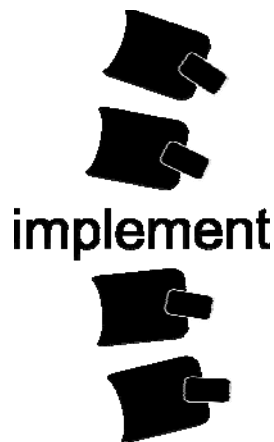


Evaluating the fidelity of a complex intervention in the context of a cluster randomised controlled trial

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Research funding provided by



Australian Government

National Health and Medical Research Council

Should we

- cease all investment in developing new complex interventions ...

and instead ...

- divert this investment into improving the “fidelity” of existing interventions?

What is intervention fidelity?

- The extent to which:
 - an intervention as implemented is faithful to the intervention as planned

Bellg et al (2004) Health Psychology



"He's right, you know. You're not allowed to bring a date to your own wedding."

What if fidelity not assessed?

- If intervention effective
 - effect may be due to unknown factors that were unintentionally added or omitted
- If intervention is ineffective
 - not be known if this is due to an ineffective intervention or due to poor implementation of an effective intervention
- In addition:
 - Don't know how generalisable the findings are
 - Can't replicate interventions
 - Don't know what the mechanism of change is

Theoretical phase

Interpretation

Intervention development and piloting phase

Cluster RCT phase

Recruitment

Outcome measurement

Analysis

Interpretation

**Intervention
fidelity**

**Cost
effectiveness
analysis**

Theoretical framework

1. Knowledge
2. Skills
3. Social/professional role and identity
4. Beliefs about capabilities
5. Beliefs about consequences
6. Motivation and goals
7. Memory, attention and decision processes
8. Environmental context and resources
9. Social influences
10. Emotion
11. Behavioural regulation
12. Nature of the behaviours

Aims for IMPLEMENT fidelity

1. To determine whether the IMPLEMENT intervention was delivered and received as intended
2. To explain trial effects by mapping the intervention components to theoretical models

Methods for IMPLEMENT intervention fidelity evaluation

- Methods based on Hardeman et al 2008 and Michie et al 2008
- Mixed methods approach:
 1. Facilitator checklist
 2. Qualitative evaluation
 3. Quantitative analysis

Hardeman et al (2008). *Psychology & Health* 23:11-24

Michie et al (2008). *Psychology & Health* 23: 25-39

Discussion



- How we will do it better next time?
- How to deal with behavioural techniques delivered but not specified in protocol
- What to do with results of fidelity evaluation?
- For trial analysis - differential effects determined by fidelity