Key principles for adapting research based interventions in HIV³⁶ • Intervention mapping to adapt an effective HIV, sexually transmitted disease, and pregnancy prevention programs³⁷ • ADAPT MAP draft guidance for adapting HIV interventions³⁸ • ADAPT-ITT model for adapting EBI for HIV³⁹ • Replicating effective programs (REP) framework⁴⁰ • ADAPTE guidelines⁴¹
Fidelity (including Intervention Development and Testing)	<ul style="list-style-type: none"> • Bauman's parameters for consideration in intervention development⁴² • The conceptual framework for adaptive interventions⁴³ • NIH Behaviour Change Consortium (BCC) fidelity concepts⁴⁴ • Comprehensive intervention fidelity guide⁴⁵ • Carroll's conceptual framework for implementation fidelity⁴⁶ • Hasson's modified conceptual framework for implementation fidelity⁴⁷ • The modified Carroll's fidelity framework⁴⁸ • Fidelity variation concepts from ASSIST RCT⁴⁹ • Figuring out fidelity⁵⁰ • Contextualised Interventions⁵¹ • Medical Research Council (MRC) guidance for process evaluations⁵² • The conceptual model for translating evidence based Interventions into community Settings⁵³ • Template for Intervention Description and Replication (TIDieR) guidance⁵⁴ • RE-AIM framework^{31 32}
Some examples from the wider literature (including general implementation literature and theories)	<p>Some examples of wider literature used to also inform IPT Framework (please note this is not comprehensive and all wider literature is referenced in the full research logbook available on request);</p> <ul style="list-style-type: none"> • Mechanisms for scale-up by Willis and colleagues⁵⁵ and large system transformation in healthcare by Best and colleagues⁵⁶ • Barriers and facilitators to scale-up, Norton and Mittman⁵⁷ • Diffusions of innovation theory, Rogers⁵⁸ • Complex adaptive systems theory, Paina and colleagues⁵⁹

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Supplemental File 2. Examples from Research Logbook for Recording Decision Making

1. Example from Research Logbook of Decision Making for Clarifying Scope of Review

Source: Fidelity, adaptation and scale-up literature from stage 1	Thought process, decision making	Clarified Scope
Adaptation guidance and frameworks mainly from high income country contexts, with a focus on HIV and substance abuse prevention. Many contain a resource heavy and highly skilled process, with some involving research institutional partnerships and intervention developers.	These may not be feasible at scale, need to learn from what is happening in practice during scale-up and adaptations.	Decision to focus on examples of scale-up in practice for stage two.
Despite recognition of the need to adapt, there is a lack of clear guidance in scale-up literature and frameworks on what actions to take when adapting for local fit.	Unable to refine question to a specific action or actions for adapting when scaling-up. Decision to keep scope of review broad at this stage to capture any actions that were reported in the examples in practice. This allows for the benefit of identifying what any and all actions that are being used in practice when scaling-up. The scope of the review could be further refined after discovery of this.	Decision to keep scope of review broad at this stage to capture <u>any actions</u> that were reported when adapting during scale up in the examples.

2. Example from Research Logbook of Decision Making for IPT framework

Source: Wider Literature Search (including general implementation literature)	Thought process, decision making	Inclusion in IPT Framework
<ul style="list-style-type: none"> • Funding and power imbalance, funding available for specific evidence based Interventions¹, choosing intervention based on funding² • Power dynamics influencing whether people could meaningfully participate (e.g. male dominance)³ • Scale free networks, power imbalance and influence⁴ 	<p>Power dynamics came up in the general implementation literature in addition to the within the scale-up frameworks.</p> <p>This was discussed in relation to funders and a potential top down power imbalance leading to selection of certain interventions or adaptations based on available funding. It was also discussed in relation to being able to meaningfully participate being limited by power dynamics within a community. Complex adaptive systems theory also speaks of scale free networks which could relate to certain people within networks being particularly influential or powerful.</p>	As a result, “power imbalance” was included in the IPT under contexts.

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Supplemental File 3. Suggested Concept Headings and Databases & Inclusion Criteria for Stage Two.

Suggested Concept Headings for Search Stage Two

1. Scale-up
2. Context (contextualize, adapt, tailor, redesign etc.)
3. Health (may also be used as a concept to further refine depending on the database)

MeSh headings, controlled vocabulary and keywords will be identified for each database as appropriate for stage two.

