Section 3.6.2

Framework for Evaluating Complex Interventions

Sasha Shepperd

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

[1]*Campbell M, Fitzpatrick R, Haines A, Kinmouth A-L, Sandercock P, Spiegelhalter D. A framework for development and evaluation of RCTs for complex interventions to improve health. BMJ 2000;321:694-6.*

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
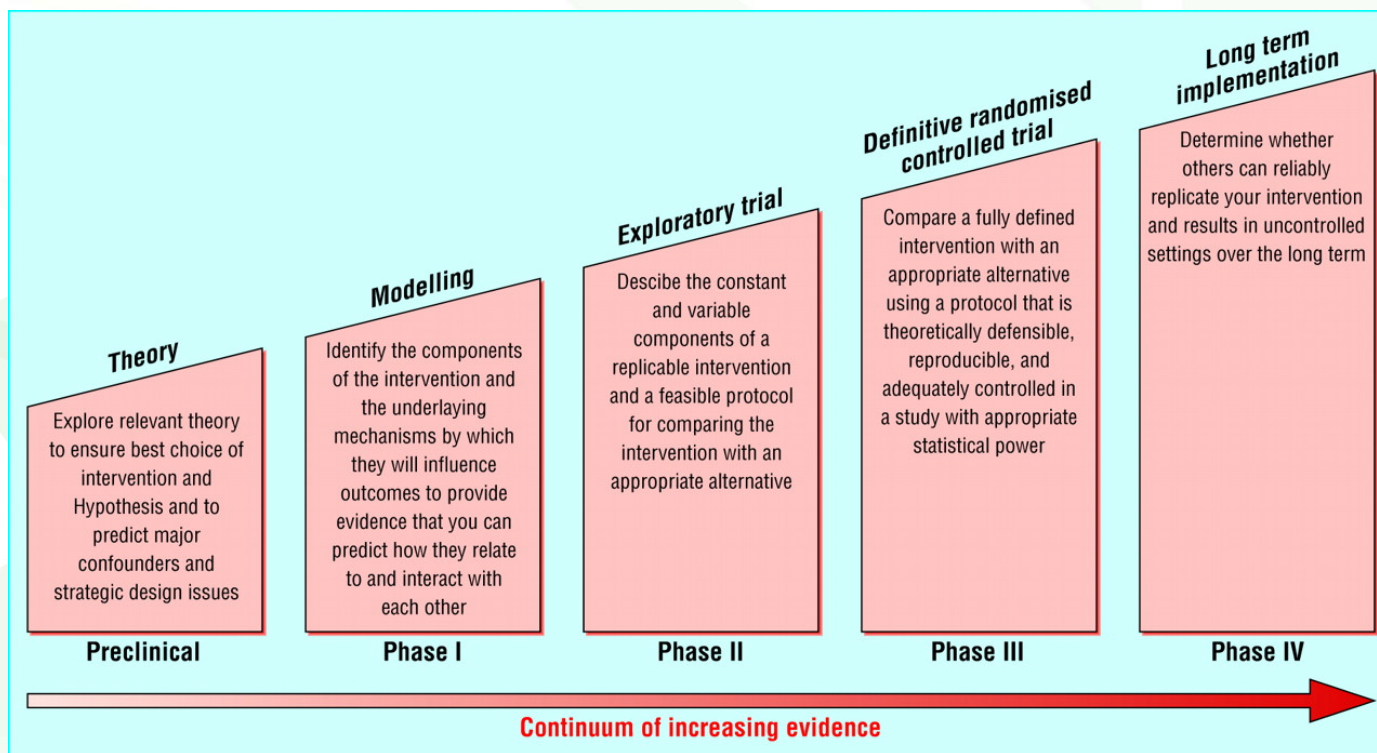
MRC Framework for Evaluating Complex Interventions

