Quality control in behavioural trials: Assessing fidelity and processes of change

Facilitators: Prof Molly Byrne and Dr Elaine Toomey

Health Behaviour Change Research Group,
School of Psychology, NUI Galway, Ireland

International Behavioural Trials Network Conference
26th May 2018
Overview
Learning objectives

To introduce and develop knowledge and skills in addressing intervention fidelity and processes of change within behavioural trials

By the end of this workshop you should be able:

• To describe approaches to the development of theory-based behaviour change interventions and outline strategies to measure mechanisms of action within behavioural trials

• To introduce participants to potential strategies for assessing and enhancing intervention fidelity within behavioural trials

• To give participants an opportunity to apply learning to examples of behavioural trials, as well as considering strategies for application to their own projects
# Workshop outline

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:00</td>
<td>Introductions and workshop overview</td>
<td>MB &amp; ET</td>
</tr>
<tr>
<td>9:15</td>
<td>So what’s the problem...? Importance of intervention fidelity and processes of change within behavioural trials</td>
<td>MB &amp; ET</td>
</tr>
<tr>
<td>9:45</td>
<td>Objective 1 Development of theory-based behaviour change interventions and strategies to measure mechanisms of action</td>
<td>MB EXERCISE 1</td>
</tr>
<tr>
<td>10:30</td>
<td>Break</td>
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<tr>
<td>10:45</td>
<td>Objective 2 Strategies for assessing and enhancing intervention fidelity</td>
<td>ET EXERCISE 2</td>
</tr>
<tr>
<td>11:45</td>
<td>Objective 3 Application to worked examples and Q&amp;A</td>
<td>MB &amp; ET</td>
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<tr>
<td>12:00</td>
<td>Finish</td>
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</table>
HRB Research Leaders Award 2013

To establish the **Health Behaviour Change Research Group** at NUI Galway, to promote the routine application of Behavioural Science to the development and evaluation of behavioural interventions within population and health-services research.
Our Vision
To improve population health by developing and promoting an evidence-based approach to health behaviour change interventions

We aim to

- **Lead** the behavioural research agenda, by identifying and pursuing behavioural research priorities which impact on health.
- **Develop, pilot and evaluate** complex interventions, using evidence-based behavioural theory and employing theory-linked behaviour change techniques.
- **Advance** the science of behaviour change and critically evaluate the evidence for different approaches to behaviour change.
- **Build** capacity by establishing a critical mass of excellent researchers, delivering innovative training and creating a vibrant learning environment.
- **Impact** on tangible health outcomes through development, evaluation and implementation of behaviour change interventions.
Our research topics include

- Cardiovascular disease
- Diabetes
- Hand hygiene in healthcare settings
- Infant feeding
- Medication adherence
- Multimorbidity
- Obesity
- Physical activity
- Primary care

Our methodological strengths are

- Complex interventions
- Conduct and reporting of trials
- Development of core outcomes sets
- Implementation science
- Qualitative research within trials
- Stakeholder engagement and consensus building
- Systematic reviews
- Fidelity assessment / Process evaluation
Capacity building

Designing Effective Interventions for Health Behaviour Change: An Introduction

Monday 16th October 2017
School of Psychology, NUI Galway (10am – 5pm)

Participants will learn about, and practice using, methods for designing and evaluating behavioural interventions. Suitable for researchers, practitioners, policy makers and students interested in behaviour change.

For more information, visit www.nuigalway.ie/hbcrg

Clinic Facilitators: Dr Molly Byrne and Dr Jenny McSharry
Health Behaviour Change Research Group, NUI Galway

Register now open! Designing Effective Interventions for Health Behaviour Change: Intensive Follow-Up Workshop

Friday 16th February 2018
School of Psychology, NUI Galway (10am – 5pm)

Limited Places Available!

To register, please visit http://tinyurl.com/HBCRG2018

Cost €100 (€40 students)

Workshop Facilitators: Dr Molly Byrne and Dr Jenny McSharry, Health Behaviour Change Research Group, NUI Galway

The follow-up workshop will provide mentoring and support to a small group of researchers, practitioners and policy makers currently engaged in the development and evaluation of behaviour change interventions.

For more information, visit www.nuigalway.ie/hbcrg

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For more on the HBCRG: valerie.parker@nuigalway.ie or molly.byrne@nuigalway.ie
Research projects

HRB RL Award

Advisory Board

Health Partners

HRB HRA

The CHARMS Study

HRB DIFA

eNow

HRB ICE

SPHeRE Structured Population and Health-services Research Education

MBMC MONTREAL BEHAVIOURAL MEDICINE CENTRE

ICUF Ireland Canada University Foundation

nbtn International Behavioural Trial Network

Capita Health National Institute for Health Research

SuMMiT-D Support through mobile messaging and digital health technology for diabetes

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES Medical Sciences Division

