Developing and evaluating complex interventions: the new MRC Guidance

Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. (2008). *British Medical Journal.* 337: a1655.

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?

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- 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

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- 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

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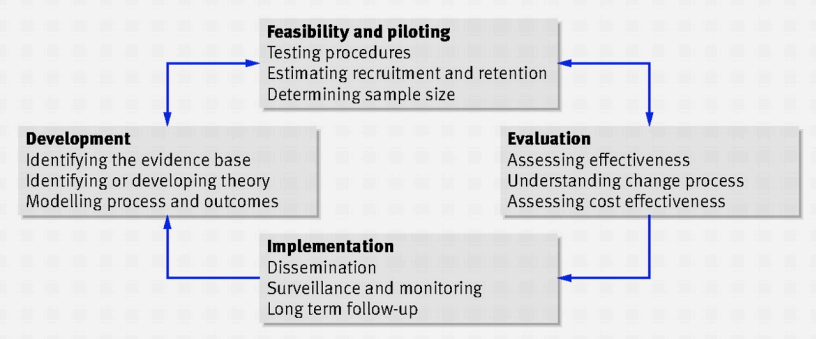
A less linear model



DEVELOPMENT

Designing and reporting interventions

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- 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

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- 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.

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FEASIBILITY AND PILOTING

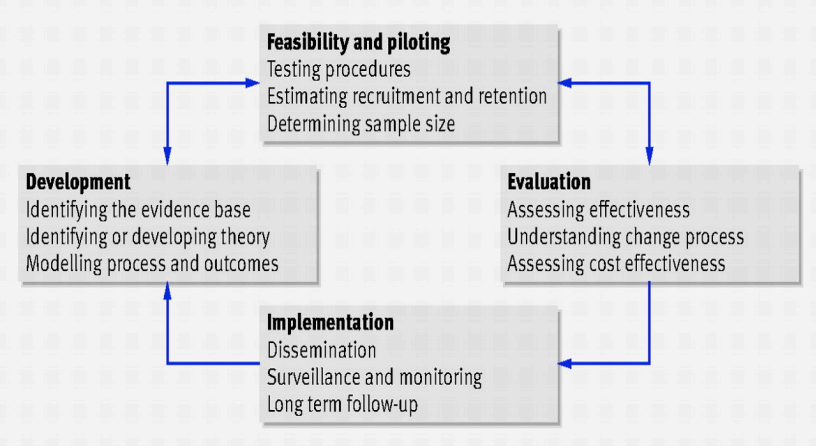
Modelling process and outcomes

- 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

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

1. Assessing Effectiveness

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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

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Two rarely used designs

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(i) the stepped wedge design

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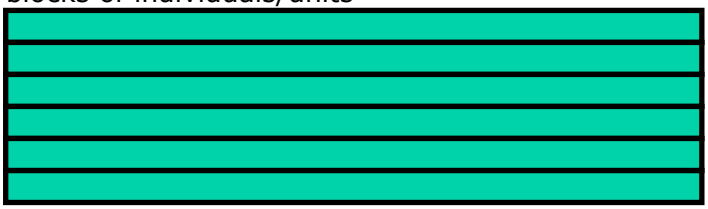
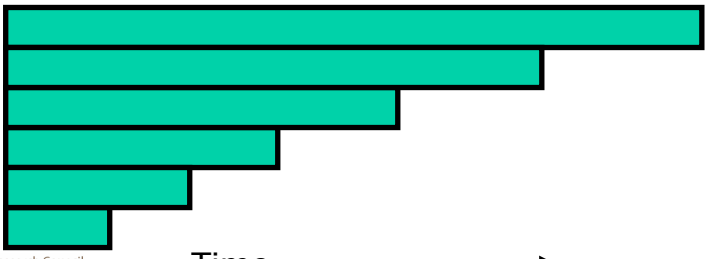
- Six blocks of individuals/units

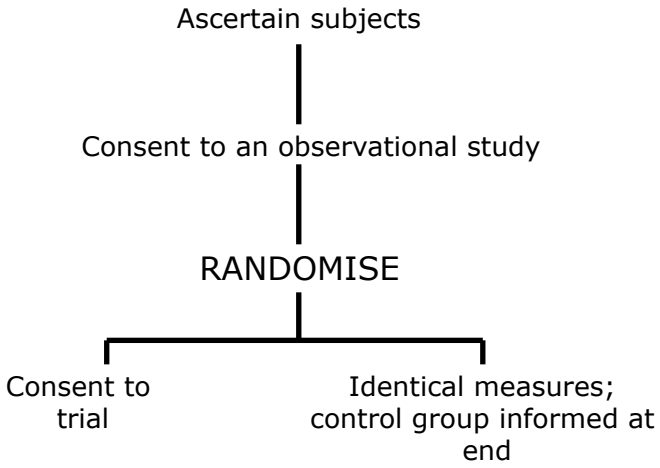


- Introduced into the trial in random order



Time →

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



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

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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

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- Failure or unanticipated outcomes are common with complex interventions
- Process evaluation can help understand such outcomes

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3. Assessing cost-effectiveness

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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

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- 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

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Conclusion

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- 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.