Suggested Databases

- Pubmed
- Cinahl
- Global Indicus Medicus
- SCOPUS
- Web of Science
- EMBASE
- Psycinfo
- Grey Lit
- Social Care Online (SCIE)
- Open Grey

For identified articles:

- Google scholar will be used for forward citation searching
- The corresponding author from the articles selected will be contacted to identify other articles on their scale-up example that could be relevant to answering the research question.

Suggested Inclusion and Exclusion Criteria for Stage 2

In order to be incorporated in this phase of the synthesis the evidence will need to meet the following three inclusion criteria;

1. Be a case example of scale up of a healthcare intervention(s)

Scale up is defined as a purposeful expansion of a health intervention to a wider population^{1 2}. This could involve expanding geographically or to a wider population within the same setting. Both scale up at national and sub-national levels will be included once the intervention was being purposefully expanded to a new wider population group. If an article or study is not based on a real-world case example but puts forward guidance, framework or aspirational steps these will be excluded.

A health intervention is defined as “an act performed for, with or on behalf of a person or population to assess, improve, maintain, promote or modify health, functioning or health conditions”³. For this study, it will be limited it to interventions where the direct target was the individual. An example of this would be provision of nutritional supplements, vaccines or medication (e.g. vitamin A, polio vaccine etc.) and/or educational or behaviour change interventions directly delivered to the individual (e.g. breastfeeding education, safe sex promotion etc.). If the primary intervention is capacity building of HRH which may have future impacts on health this was considered indirect and not included. As scale-up often occurs as a

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2
3 package of interventions, case examples of this will be included if a specific direct health
4 intervention was identified as a primary part of this package. Where case studies were general
5 service delivery for example provision of mental health services at scale but did not specify a
6 specific health intervention these will be excluded.
7

8 9 **2. Adaptations were made for health intervention(s) to fit local settings**

10 **Adaptations** will be defined as “deliberate and/or unintended changes to the intervention
11 content, context or training and delivery”. For inclusion in this study these adaptations will need
12 to have occurred during scale-up to adapt for local contexts. If the adaptations occurred during
13 the RCT or pilot stage and the same intervention was rolled out nationally (or sub-nationally)
14 without further adaptations to the content, context or delivery these will be excluded.
15

16 17 **3. Discusses in detail action(s) for modifying health intervention(s) at scale**

18 **Actions** used to make adaptations will need to be explained in detail. In detail meaning to give
19 sufficient information to be relevant to answering the research question(s) using criteria of
20 relevance and rigour below. If the article discussed the adaptation without discussing what
21 process was used it was excluded.
22
23

24 **Time limit:** No time limit will be placed on evidence as it was noted that scale-up occurs over a long
25 time period with an estimated 15 years to reach national scale⁴.
26
27

28 **Language:** Searches will be carried out in English. Languages will be limited to those spoken by the
29 review team; English, Spanish, Portuguese and French.
30
31

32 **Relevance and Rigour**

33 As realist philosophy does not exclude evidence based on type of study, the criteria of relevance and
34 rigour will be used for further appraisal as per RAMESES guidance⁵. For exploring examples of scale-
35 up and adaptation in practice it was felt that evidence may come from a variety of sources including
36 grey literature. Therefore, the relevance of the piece of evidence to the research question and
37 whether the evidence or document was rigorous enough to hold value to theory building, testing or
38 refinement will be decided. Any exclusions and reasoning from these criteria of relevance and rigour
39 will be recorded for transparency in the research logbook.
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3 **Supplemental File 4. Draft Data Extraction Form (to be further refined as needed)**
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5 **Scale-up example (location, intervention):**

6 **References of articles/documents included:**

7 **Details of Intervention:**

8 **Topic (e.g. nutrition, HIV):**

9 **Study Type(s):**

10 **Summary (short description of case example of scale-up):**
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13 **1. Adaptations** (Please see codebook for further descriptions as needed)

14 **What adaptations were made and to what elements?** (give details where discussed)

15 **(i) Content** (e.g. changes to intervention procedure, materials or delivery):
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18 **(ii) Context** (e.g. changing the delivery channel, format, setting, personnel, population):
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20 **(iii) Training/Evaluation** (e.g. longer/shorter training, style of training etc.):
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22 **At what level was the adaptation made?** (where discussed, refer to codebook as needed)
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24 **Who made decision to adapt?** (where discussed, refer to codebook as needed)
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26 **Why decision to adapt?** (where discussed)
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29 **2. Actions**