Health Behaviour Change Research Group

TMRN Trinity Methodology Research Network

HRB Primary Care CTNI CLINICAL TRIALS NETWORK IRELAND

2017 CALL for Entries

Ulysses
Research projects

HRB RL Award

HRB HRA
The CHARMS Study

HRB DIFA
D1Now

HRB HRA

HRB ICE

Health Partners

Advisory Board

Montreal Behavioural Medicine Centre

ICUF
Ireland Canada University Foundation

MBMC

Australia Hospital Research Institute
Institut de recherche de l'Hôpital d'Ottawa

ibtn
International Behavioural Trials Network

HRB Health Research Board

Health Behaviour Research Group

Ulysses

SuMMiT-D
Support for managing health and dietary technology for diabetes

SPHeRE
Structured Population and Health Services Research Education

HRB ICE

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES
Medical Sciences Division

National Institute for Health Research
HRB Interdisciplinary Capacity Enhancement (ICE) Award 2015

‘Develop and evaluate an infant feeding intervention to prevent childhood obesity in primary care’

Dr. Karen Matvienko-Sikar
Health Psychology

Dr. Michelle Queally
Health Economics

Dr. Elaine Toomey
Implementation Science/Intervention fidelity
PhD research

‘Exploring implementation fidelity within a physiotherapy self-management intervention in chronic low back pain and osteoarthritis’
The CHARMS Study

Implementation science, intervention fidelity, process evaluation

Physiotherapy, chronic pain → Cardiovascular disease → Public health, childhood obesity

Health behaviour change, complex interventions
WHO ARE YOU?
So what’s the problem?
The Formula for Good Health

- 0 Cigarettes
- 5 Servings of fruits and vegetables per day
- 10 Minutes of silence, relaxation or meditation per day
- 30 Body Mass Index < 30 kg/m²
- 150 Minutes of exercise per week (e.g., brisk walking or equivalent)

Place a ✓ for what you already do and an ✗ for what you commit to working on.
Conclusions

Four health behaviours combined predict a 4-fold difference in total mortality. The mortality risk for those with four compared to zero health behaviours was equivalent to being 14 y younger in chronological age.
Behaviour change interventions can be effective
A gender-sensitised weight loss and healthy living programme for overweight and obese men delivered by Scottish Premier League football clubs (FFIT): a pragmatic randomised controlled trial

Kate Hunt, Sally Wyke, Cindy M Gray, Annie S Anderson, Adrian Brady, Christopher Kurn, Peter T Dronnan, Elisabeth Fenwick, Eleanor Grieve, Jim Leishman, Evan Miller, Nonette Mutrie, Petro Rouchhaus, Alan White, Shoun Treweek

Figure 2: Mean weight (kg, 95% CI) in participants allocated to the Football Fans in Training weight loss programme or waiting list comparison group 12 weeks and 12 months after baseline measurement.
Behaviour change: the principles for effective interventions

Issued: October 2007

NICE public health guidance 6
guidance.nice.org.uk/ph6

Behaviour change: individual approaches

Issued: January 2014

NICE public health guidance 49
guidance.nice.org.uk/ph49
NICE recommendations

Plan & evaluate interventions carefully

- Take account of local and national context
- Use evidence-based techniques
- Describe mechanisms of change – how the intervention works!

Train practitioners in evidence-based behaviour change skills & competencies

Effective interventions:

- Target multiple ‘levels’: individual, community and population
- Individual level:
  - Provide realistic information about outcomes and emphasise personal salience;
  - Enhance self-efficacy;
  - Focus on immediate, tangible positive aspects of outcomes;
  - Assist with planning and goal setting;
  - Feedback, monitoring and structured follow up;
  - Employ social support and utilise people’s reference groups/significant others;
  - Increasing motivation through motivational interviewing when resistance to change
  - Use 2+ strategies
Behaviour change is complicated
Behaviour change isn't rocket science (it's harder)
Many interventions designed according to the ISLAGIATT principle

**It Seemed Like A Good Idea At The Time**

Patient has changed their behaviour!
Intervention worked!

But how did it work?
Can we do it again?
Can we train others to do the same?
Need for a common language
Biomedicine vs Behavioural Science

Varenicline (JAMA 2006)
- Intervention content:
  - Varenicline titrated to 1 mg twice daily (n = 344) or bupropion SR titrated to 150 mg twice daily (n = 342) or placebo (n = 341) for 12 weeks
- Mechanism of action

Behaviour counselling (Cochrane 2005)
- Intervention content:
  - Review smoking history & motivation to quit
  - Help identify high risk situations
  - Generate problem-solving strategies
  - Non-specific support & encouragement
- Mechanism of action

Which of these would you find easier to replicate?
Which of these could you explain to someone else?
Summary: So what’s the problem?

- Poor definition of interventions
  - Limited ability to develop science/theory
  - Limited ability to generalise findings
- No understanding of mechanisms of change
  - If effective, unclear why it worked, can’t replicate...
  - If ineffective, not sure why...

