Understanding why health promotion interventions work (or not)
MRC guidance for process evaluation

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Seminar Finnish Section of Behavioral Medicine.
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Key collaborators
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- University College London: Susan Michie
- University of Aberdeen: Marie Johnston
- University of Oxford: Andrew Farmer
- University of Tampere: Nelli Hankonen
- MRC process evaluation guidance group
- BCT Taxonomy v1 team
Outline

- Health promotion: a complex intervention
- MRC process evaluation guidance
- Specification of intervention and hypothesised mechanisms
- Process evaluation: case studies
- Conclusions

Health promotion as a complex intervention
Complex interventions

- Various components which may interact
- Multiple groups or organisational levels targeted
- Multiple processes involved with delivering or receiving the intervention
- Multiple outcomes, e.g., clinical, behavioural, organisational
- Difficult to know how much flexibility or tailoring of the intervention is allowed

Craig et al, BMJ 2008
MRC framework for complex interventions

Key elements of the development and evaluation process

Craig et al., BMJ 2008

Process evaluation of complex interventions

UK Medical Research Council Guidance
Process evaluation

- Assessing intervention effects is key
- But ... also need a detailed understanding about the intervention to inform policy and practice

Development of the guidance

- MRC PHSRN funded workshop in 2010
- Guideline development group formed
  - Lead: Graham Moore
  - Chair: Janis Baird
  - Guidance development group (in alphabetical order): Suzanne Audrey, Mary Barker, Lyndal Bond, Chris Bonell, Wendy Hardeman, Laurence Moore, Alicia O’Cathain, Tannaze Tinati, Danny Wight
MRC Guidance on Process Evaluation of Complex Interventions

Moore et al. BMJ 2015

Key components

- **Implementation**: the structures, resources and processes through which delivery is achieved, and the quantity and quality of what is delivered
- **Mechanisms of impact**: how intervention activities, and participants’ interactions with them, trigger change
- **Context**: how external factors influence the delivery and functioning of interventions
Process measures: mixed methods

Figure 3. Examples of common methods for process evaluation and their relationship to each core function of process evaluation.

Figure 1: Key functions of process evaluation and relationships amongst them (blue boxes represent components of process evaluation, informed by the intervention description, which inform intervention of a process).
Need to specify the intervention and hypothesised mechanisms of effects

Specification of the intervention and hypothesised mechanism of effect

Theory and active ingredients
The problem

- Many interventions are poorly defined in terms of:
  - hypothesised mechanism of effect
  - content
- This limits our understanding of:
  - why they are effective (or not)
  - their effective components
and our ability to replicate effective interventions in practice and policy

A causal modelling approach

- A priori model of how the intervention is assumed to achieve its effects

<table>
<thead>
<tr>
<th>Table 11. Generic causal model</th>
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<tbody>
<tr>
<td>Level</td>
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<tr>
<td>1</td>
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<tr>
<td>2</td>
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Hardeman et al., Health Education Research 2005
ProActive causal model

Based on the Theory of Planned Behaviour (Ajzen 1991)

Mapping intervention and measures against the causal model
Specifying active ingredients: Behaviour Change Technique (BCT) Taxonomy V1

- International consensus project to define intervention content (2010-2013)
- Online training: www.bct-taxonomy.com