30 **Actions for Adaptations** (please list with short descriptions of what was carried out, refer to
31 codebook as needed):
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34 **3. Context-Mechanism-Outcomes (CMOCs)**

35 Please provide details of CMOCs identified below relating to actions for adaptations, please provide
36 quotes to support and any reasoning for any inferred contexts or mechanisms, refer to codebook as
37 needed.
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40 **CMOC 1.**

41 Action (mechanism resource):

42 Context:

43 Mechanism (reasoning or response):

44 Outcome:

45 CMOC:

46 Supporting quotes or reasoning:
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49 **CMOC 2.**

50 Action (mechanism resource):

51 Context:

52 Mechanism (reasoning or response):

53 Outcome:

54 CMOC:

55 Supporting quotes or reasoning:
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58 **Please add as many as needed below e.g. CMOC 3, CMOC 4**
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Supplemental File 5. Draft Data Extraction Guidance and Sample Codebook (to be further refined as per protocol)

Adaptations definition and coding (based on Stirman and colleagues taxonomy of modifications¹)	
<p>Notes: Headings and description for the taxonomy of modifications below. If any of these are not stated to mark as such on the data extraction form.</p> <ul style="list-style-type: none"> • Firstly, to identify and briefly state what adaptation was made and whether it was to the content, context of training/evaluation. If the adaptation was to the content, this can be further classified under the 12 suggested headings if applicable. If not to mark as “other” • Secondly to identify where stated at what level the adaptation was made (e.g. at individual recipient level or community level) using the seven suggested headings or the other category • Thirdly to capture who made the decision to adapt where stated • Finally, if the reason was given for why adaptation was needed 	
Adaptations	Deliberate and/or unintended changes to the intervention content, context or training and delivery
Adaptations to Content	<p>Changes to intervention procedure, materials or delivery.</p> <p>These can be further classified as (note as many as apply on data extraction form);</p> <ol style="list-style-type: none"> 1. Tailoring, tweaking, refining - minor change, leaves all major principles in place e.g. modifying language 2. Adding elements - consistent with fundamentals of intervention 3. Removing elements - e.g. those that are culturally not appropriate 4. Shortening, condensing (pacing/timing) - shorter amount of time or no of sessions 5. Lengthening, extending (pacing/timing) 6. Substituting elements - a module or activity is replaced with another (e.g. condom application replaced with abstinence talk) 7. Re-ordering elements 8. Integrating another approach - intervention used as starting point but other techniques added 9. Integrating prevention into another approach - starting with another approach, but intervention added in 10. Repeating elements 11. Loosening structure - flexibility with programme/process e.g. opening and closing, layout can be different 12. Departing from the intervention (drift) - Intervention no longer used in given situations <p>Other (Give details)</p>
Adaptations to Context	Changing the delivery channel, format, setting, personnel, population etc.
Adaptations to Training/Evaluation	Longer/shorter training, style of training etc.
At what level was the adaptation made	<p>This can be classified as (please note as many as apply on data extraction form);</p> <ol style="list-style-type: none"> 1. Individual recipient e.g. changed for a person's needed e.g. literacy, hearing, physicality

	<p>2. Cohort level - for individuals grouped within a setting</p> <p>3. Population level - Intervention modified for cultural, ethnic, social groups</p> <p>4. Provider/facilitator level - modified for all of a certain practitioners clients</p> <p>5. Unit level - modified for all in that unit e.g. clinic, department</p> <p>6. Hospital/Organization level - entire organisation</p> <p>7. Networks/Community Level - entire networks or systems (e.g. all hospitals, facilities)</p> <p>Other (Give details)</p>
Who made decision to adapt	Please state where present (e.g. individual practitioner, team, non-programme staff, administration, programme developer, researcher, coalition of stakeholders, other)
Why decision to adapt	Please state where present (e.g. feasibility, acceptability)