- NEED TO ARTICULATE AND TEST CAUSAL MECHANISMS OF CHANGE
Importance of scientific methods
How to improve behaviour change interventions

1. **Specify** target behaviour precisely
2. Use behavioural **theory** to develop interventions **systematically**
3. Describe and measure **mechanisms** through which these work
4. Specify **behaviour change techniques**, linking these to theory
5. Improve **reporting**, using standardised, shared terminology
6. Facilitate **combining evidence** in systematic reviews to **inform** practice
Why and how do these interventions work?
Or not?
Intervention fidelity

- Intervention fidelity – ‘extent to which intervention is implemented as intended by developers’
- Key in understanding why or how interventions succeed or fail
- Key component of MRC process evaluations of complex interventions
  - Mechanisms of action
  - Context
  - Fidelity

Carroll et al 2007, Moore et al 2015
Intervention fidelity

• Intervention fidelity.... OR

• Treatment fidelity, treatment integrity, intervention adherence, implementation fidelity, programme fidelity, programme integrity, procedural reliability, therapist adherence/competence.....
More than just the delivery....
Intervention without fidelity procedures:

Inform providers of what the intervention is and what is expected of them: e.g. provision of information session and nicotine patches

Assess study outcomes e.g. self-reported cigarette use
Intervention with fidelity procedures:

Design: Base intervention hypothesis on theory, assess application

Training: Ensure all providers receive similar training, assess this

Delivery: Facilitate all providers to deliver similar intervention, assess this

Receipt: Enhance all pts understanding intervention, assess this

Enactment: Enhance all pts use of intervention skills – assess this

Assess study outcomes e.g. self-reported cigarette use
• Accurate interpretation of effectiveness

• Increasing chance of intervention success

• Understand how and why intervention failed – guide refinement

• Understand key components of effective interventions – replication/implementation

• Complex interventions – numerous components
What are the gaps?

1991
• Moncher and Prinz

1998
• Dane and Schneider

2007
• Parham et al

2010
• Naleppa and Cagle

2012
• McArthur et al

2014
• Schinckus et al
• Garbacz et al

2015
• Prowse and Nagel
• Toomey et al

2016
• O’Shea et al

2017
• Rixon et al
• Walton et al
• Lambert et al

2018
• Toomey et al
Why??

- Several barriers previously identified
  - Time, resources, lack of guidance/knowledge, lack of editorial requirement, lack of buy-in

- Specific to psychotherapy and educational psychology research (Perepletchikova et al. 2009; Cochrane and Laux 2008)
Surveying intervention fidelity within trials of complex healthcare interventions

To explore knowledge, practice, attitudes and barriers and enablers to addressing intervention fidelity amongst researchers, triallists and healthcare professionals with experience of trials of complex healthcare interventions

Mr. Daragh McGee¹, Dr. Fabiana Lorenatto¹, Dr. Karen Matvienko Sikar¹, Dr. Elaine Toomey¹
¹National University of Ireland Galway, ²University College London, ³University College Cork
Methods

• Online survey
  • ([www.google.com/forms](http://www.google.com/forms))

• Inclusion criteria:
  – Researchers, triallists, healthcare professionals with research experience of trials of complex healthcare interventions
  – All areas of healthcare

• Exclusion criteria:
  – Study subjects/patient participants
  – Experience of drug/pharma trials only
Methods

– survey development

• 34 item questionnaire (30 closed-ended, 4 open-ended questions)

– Demographics

– Knowledge (5 questions)

– Practice (15 questions)

– Attitudes (5 questions)

• Questions piloted for content, feasibility, readability

Knowledge

12. Are you familiar with the term intervention fidelity?
Mark only one oval.

☐ Yes  Skip to question 17.
☐ No   Skip to question 17.

13. Which of the following do you think are components of intervention fidelity? (Tick all that apply)
Check all that apply.

☐ Ensuring that interventions adequately reflect their underlying theory (e.g. Theory of Planned Behaviour) or hypothesised mechanisms of action (e.g. using mediation analysis)
☐ Ensuring adequate difference between the treatment and control groups (i.e. treatment differentiation)

28. Please list what you feel are the three most important barriers to assessing, enhancing addressing or reporting intervention fidelity in trials of complex healthcare interventions.

_________________________________________________________________________

_________________________________________________________________________

_________________________________________________________________________

29. Which, if any, of the following do you think may be enablers/facilitators to enhancing addressing or reporting intervention fidelity in trials of complex healthcare interventions? (Tick all that apply)
Check all that apply.

☐ Clear understanding of the definition of intervention fidelity
☐ Good knowledge of how to assess or enhance it
☐ Availability of validated tools or checklists for assessment or enhancement
☐ Availability of practical guidance on strategies and how to adapt them to individual trials
☐ Perceived importance by researchers
☐ Perceived importance by academic journals
☐ Availability of reporting criteria specific to intervention fidelity
☐ Space allowances/reporting requirements within academic journals
☐ Accessibility of methodologists or people with skills to implement strategies
☐ Funding or monetary resources

Practice

16. In your experience of trials of complex interventions, was intervention fidelity ever assessed (i.e. the use of strategies to assess fidelity to the intervention) or enhanced (i.e. the use of strategies to improve fidelity to the intervention)?
Mark only one oval.