Online training: www.bct-taxonomy.com
### 93 BCTs organised in 16 groupings

<table>
<thead>
<tr>
<th>No.</th>
<th>Grouping and BCTs</th>
<th>Page</th>
<th>Grouping and BCTs</th>
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<th>Grouping and BCTs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1. Goals and planning</td>
<td>5</td>
<td>8. Comparison of behaviour</td>
<td>16</td>
<td>12. Antecedents</td>
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<tr>
<td></td>
<td>1.1. Goal setting (behaviour)</td>
<td>5</td>
<td>6.1. Demonstration of the behaviour</td>
<td>16</td>
<td>12.2. Restructuring the physical environment</td>
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<tr>
<td></td>
<td>1.2. Problem solving</td>
<td>5</td>
<td>6.2. Social comparison</td>
<td>16</td>
<td>12.3. Restructuring the social environment</td>
</tr>
<tr>
<td></td>
<td>1.3. Goal setting (outcome)</td>
<td>5</td>
<td>6.3. Information about others’ approval</td>
<td>16</td>
<td>12.4. Avoidance/reducing exposure to cues for the behaviour</td>
</tr>
<tr>
<td></td>
<td>1.4. Action planning</td>
<td>5</td>
<td>6.4. Antecedents for the behaviour</td>
<td>16</td>
<td>12.5. Distraction</td>
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<td>1.5. Review behaviour goal(s)</td>
<td>5</td>
<td>6.5. Antecedents for the behaviour</td>
<td>16</td>
<td>12.6. Adding objects to the environment</td>
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<tr>
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<td>1.6. Discrepancy between current behavior and goal</td>
<td>5</td>
<td>6.6. Antecedents for the behaviour</td>
<td>16</td>
<td>12.7. Body changes</td>
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<td></td>
<td>1.7. Review outcome goal(s)</td>
<td>5</td>
<td>7. Associations</td>
<td>17</td>
<td>13. Identity</td>
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<tr>
<td></td>
<td>1.9. Commitment</td>
<td>5</td>
<td>7.2. Cue signalling</td>
<td>17</td>
<td>13.3. Framing/reframing</td>
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<tr>
<td>2</td>
<td>2. Feedback monitoring</td>
<td>9</td>
<td>7.3. Reduce prompts/cues</td>
<td>17</td>
<td>13.4. Incompatible beliefs</td>
</tr>
<tr>
<td></td>
<td>2.1. Monitoring of behaviour by others without feedback</td>
<td>9</td>
<td>7.4. Remove access to the reward</td>
<td>17</td>
<td>13.5. Valued self-identity</td>
</tr>
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<td>2.2. Feedback on behaviour</td>
<td>9</td>
<td>7.5. Remove aversive stimulus</td>
<td>17</td>
<td>13.6. Identity associated with changed behavior</td>
</tr>
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<td></td>
<td>2.4. Self-monitoring of outcome(s) of behaviour</td>
<td>9</td>
<td>7.7. Exposure</td>
<td>17</td>
<td>13.8. Cognitive therapy techniques</td>
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<td></td>
<td>8.2. Behavior substitution</td>
<td>10</td>
<td>8.3. Behavioural practice/behavior</td>
<td>18</td>
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### Example: Goal setting (behaviour)

<table>
<thead>
<tr>
<th>No.</th>
<th>Label</th>
<th>Definition</th>
<th>Examples</th>
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<tbody>
<tr>
<td>1.1</td>
<td>Goal setting (behavior)</td>
<td>Set or agree on a goal defined in terms of the behavior to be achieved. <strong>Note:</strong> only code goal setting if there is sufficient evidence that goal set as part of intervention; if goal unspecified or a behavioral outcome, code 1.3, Goal setting (outcome). If the goal defines a specific context, frequency, duration or intensity for the behavior, also code 1.4, Action planning.</td>
<td>Agree on a daily walking goal (e.g. 3 miles) with the person and reach agreement about the goal. Set the goal of eating 5 pieces of fruit per day as specified in public health guidelines.</td>
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</table>
Process evaluation: case studies

ProActive, SAMS and ADDITION Plus

Figure 1: Key functions of process evaluation and relationships amongst them (blue boxes represent components of process evaluation, informed by the intervention description, which inform interpretation of outcomes).
**ProActive: explaining lack of effect**

- An intervention to promote physical activity among adults at risk of type 2 diabetes
- A one-year intervention delivered at participants’ homes or by phone was no more effective than a brief advice leaflet

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**Limited, short-term impact on hypothesised mediators of physical activity**

**ProActive**

- PI: Ann Louise Kinmonth, University of Cambridge
- Funding: MRC, NHS R&D

**Proactive**

- Proactive
- Why increase physical activity?

