A methodological systematic review of the development of complex interventions aimed at improving health outcomes

Alicia O’Cathain, Elizabeth Croot, Katie Sworn

Review question
What approaches to developing interventions are there?
What are the rationales for taking different approaches?
What are the core principles and practices of intervention development?
What contexts are approaches used within?
What research methods are used at different steps of each approach?
What are the strengths and weaknesses of each approach?

Note: Our review approach is broad as we are looking at all health-related complex interventions in a way that cuts across all health conditions and outcomes.

Searches
Sources will be identified from formal and informal database search techniques. Our review focus will be sources published in the last 10 years. We will perform up to three iterations of database searches in MEDLINE, CINAHL, PsycINFO, ASSIA and ERIC databases. The formal database searches will identify the most recent papers published January 2015–December 2016.
Iteration 1 will use the term ‘intervention development’. Iteration 2 will include wider range of terms about intervention development (‘complex behavioural intervention’) and the development stages (develop, design, phase I, exploratory, refine and translate). Subsequent iterations will be contingent on results of the previous iterations. If the subsequent iterations appear to have low specificity a sample may be screened for relevant papers.

Methodological sources acquired for this review will be retrieved through informal forms of searching such as Google Scholar, the reference libraries of team members and reference searching of included studies. Terms used included ‘intervention development’, ‘complex intervention development’, ‘intervention optimisation’, ‘complex intervention pre-clinical’, ‘intervention adaptation’ and ‘intervention modification’. Sources will include: core methodological books, guidance and methodologies provided in papers within key journals.
Searching will employ a maximum variation approach in order to present the widest range of methodologies possible. However, searches will be comprehensive, not exhaustive. Searching will cease when the research team judge they have reached theoretical saturation.

Types of study to be included
Inclusion and exclusion criteria for the searches:
Inclusion criteria

- International complex intervention methodological sources.
- Published material from a number of sources (books, papers, guidelines or frameworks).
- Methodological material must have potential to be applied to the development of complex intervention with health-related outcomes.
• Focus on planning and design phases prior to full feasibility and acceptability testing. Methodologies do not have to be proven to increase successfulness of interventions.

Exclusion criteria
• Methodologies applied exclusively to simple interventions involving efficacy of drugs or procedures. Refinement of interventions at the pilot or full randomised controlled trial phase and beyond. Materials not translated into English.

Condition or domain being studied
The domain being studied is approaches to developing complex interventions.

Participants/population
This review encompasses methodological materials to be used in complex intervention development for the recipients of any intervention which has a health-related outcome.

Intervention(s), exposure(s)
The complex interventions might work at any level: individual, group or multi-level.

Comparator(s)/control
Not applicable

Context
The contexts of the development methodologies are likely to be health or health-related disciplines. The context of the studies in which the methodologies are applied could be extremely diverse across international health settings. Methodologies from educational settings will be considered where health-related outcomes could be possible in development studies.

Main outcome(s)
The outcome of the review is to identify and analyse methodological approaches and associated methods to inform guidance for complex interventions developers.

Timing and effect measures
Not applicable

Additional outcome(s)
Not applicable

Timing and effect measures
Not applicable

Data extraction (selection and coding)
Methodological sources will be gathered into an electronic library and reference management software. Data extraction will take place using tables produced in Word. The reviewers will differentiate between data derived from the sources and interpretations made by the review team. The reviewer will link methodologies
to broad methodological categories. Other data extraction variables will relate to methodological and methods characteristics, such as: approaches, author, rationale, context and steps. The reviewer will extract any strengths and limitations provided by the methodologists.

Risk of bias (quality) assessment

No formal assessment of methodological quality will take place and no methodological source will be excluded on the basis of quality (e.g. evidence of take up in the literature base). The appraisal of the strengths and weaknesses of the methodologies is part of the analytical remit of the review.

Strategy for data synthesis

The constant comparison method will be applied to the extracted data (Gentles, 2016). Synthesis will generate a list of principles and practices of intervention development. The reviewers will create their own interpretation of the strengths and limitations of methodologies and these interpretations will be discussed with the review team and wider study team.

Analysis of subgroups or subsets

None planned

Contact details for further information

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Review_Ongoing

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Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

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Versions
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