☐ Yes  Skip to question 17.
☐ No   Skip to question 23.
## Results - participants

- **264 participants – 15 countries**

<table>
<thead>
<tr>
<th>Country</th>
<th>N (%)</th>
<th>Country</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK</td>
<td>111 (42)</td>
<td>The Netherlands</td>
<td>2 (0.8)</td>
</tr>
<tr>
<td>Ireland</td>
<td>91 (34.5)</td>
<td>Switzerland</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Canada</td>
<td>31 (11.7)</td>
<td>Ethiopia</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Australia</td>
<td>11 (4.2)</td>
<td>South Africa</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>USA</td>
<td>5 (1.9)</td>
<td>Italy</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Denmark</td>
<td>4 (1.5)</td>
<td>Prefer not to say</td>
<td>2 (0.8)</td>
</tr>
<tr>
<td>Norway</td>
<td>3 (1.1)</td>
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<tr>
<td>Area of research</td>
<td>N (%)</td>
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<tr>
<td>Medical</td>
<td>122 (46.2)</td>
<td></td>
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<tr>
<td>Health services research</td>
<td>116 (43.9)</td>
<td></td>
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<tr>
<td>Allied health professionals</td>
<td>86 (32.6)</td>
<td></td>
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<tr>
<td>Nursing/midwifery</td>
<td>66 (25.0)</td>
<td></td>
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<tr>
<td>Psychology</td>
<td>64 (24.2)</td>
<td></td>
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<tr>
<td>Public health</td>
<td>63 (23.9)</td>
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<table>
<thead>
<tr>
<th>Previous training/research in intervention fidelity</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never received any formal or informal training</td>
<td>137 (51.7)</td>
</tr>
<tr>
<td>Informal self-directed research</td>
<td>83 (31.6)</td>
</tr>
<tr>
<td>Formal teaching (e.g. lectures, seminars)</td>
<td>24 (9.1)</td>
</tr>
<tr>
<td>Formal research (e.g. PhD, MSc)</td>
<td>20 (7.6)</td>
</tr>
<tr>
<td>Unsure</td>
<td>1 (0.4%)</td>
</tr>
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</table>
Results – knowledge

‘Are you familiar with intervention fidelity?’

- No: 30.3%
- Yes: 69.7%

Self-reported understanding of intervention fidelity was 5.84 ± 2.26
1(poor) to 10 (excellent)
What are the barriers to intervention fidelity?

- Cost: 37.2%
- Poorly identified core components: 40.2%
- Appropriate strategies not identified: 41.8%
- Inconsistent definitions: 42.9%
- Lack of perceived importance: 49.4%
- Inconsistent terminology: 56.7%
- Time restraints: 60.2%
- No criteria for acceptable levels: 62.8%
- Lack of practical guidance: 64%
- Poor knowledge/understanding: 77.4%
What are the **facilitators** to intervention fidelity?

<table>
<thead>
<tr>
<th>Facilitator</th>
<th>%</th>
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<tbody>
<tr>
<td>Time</td>
<td>43.7</td>
</tr>
<tr>
<td>Availability of reporting criteria</td>
<td>46.4</td>
</tr>
<tr>
<td>Accessibility of methodologists/expertise</td>
<td>47.1</td>
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<tr>
<td>Perceived importance by journals</td>
<td>50.6</td>
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<tr>
<td>Funding</td>
<td>52.1</td>
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<tr>
<td>Perceived importance by researchers</td>
<td>62.8</td>
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<tr>
<td>Clear understanding of the definition</td>
<td>72</td>
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<tr>
<td>Availability of practical guidance</td>
<td>69</td>
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<tr>
<td>Availability of validated tools/checklists</td>
<td>77.4</td>
</tr>
<tr>
<td>Knowledge</td>
<td>80.1</td>
</tr>
</tbody>
</table>
## Results

**Top 3 Barriers:**

1. Time (n=71)
2. Knowledge/understanding (n=64)
3. Cost (n=59)

**Top 3 Facilitators:**

1. Available tools/checklists (n=61)
2. Good knowledge (n=54)
3. Funding (n=48)
Survey conclusions

- Good awareness of intervention fidelity and importance
- Lack of knowledge and understanding
- Practical issues – time, cost

- Need for better clarification of terminology and components
- Need for further training and education
- Need for practical guidance (i.e. feasibility)
Summary: So what’s the problem?

- Behaviour change is a complex and important topic...