Definitions of Actions, Contexts, Mechanisms, Outcomes and CMOCs	
Actions	<p>Mechanisms are often seen as the integral link between the context and the outcome². They uncover the “why” a given outcome may have occurred. Dalkin and colleagues³ conceptualised mechanisms as either resources or reasoning. They put forward that resources are introduced in a context, which trigger a response, which results in an outcome.</p> <p>For this research, we viewed actions used to make adaptations when scaling-up as a mechanism in the form of a resource. Actions can be acts, processes or interventions used to make, guide or support adaptations when scaling up. For example, generation of evidence which informs adaptations or participation of stakeholders. These under the right contextual conditions may fire a mechanism in the form or reasoning or response, for example awareness or commitment, which in turn may generate the outcome of interest.</p> <p>Actions may be captured twice.</p> <ul style="list-style-type: none"> • Firstly, to identify what actions were used and give a brief description (heading 2 in data extraction form). Please do not limit to actions only in the IPT and allow new actions to emerge from the data also. • Secondly, if there is a CMOC associated with that action it will be captured under the CMOC heading below (heading 3 on data extraction form). Note not all actions may have CMOCs related to them.
Contexts	Contexts relate to conditions that affect mechanisms and therefore outcomes. A context can act like a dimmer switch for the triggering of mechanism to varying degrees ³ . Pawson and Tilley ⁴ note context “ <i>may not only relate to place but also to systems of interpersonal and social relationships, and even to biology, technology, economic conditions</i> ” ^{p8} .

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Mechanisms	For this research actions were seen as a “resource”, and resulting mechanisms were the “reasoning” or response. For coding as a mechanism, it would be a response to a given action. Mechanisms in the form of reasoning are often hidden and unseen, for example awareness or commitment.
Outcomes	Outcomes can be intended or unintended consequences from actions or interventions in given context. They can be positive or negative. For this research outcomes can be proximal or distal. With distal outcomes relating to the overall aim for example adaptations with local fit or sustainability as reported by the evidence, and proximal outcomes relating to those that may occur prior to this for example ownership of intervention or consensus for adaptations.
CMOC	Context-mechanism-outcome-configuration. This is the combination of the action, context, mechanism and outcome together. This may be presented as a narrative sentence which describes the CMO combination. For example, when XX is carried out in the context of XX, this caused a response of XX which led to outcome XX.

Potential Actions, Contexts, Mechanism and Outcomes identified from the IPT framework below		
Notes: Please do not limit data extraction to these codes, allow new codes to emerge as they appear in the data, or more detailed codes and categorization of below as needed.		
Additionally, what is categorised as an action, context, mechanism or outcome in one instance may be categorised under another heading in another CMOC depending on the configuration. For example, ownership may be an outcome in one CMOC and a context in another. Please categorize under whichever heading is appropriate for the CMOC. Reasoning can be documented as needed.		
Potential Actions	Creating and using knowledge	The creation of knowledge e.g. through evaluation, local knowledge, continual assessment mechanisms and/or the use of existing knowledge e.g. local data, real time data, routine data, evidence for intervention
	Identification of theory and core elements of intervention	The identification of theory or core elements/components of the intervention. This could involve purposeful selection of an intervention where these are known or seeking out this information for the selected intervention
	Guidance to sites	Providing guidance to local sites on intervention theory or core elements, or on how to adapt intervention
	Participation	Participation / engagement of; service users, providers, community, local organisational or government HR. This could be through various activities for example; consultations, partnerships, CBPR, local decision making
	Communication	Communication between individuals or at organisational levels
	Local decision making	Involvement of; local service users, providers, community, local organisational or government HR for decision making for adaptations. Autonomy given to local level for adaptations

	Feedback loops	Feedback loops or mechanisms in place to guide decision making for adaptations this could involve monitoring and evaluation at time points, planned consultations etc.
	Definition of roles	The transparent clarification and definition of roles and responsibilities for adaptation during scale-up
	Consideration of future adaptations and sustainability	Consideration of future adaptations and sustainability and actions planned to allow for this. This includes recognition of contexts changing overtime and actions planned to allow for this
	Create opportunities for learning	Creating opportunities for learning is purposeful activities that could assist in learning for implementers, organisational staff, the community or service users. It could relate to building capacity to complete adaptations, or learning of the context, adaptations or strategies used to address local fit. This could be formal e.g. through learning networks, or informal e.g. arranged through social networks
	Systems thinking	Systems thinking applies to an in-depth consideration of the complex links, relationships, inter-dependencies within a system. This may be difficult to capture however if an example reports use of systems thinking or describes this process it can be included as this
	Further actions to be added as identified	
Potential Contexts	Wider context	
	Political, socio-cultural and environmental factors	This is a broad heading that can capture elements of the wider system e.g. political, economic, environment that influence whether a mechanism fires. This heading will be added to and refined and learning progresses
	Community	
	Partnerships	This could be between community and an organisation. This could include the nature of the partnerships in terms of history and trust for example
	Organisational	
	Readiness	Where the organisation (or community) are ready for intervention and implementation, for example with resources, capacity in place, community sensitized to intervention, buy in for intervention exists etc. This could also capture a lack of readiness or rushing to scale
	Resources	Resources or lack of resources such as; financial, logistical or human resource availability
	Leadership	This could relate to strong leadership, or a lack of leadership which may influence adaptation and scale-up
	Organisation flexible and responsiveness to local needs	Organisation flexible and responsiveness to local needs. This could relate to where the organisation is open to receiving and acting on feedback
Interpersonal Relationships		