- **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
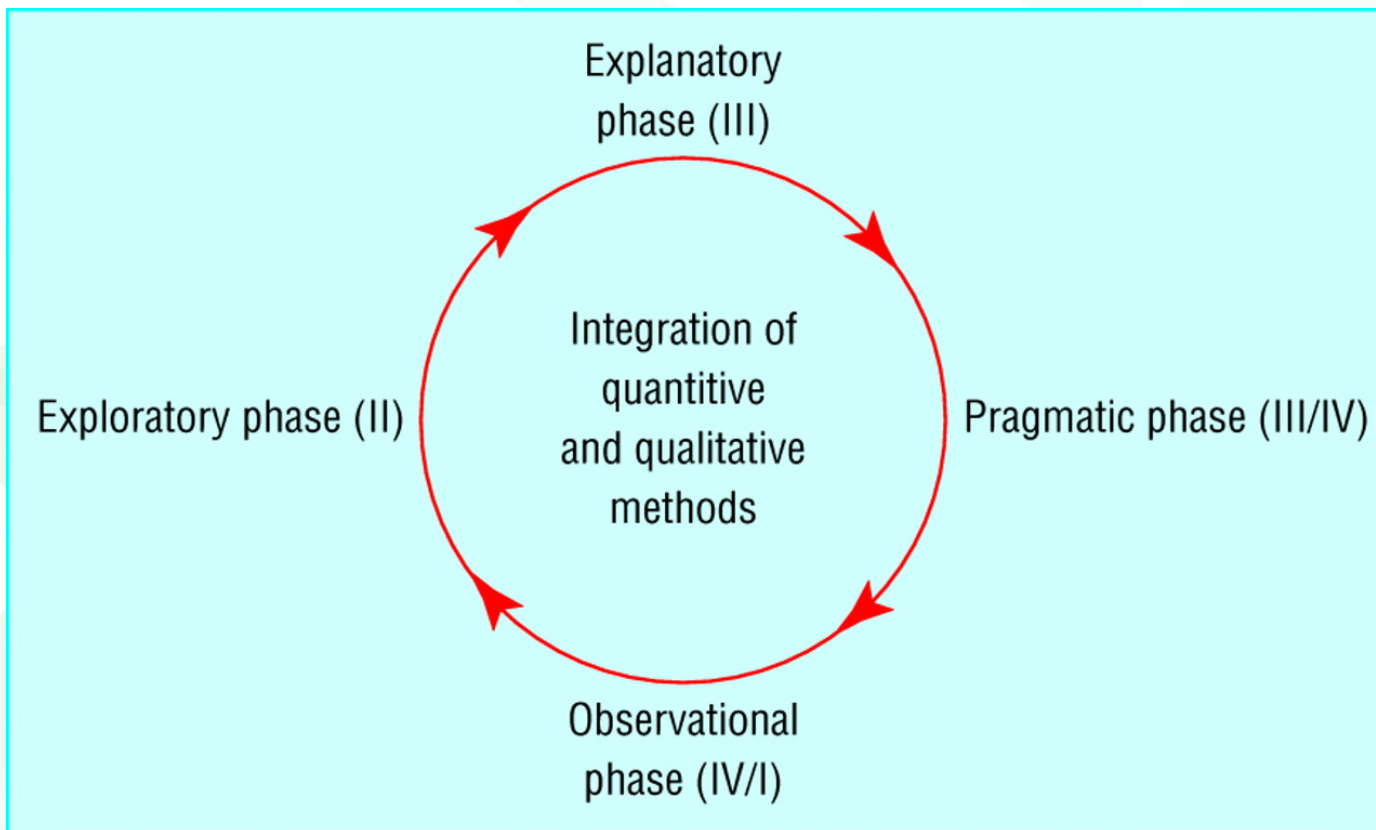 - Key to KT

MRC Framework for Evaluating Complex Interventions

Campbell, M. et al. BMJ 2000;321:694-696

Campbell, M. et al. BMJ 2000;321:694-696

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