- Trials of behaviour change interventions limited by:
  - Focusing on outcome only with limited focus on process
    » Limited understanding mechanisms of action
  - Poor focus on intervention fidelity/why or how interventions succeed or fail
    » Limited interpretation of outcomes
    » Limited ability to replicate successful interventions
1. Theory-based interventions and mechanisms of action
Developing and evaluating complex interventions: the new Medical Research Council guidance

Peter Craig, programme manager, Paul Dieppe, professor, Sally Macintyre, director, Susan Michie, professor, Irwin Nazareth, director, and Mark Petticrew, professor

Author information Article notes Copyright and License information

Feasibility and piloting
Testing procedures
Estimating recruitment and retention
Determining sample size

Development
Identifying the evidence base
Identifying or developing theory
Modelling process and outcomes

Evaluation
Assessing effectiveness
Understanding change process
Assessing cost effectiveness

Implementation
Dissemination
Surveillance and monitoring
Long term follow-up
The six steps of Intervention Mapping

1. Logic Model of the Problem
   - Establish and work with a planning group
   - Conduct a needs assessment to create a logic model of the problem
   - Describe the context for the intervention including the population, setting, and community
   - State program goals

2. Program Outcomes and Objectives; Logic Model of Change
   - State expected outcomes for behavior and environment
   - Specify performance objectives for behavioral and environmental outcomes
   - Select determinants for behavioral and environmental outcomes
   - Construct matrices of change objectives
   - Create a logic model of change

3. Program Design
   - Generate program themes, components, scope, and sequence
   - Choose theory- and evidence-based change methods
   - Select or design practical applications to deliver change methods

4. Program Production
   - Refine program structure and organization
   - Prepare plans for program materials
   - Draft messages, materials, and protocols
   - Pretest, refine, and produce materials

5. Program Implementation Plan
   - Identify potential program users (implementers, adopters, and maintainers)
   - State outcomes and performance objectives for program use
   - Construct matrices of change objectives for program use
   - Design implementation interventions

6. Evaluation Plan
   - Write effect and process evaluation questions
   - Develop indicators and measures for assessment
   - Specify the evaluation design
   - Complete the evaluation plan
The Behaviour Change Wheel

Systematic Review: 19 frameworks Combined into the BCW
Intervention Development Process

**Stage 1: Understand the behaviour**
1. Define the problem in behavioural terms
2. Select target behaviour
3. Specify the target behaviour
4. Identify what needs to change

**Stage 2: Identify intervention options**
- Identify:
  - 5. Intervention functions
  - 6. Policy categories

**Stage 3: Identify content and implementation options**
- Identify:
  - 7. Behaviour change techniques
  - 8. Mode of delivery
The Capability Opportunity Motivation – Behaviour (COM-B) Model

Changing any behaviour involves identifying what needs to change in terms of: Capability, Motivation, Opportunity.
The COM-B Model

- **Capability**: Ability to engage in behaviour
- **Motivation**: Brain processes that energize and direct behaviour
- **Opportunity**: Environments that enable the behaviour
The COM-B Model

**Capability**
- Ability to engage in behaviour
  - **Physical capability (e.g. skills)**
    - Physical skill, strength, or stamina
  - **Psychological capability (e.g. knowledge)**
    - Knowledge or psychological skills, strength or stamina to engage in the necessary mental processes

**Motivation**
- Brain processes that energize and direct behaviour:
  - **Automatic (e.g. habits)**
    - Automatic processes involving emotional reactions, wants and needs, impulses, and reflex responses
  - **Reflective (e.g. goals)**
    - Reflective processes involving plans (self-conscious intentions) and evaluations

**Opportunity**
- Environments that enable the behaviour:
  - **Social opportunity (e.g. social norms)**
    - Interpersonal influences, social cues and cultural norms that influence the way we think about things
  - **Physical opportunity (e.g. affordability)**
    - Opportunity afforded by the environment involving time, resources, locations, cues, physical ‘affordance’
9 Intervention functions: Broad categories through which an intervention can change behaviour
Selecting Intervention Functions
Linking with COM-B components

http://www.behaviourchangewheel.com/

Enablement
## Selecting Intervention Functions

Linking with COM-B components

<table>
<thead>
<tr>
<th></th>
<th>Education</th>
<th>Persuasion</th>
<th>Incentivisation</th>
<th>Coercion</th>
<th>Training</th>
<th>Restriction</th>
<th>Environmental restructuring</th>
<th>Modelling</th>
<th>Enablement</th>
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<tbody>
<tr>
<td>C-Ph</td>
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## Selecting Intervention Functions
### APEASE Criteria

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<th>BCW Intervention Functions</th>
<th>Affordability</th>
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<th>Effectiveness and cost effectiveness</th>
<th>Acceptability</th>
<th>Side effects/safety</th>
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<td>✗</td>
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</table>
Behaviour Change Technique (BCT)

“An observable, replicable, and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour”

→ Active ingredients of behaviour change interventions

(Abraham & Michie, 2008)

• Provides a common standardized vocabulary to define behaviour change intervention components
The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions

Susan Michie, DPhil, CPsychol • Michelle Richardson, PhD • Marie Johnston, PhD, CPsychol • Charles Abraham, DPhil, CPsychol • Jill Francis, PhD, CPsychol • Wendy Hardeman, PhD • Martin P. Eccles, MD • James Cane, PhD • Caroline E. Wood, PhD

Published online: 20 March 2013
© The Society of Behavioral Medicine 2013

ORIGINAL ARTICLE

Consensus study with experts
### Electronic Supplementary Materials Table 3. BCT Taxonomy (v1): 93 hierarchically-clustered techniques

<table>
<thead>
<tr>
<th>Page</th>
<th>Grouping and BCTs</th>
<th>Page</th>
<th>Grouping and BCTs</th>
<th>Page</th>
<th>Grouping and BCTs</th>
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<td>6. Comparison of behaviour</td>
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<td>6.1. Demonstration of the behavior</td>
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<td>12.1. Restructuring the physical</td>
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<td>6.2. Social comparison</td>
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<td>12.3. Avoidance/reducing exposure to</td>
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<td>12.4. Distraction</td>
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<td>cues for the behavior</td>
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<td>12.5. Adding objects to the</td>
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<tr>
<td></td>
<td>1.7. Review outcome goal(s)</td>
<td></td>
<td></td>
<td></td>
<td>environment</td>
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<td>1.9. Commitment</td>
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<td></td>
<td>7.2. Cue signalling reward</td>
<td></td>
<td>7.2. Cue signalling reward</td>
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<td>13.1. Blue-printing</td>
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<td>7.3. Reduce prompts/cues</td>
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<td>5. Natural consequences</td>
<td>10</td>
<td>15. Self-belief</td>
<td>19</td>
<td>14.3. Reduce reward frequency</td>
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<td>5.1. Information about health</td>
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<td>14.4. Remove punishment</td>
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<td>4.1. Instruction on how to perform the</td>
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<td>16.1. Imaginary punishment</td>
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<tr>
<td></td>
<td>behavior</td>
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<td>4.2. Information about Antecedents</td>
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<td></td>
<td>4.3. Re-attribute</td>
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<td></td>
<td>4.4. Behavioral experiments</td>
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</tr>
<tr>
<td>1</td>
<td>3. Social support (practical)</td>
<td>9</td>
<td>10. Reward and threat</td>
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<tr>
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<td>3.3. Social support (emotional)</td>
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<td>10.1. Material incentive (behavior)</td>
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<td>6. Credible source</td>
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<td>10.2. Material reward (behavior)</td>
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<tr>
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<td>6.2. Pros and cons</td>
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<td>10.3. Non-specific reward</td>
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<td>1</td>
<td>6.3. Comparative imagining of</td>
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<td>10.4. Social reward</td>
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<tr>
<td></td>
<td>future outcomes</td>
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<td>10.5. Social incentive</td>
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<td></td>
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<td>10.6. Non-specific incentive</td>
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</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td>10.7. Self-incentive</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### 1.1 Goal setting (behavior)

Set or agree on a goal defined in terms of the behavior to be achieved.

*Note: 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.*

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.
Identify Behaviour Change Techniques linked to intervention functions

<table>
<thead>
<tr>
<th>Environmental restructuring</th>
<th>Most frequently used BCTs:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Adding objects to the environment</td>
</tr>
<tr>
<td></td>
<td>• Prompts/cues</td>
</tr>
<tr>
<td></td>
<td>• Restructuring the physical environment</td>
</tr>
</tbody>
</table>

Less frequently used BCTs:

- Cue signalling reward
- Remove access to the reward
- Remove aversive stimulus
- Satiation
- Exposure
- Associative learning
- Reduce prompt/cue
- Restructuring the social environment
Implementing international sexual counselling guidelines in hospital cardiac rehabilitation: development of the CHARMS intervention using the Behaviour Change Wheel

J. Mc Sharry*, P. J. Murphy and M. Byrne
This section is all to do with your leisure activity and how much exercise you take.

B1. In a **normal week**, how many times on average do you do the following kinds of exercise for more than 20 minutes during your free time?

(Please write the number of times on each line)

<table>
<thead>
<tr>
<th>Times per Week</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) STRENUOUS EXERCISE (HEART BEATS RAPIDLY)</td>
</tr>
<tr>
<td>(e.g. running, jogging, hockey, football, soccer, squash, basketball, judo, roller skating, vigorous swimming, vigorous long distance cycling)</td>
</tr>
<tr>
<td>b) MODERATE EXERCISE (NOT EXHAUSTING)</td>
</tr>
<tr>
<td>(e.g. fast walking, tennis, badminton, easy swimming, easy cycling, volleyball, baseball, dancing, heavy gardening)</td>
</tr>
<tr>
<td>c) MILD EXERCISE (MINIMAL EFFORT)</td>
</tr>
<tr>
<td>(e.g. yoga, golf, easy walking, fishing, bowling, light gardening)</td>
</tr>
</tbody>
</table>

---

B2. In a typical week, during your leisure time, how often do you engage in any regular activity, such as jogging or cycling, long enough to work up sweat?

