Section 3.6.2
Framework for Evaluating Complex Interventions
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Overview of the chapter structure:

- This chapter is divided into the following sections:
  - A framework for evaluating complex interventions
  - Knowledge translation, complex interventions and the iterative loop
  - Future research
Key Learning Points

- The active ingredient(s) of complex interventions can be difficult to identify.
- Stakeholders can inform trialists on which element(s) of a complex intervention are essential to reproduce.
- Other types of evidence can improve the relevance of trials for policy makers.
- The MRC Framework for the Development and Evaluation of Randomised Controlled Trials for Complex Interventions to Improve Health\(^1\) provides a mechanism for formally integrating other types of evidence and may support the transfer of evidence based interventions.
- External validity can be strengthened through the involvement of key health care decision makers.

A Framework for Evaluating Complex Interventions

• The MRC Framework provides an iterative step-wise approach to determine the state of knowledge about a complex intervention
MRC Framework for Evaluating Complex Interventions

• **Step 1 Defining the intervention**
  – Identify the existing evidence and any theoretical basis for the intervention in order to describe the components of the intervention

• **Step 2 An exploratory phase**
  – Assess the acceptability and feasibility of delivering the intervention, and the comparison intervention
  – Pilot the study design

• **Step 3 An explanatory phase**
  – The final trial design is implemented in a relevant setting with appropriate eligibility criteria

• **Step 4 A pragmatic phase**
  – Implementation and fidelity are examined
  – Key to KT
MRC Framework for Evaluating Complex Interventions

MRC Framework for Evaluating Complex Interventions

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Knowledge Translation, Complex Interventions and the Iterative Loop

- Involve decision makers in shaping the research question and defining the intervention
- Systematically identify and integrate additional forms of evidence relevant to decision makers
- Measure outcome and process variables relevant to KT
- Measure degree the intervention has been sustained outside a research setting
- Be aware of a changing political context
Areas for Future Research

• Generate empirical evidence to assess the benefits of involving stakeholders, in the design phase of research, on subsequent implementation.

• Research describing the iterative process, how key decision makers are identified and contribute to decision making.