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	Culture of respect	Culture of respect between individuals, or within an organisation. This could include placing value on the knowledge and opinions of those in the local setting
	Culture of trust	Culture of trust between individuals, or within an organisation. This could also relate to a history or relationship of trust built over time.
	Power imbalance	Power imbalance between individuals or organisations. This could relate to a power imbalance within a community setting limiting individual’s participation, or could relate to top-down/bottom-up power imbalance between funders and an organisation, or between different levels of the health system
	Individual	
	Capacity to adapt interventions	Capacity to carry out actions needed to adapt and/or implement interventions
	Intervention characteristics	
	Factors relating to make up of the intervention	For example; relative advantage, compatibility, complexity, trialability and observability. This could also include whether the intervention was simple or complex
	Intervention theory and core components known	Theory and core components of intervention known and available to sites
	Further contexts to be added as identified	
Potential Mechanisms	Awareness	“Knowledge or perception of a situation or fact” ⁵ . This could relate to the local context, the need to adapt, the intervention itself or the scale-up or adaptation process
	Empowerment	The process of becoming more powerful or confident in the ability to do something ⁵ . This can include authority or power given to someone to do something
	Trust	“Firm belief in the reliability, truth, or ability of someone or something” ⁵ . Trust could relate to the intervention itself, the scale-up or adaptation process or trust between actors e.g. service users, organisation, implementers etc.
	Motivation	Intrinsic or extrinsic motivation towards the intervention, its adaptation or scale-up. Motivation is an internal process that may cause a desire or willingness ⁵ towards something this is not seen, however relating actions could be
	Support	This may capture support from an individual, community or organisation. They may approve of or encourage the intervention, the adaptation or scale-up process. This may also capture the concept of buy-in
	Commitment	“The state or quality of being dedicated to a cause, activity, etc.” ⁵ . This could relate to a commitment to the problem (e.g. addressing the health problem), the intervention, adaptation or scale-up process. This differs from support as it relates to dedication or engagement and so it is more active than support alone

	Confidence	“The feeling or belief that one can have faith in or rely on someone or something.” ⁵ . Confidence relates more to self-assurance ⁶ or certainty in an ability of oneself or others. This could be confidence in the ability to adapt or implement the intervention, in the intervention itself or of other people’s ability to complete actions or goals for scale-up
	Further mechanisms to be added as identified	
Outcomes (Proximal)	Champions	Champions who support, encourage, commit to or drive the intervention and/or scale-up or adaptation process
	Ownership	A feeling or sense of ownership of the intervention and/or scale-up or adaptation process by an individual, community or organisation
	Consensus	Shared agreement or vision on the intervention, adaptation or elements of scale-up process
Outcomes (Distal)	Adaptations with local fit (acceptability, feasibility)	Adaptations made which are acceptable and/or feasible in local settings. This could be demonstrated by demand for intervention by service users, or where Interventions match local needs and resources
	Scale up with local fit	Intervention is scaled-up across sites with local fit where intervention is acceptable and/or feasible
	Sustainability	Intervention is continued to be delivered at sites or the outcome of the intervention is sustained at sites over a time. This intervention may be continually adapted and does not need to remain the same
	Further outcomes to be added as identified	

References

1. Stirman SW, Miller CJ, Toder K, et al. Development of a framework and coding system for modifications and adaptations of evidence-based interventions. *Implement Sci* 2013;**8**:65. doi: 10.1186/1748-5908-8-65
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3. Dalkin SM, Greenhalgh J, Jones D, et al. What’s in a mechanism? Development of a key concept in realist evaluation. *Implement Sci* 2015;**10**:49. doi: 10.1186/s13012-015-0237-x
4. Pawson R, Tilley N. Realist Evaluation. South Australia: Community Matters 2004.
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6. Willis CD, Riley BL, Stockton L, et al. Scaling up complex interventions: insights from a realist synthesis. *Health Research Policy and Systems* 2016;**14**:88. doi: 10.1186/s12961-016-0158-4