Developing and evaluating complex interventions: the new MRC Guidance


Why update?

- Incorporate experience gained since 2000
- Address limitations in the 2000 framework
  - Better definition of complexity
  - A less linear model of the evaluation process
  - More attention to piloting/development work
  - Randomised trials and alternative methods
  - Need to understand process as well as outcomes
  - Importance of context
What is a complex intervention?

- Number of interacting components
- Number and difficulty of behaviours involved
- Number of groups or organisational levels targeted
- Number and variability of outcomes
- Degree of flexibility or tailoring permitted

Some implications for evaluation

- Good theoretical grasp of the change process
- Implementation vs. intervention failure
- Individual variation may reflect higher level processes
- A range of outcome measures
- Interventions may work better if adaptation to local context is permitted
A less linear model

DEVELOPMENT
Designing and reporting interventions

- Develop interventions systematically using carefully phased approach
  - Use best available evidence
    - Systematic review
  - Develop theoretical understanding of process of change
    - Identify appropriate theory/ies
- Modelling process and outcomes
  - Series of pilot studies targeted at each of key uncertainties in design
  - Exploratory, then definitive evaluation

- An iterative, not necessarily linear process
  - May go “back” to an earlier phase at any phase
  - Implementation of intervention should guide all phases

Identifying appropriate theory

- Theory allows the investigation of processes of change (or mechanisms of action)
  - How the intervention works
  - Lays basis for
    - developing more effective interventions
    - developing theoretical understanding
- May require primary as well as secondary research
- Example of criteria used in ProActive intervention
  - use in interventions aimed at similar target behaviours
  - applicability to the target group
  - clear definition of causal, testable pathways between behavioural determinants and behaviour
  - strength of evidence about predictive validity
  - clear guidelines for measurement.
FEASIBILITY AND PILOTING

Modelling process and outcomes

- Series of pilot studies to refine design of both
  - intervention (including content) and
  - evaluation (including process)
Assessing feasibility

- Address sources of uncertainty e.g.
  - Acceptability of intervention
  - Fidelity of delivery
  - Rates of recruitment and retention
  - Required sample sizes
- Interpret all the above cautiously!
  - Likely to be smaller effects, more variability, lower response rates, more problems when scaled up

Assessing complex interventions – the ‘new’ model
EVALUATION

1. Assessing effectiveness
2. Understanding change process
3. Assessing cost effectiveness

1. Assessing Effectiveness

Choosing an appropriate trial design

There ARE alternatives to the classical RCT, e.g:

1. Cluster randomisation
2. Stepped wedge designs
3. Preference designs
4. Randomised consent
5. N-of-1 studies
Two rarely used designs

(i) the stepped wedge design

- Six blocks of individuals/units
- Introduced into the trial in random order

Time
(ii) the pre-randomised trial nested within an observational study

Consent to an observational study

RANDOMISE

Consent to trial

Identical measures; control group informed at end

Use of non-randomised designs

- Randomisation is occasionally unnecessary or inappropriate
- Randomisation is quite often impossible, e.g. if the intervention has already been implemented
- Observational studies can provide important data – and are often better than nothing
Use of non-randomised designs

An example: Does air pollution kill people?

- This question is unlikely to be answered by a classical RCT so we have to rely on obtaining observational ‘before and after’ data when and if governments choose to do something about air pollution
- Two observational studies of air pollution controls
  - Clancy et al., Lancet 2002 – looked at death rates before and after Dublin banned coal sales
  - Hedley et al., Lancet 2002 – studied death rates before and after Hong Kong switched to low sulphur fuels
    - Less air pollution DOES reduce death rates

2. Understanding the change process

- Failure or unanticipated outcomes are common with complex interventions
- Process evaluation can help understand such outcomes
3. Assessing cost-effectiveness

Cost-effectiveness of what?

• Including an economic evaluation should make the results of an evaluation study much more useful for decision-makers, but you should also ask the question, ‘Is this study worth doing?’

• For large, expensive trials, a formal approach to assessing the ‘expected value of information’ from the study should be included in the planning process.

IMPLEMENTATION

• Involve stakeholders in planning the research
• Provide evidence in an integrated and graded way
• Identify the elements relevant to decision-making
• Make recommendations as specific as possible
• Take a multifaceted approach

• Exploit opportunities for long-term follow-up
Conclusion

• Adequate, rigorous assessment of a complex intervention requires careful choice of
  • evaluation design,
  • outcome measures and
  • process measures

• Intervention development, evaluation and implementation are not necessarily sequential activities; all stages should inform, and be informed by, each other.