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**ProActive**

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Facilitators delivered half of the intervention package (108 sessions)

Median 44%

Hardeman et al. Michie et al., Psych & Health 2008

SAMS: unanticipated mechanisms of effect

- A nurse-led intervention in primary care to support medication adherence in type 2 diabetes
- Two components: motivational and action planning

PIs: Ann Louise Kinmonth, University of Cambridge; Andrew Farmer, University of Oxford
Funding: MRC, NHS R&D
Intervention increased adherence but not as hypothesised

- Small effect on objectively measured medication adherence
- Intervention did not strengthen intention or self-reported habits
- Assessment of all 194 intervention and control consultations

Nurses elicited patient beliefs but rarely prompted problem solving

[Bar chart showing % patients for whom nurses prompted problem solving of barriers or concerns]
Action planning

- Three-quarter of patients defined an action plan for each dose and visualised and vocalised plans to a great extent
- Action plans differed very little from current routines
- Mental rehearsal of successful performance of current routines, combined with action planning may have been the mechanism

ADDITION-Plus: Patient responses

- One-year intervention in primary care for people with recently diagnosed type 2 diabetes
- Facilitators taught patients a range of BCTs to achieve behaviour change and maintenance over time
  1. Goal setting
  2. Action planning
  3. Use of prompts and reminders
  4. Motivating oneself to sustain changes
  5. Social support
  6. Self-monitoring
  7. Goal review
  8. Preparing for setbacks

Griffin et al. Diabetologia 2014
Multiple behaviour change intervention and outcomes in recently diagnosed type 2 diabetes: the ADDITION-Plus randomised controlled trial

Simon J. Griffin · Rebecca K. Simmons · A. Toby Prevost · Kate M. Williams · Wendy Hardeman · Stephen Sutton · Serena Bragg · Ulf Ekelund · Richard A. Parker · Nicholas J. Wareham · Ann Louise Kinmonth · on behalf of the ADDITION-Plus study team

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Abstract

Hypothesis: The aim of this study was to assess whether or not a theory-based behaviour change intervention delivered by trained and quality-assured lifestyle facilitators can achieve and maintain improvements in physical activity, dietary change, medication adherence and smoking cessation in people with recently diagnosed type 2 diabetes.

Methods: An explanatory randomised controlled trial was conducted in 34 general practices in Eastern England (Anglo-Danish-Dutch Study of Intensive Treatment in People with Screen Detected Diabetes in Primary Care-Plus [ADDITION-Plus]). In all, 497 patients meeting eligibility criteria (age 40 to intensive treatment (n=259)) or intensive treatment plus a theory-based behaviour change intervention led by a facilitator external to the general practice team (n=239). Randomisation was central and independent using a partial minimisation procedure to balance stratifiers between treatment arms. Facilitators taught patients skills to facilitate change in and maintenance of key health behaviours, including goal setting, self-monitoring and building habits. Primary outcomes included physical activity energy expenditure (individually calibrated heart rate monitoring and movement sensing), change in objectively measured fruit and vegetable intake (plasma vitamin C), medication adherence (random drug levels) and...

Role of enactment: self-reported use of behaviour change techniques

Is BCT use associated with change in behaviour and BMI?

- Is the number of BCTs used by intervention participants associated with change in dietary intake, physical activity and BMI?
- Are specific BCTs associated with change in dietary intake, physical activity and BMI?

**Summary of findings**

<table>
<thead>
<tr>
<th></th>
<th>Number of BCTs</th>
<th>Specific BCTs?</th>
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<tbody>
<tr>
<td>Change in self-reported PA</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Objective PA</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Change in self-reported fat intake</td>
<td>-</td>
<td>Goal setting (diet) Goal review (diet) Preparing for setbacks (diet)</td>
</tr>
<tr>
<td>Change in plasma vitamin C</td>
<td>-</td>
<td>Goal review (diet)</td>
</tr>
<tr>
<td>Change in BMI</td>
<td>More BCTs (\rightarrow) more weight loss</td>
<td>Goal setting (PA &amp; diet) Social support (PA &amp; diet) Goal review (PA &amp; diet)</td>
</tr>
</tbody>
</table>
Conclusions

- Process evaluation is crucial to understanding why and how health promotion interventions work (or not), for whom and when
- It can inform theory development, future interventions, adaptations to interventions and illuminate outcome evaluation
- It requires a well-specified intervention and hypothesised mechanism of effects
- Use of theory and the BCT Taxonomy v1 aid the development of well-specified interventions
Thank You

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www.researchgate.net/profile/Wendy_Hardeman