---

*why don't you do some research about sex? Nobody mentions this*
Sexual problems twice as high in cardiac sample as general population

No high quality evidence for sexual counselling in cardiac rehab

Patients rarely receive support with sexual problems

Patients want more support
CHARMS Intervention: Specifying the Behaviour

<table>
<thead>
<tr>
<th>Who needs to perform the behaviour?</th>
<th>Cardiac rehabilitation healthcare providers</th>
</tr>
</thead>
</table>
| **What do they need to do differently to achieve the desired change?** | • Assess all patients for sexual concerns  
• Provide information and guidance about resuming sexual activity after a cardiac event  
• Assist patients with dealing with anxiety related to sexual concerns |
| **When do they need to do it?** | During phase III cardiac rehabilitation |
| **Where do they need to do it?** | Hospital cardiac rehabilitation centres in the Republic of Ireland |
| **How often do they need to do it?** | Once for every patient and respond appropriately to approaches from patients thereafter |
| **With whom do they need to do it?** | All patients attending phase III cardiac rehabilitation |
### CHARMS Intervention: Understanding the Behaviour

<table>
<thead>
<tr>
<th>Barriers identified from qualitative study (D’Eath et al., 2013)</th>
<th>Barriers identified from national survey (Doherty et al., 2011)</th>
<th>COM-B Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Lack of knowledge</td>
<td>• Lack of knowledge</td>
<td>CAPABILITY-PSYCHOLOGICAL</td>
</tr>
<tr>
<td>• Lack of information</td>
<td>• Lack of training</td>
<td></td>
</tr>
<tr>
<td>• Fear of offending</td>
<td>• Patients lack of readiness</td>
<td>MOTIVATION-REFLECTIVE</td>
</tr>
<tr>
<td>• Perceived lack of patent awareness</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **CHARMS** stands for Comprehensive Approach to Reducing Medication Use, Suicide, and Harm.
## Selecting Intervention Functions

Linking with COM-B components

<table>
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<tr>
<th></th>
<th>Education</th>
<th>Persuasion</th>
<th>Incentivisation</th>
<th>Coercion</th>
<th>Training</th>
<th>Restriction</th>
<th>Environmental restructuring</th>
<th>Modelling</th>
<th>Enablement</th>
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<td>C-Ph</td>
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<td>O-So</td>
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<td>M-A</td>
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<td>M-R</td>
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</table>
Selected intervention functions for CHARMS

Based on the APEASE criteria, the following intervention functions were selected:

- Education
- Persuasion
- Training
- Modelling
- Enablement
**Selecting Intervention Functions**

**APEASE criteria**

<table>
<thead>
<tr>
<th>BCW Intervention Functions</th>
<th>Affordability</th>
<th>Practicability</th>
<th>Effectiveness and cost effectiveness</th>
<th>Acceptability</th>
<th>Side effects/safety</th>
<th>Equity</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Education                  | ✓             | ✓              | ✓                                   | ✓             | ✓                   | ✓      | Education was judged to meet all of the APEASE criteria:  
- Affordability: it is covered within budgetary allocations  
- Practicability: it can be delivered as a staff training module  
- Effectiveness: this is uncertain, but judged to be worth evaluating as part of the pilot study  
- Acceptability: CR staff would welcome relevant education and training (D’Eath et al)  
- Side-effects: risk of unwanted side-effects was judged to be minimal  
- Equity: no negative impact |
|                            |               |                |                                     |               |                     |        | Decision  |
|                            |               |                |                                     |               |                     |        | Yes/No    |
Linking it All Together: Moving from COM-B to intervention function to BCTs to final intervention...

<table>
<thead>
<tr>
<th>Barriers identified (Source)</th>
<th>COM-B Component</th>
<th>Selected Intervention Functions</th>
<th>Selected Behaviour Change Techniques</th>
<th>Translation of BCTs within the intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of training (Doherty et al., 2011)</td>
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Linking it All Together: Moving from COM-B to intervention function to BCTs to final intervention...

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<tbody>
<tr>
<td>Lack of training (Doherty et al., 2011)</td>
<td>CAPABILITY-PSYCHOLOGICAL</td>
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Linking it All Together: Moving from COM-B to intervention function to BCTs to final intervention...

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<tr>
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<td>CAPABILITY-PSYCHOLOGICAL</td>
<td>Training</td>
<td></td>
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</tr>
</tbody>
</table>

![Diagram of sources of behaviour, intervention functions, and policy categories.](image)
### Linking it All Together: Moving from COM-B to intervention function to BCTs to final intervention...

<table>
<thead>
<tr>
<th>Barriers identified (Source)</th>
<th>COM-B Component</th>
<th>Selected Intervention Functions</th>
<th>Selected Behaviour Change Techniques</th>
<th>Translation of BCTs within the intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of training (Doherty et al., 2011)</td>
<td>CAPABILITY-PSYCHOLOGICAL</td>
<td>Training</td>
<td>4.1 Instruction on how to perform a behaviour</td>
<td>Provide manual and checklist of how to deliver group session Provide step by step guidance on how to address sexual concerns if raised</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6.1 Demonstration of behaviour</td>
<td>Show videos clips of good examples of HCPs interacting with patients who raise sexual concerns</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>8.1 Behavioural practice/rehearsal</td>
<td>Role play exercises of interacting patients who raise sexual concerns</td>
</tr>
</tbody>
</table>
## Linking it All Together: Moving from COM-B to intervention function to BCTs to final intervention...

<table>
<thead>
<tr>
<th>Barriers identified (Source)</th>
<th>COM-B Component</th>
<th>Selected Intervention Functions</th>
<th>Selected Behaviour Change Techniques</th>
<th>Translation of BCTs within the intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low confidence (among staff in the area of sexual counselling)</td>
<td>MOTIVATION-REFLECTIVE</td>
<td>Persuasion</td>
<td>15.1 Verbal persuasion about capability</td>
<td>The CHARMS Educator will provide verbal support and reassurance throughout the training session, telling the staff members that they can successfully provide sexual counselling to their patients.</td>
</tr>
<tr>
<td>Modelling</td>
<td>6.1 Demonstration of the behaviour</td>
<td>Show video clips depicting a cardiac rehabilitation staff member providing sexual counselling in a confident, assured manner.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1. The CHARMS Staff Intervention:
A two-hour training session for cardiac rehabilitation staff in sexual counselling skills

2. The CHARMS Patient Intervention:
A staff-led patient education and support session embedded within the cardiac rehabilitation programme

3. A Patient Information Booklet:
Developed by an expert panel for the American Heart Association and adapted for use in the CHARMS study

4. An Awareness Raising Poster

**Figure 1** Process map of behaviour change in SOLAS intervention.
Monitoring and Evaluation – Ongoing monitoring and evaluation of patient, service and implementation outcomes to inform ongoing improvements

**Inputs**
- Clinical Guideline Development Group
- Implementation team(s)
- Clinical Effectiveness Unit, Department of Health
- National Patient Safety Office, Department of Health
- National Clinical Effectiveness Committee
- Health Service Executive
- National Clinical Guideline
- Supporting documentation and tools
- Healthcare staff and professionals
- Champions
- Implementation & implementation support resources

**Activities & Outputs**
- Communication & stakeholder engagement
- Develop and deliver implementation plan
- Adapt/change policies, procedures, and/or systems as required
- Dissemination of guideline
- Training for relevant staff
- Provide ongoing professional development supports to staff
- Implement guideline recommendations

**Short/medium-term Outcomes**
- Recommendations are feasible to implement across Irish health service systems
- Stakeholders accept the recommendations
- Healthcare staff, services and systems adopt the interventions
- Improvements in quality and effectiveness of healthcare delivery
- Health service users more satisfied with patient care
- Improvements in patient outcomes in settings where recommendations are implemented

**Long-term Outcomes**
- Recommendations implemented across systems with fidelity
- Delivery of recommendations are cost-effective and sustained
- Healthcare outcomes improved

**Evidence** – Systematic reviews of evidence; budget impact assessment; stakeholder engagement, including patients; scoping of feasibility and implementability of recommendations; expert review

This draft template was shared at the 2-day Training in Implementation Science on the 17th and 18th May 2017 organised by the Clinical Effectiveness Unit in the Department of Health
Intervention to promote physical activity

Evidence – Systematic reviews of evidence; budget impact assessment; stakeholder engagement, including patients; scoping of feasibility and implementability of recommendations; expert review

This draft template was shared at the 2-day Training in Implementation Science on the 17th and 18th May 2017 organised by the Clinical Effectiveness Unit in the Department of Health
Activity 1
Break
2. Enhancing and assessing intervention fidelity
Intervention fidelity

- Intervention fidelity – ‘extent to which intervention is implemented as intended by developers’ (Carroll et al 2007)

- ‘Methodological strategies to monitor (assess) and enhance (improve) reliability and validity of behavioural interventions’ (Bellg et al 2004)
What do we know?

- Fidelity is **complex** – important to address systematically, comprehensively
- Good theoretical papers and frameworks exist
- 73.6% of researchers, triallists and healthcare professionals - never used specific fidelity framework/tool (McGee et al. under review)
## Survey findings

<table>
<thead>
<tr>
<th>Fidelity frameworks/tools used if used</th>
<th>N (68 total possible) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011 Updated NIHBCC Treatment Fidelity Framework (Borrelli 2011)</td>
<td>26 (10.1)</td>
</tr>
<tr>
<td>Conceptual Framework for Implementation Fidelity (Carroll et al 2007)</td>
<td>26 (10.1)</td>
</tr>
<tr>
<td>2004 NIHBCC Treatment Fidelity Framework (Borrelli et al 2005)</td>
<td>19 (7.4)</td>
</tr>
<tr>
<td>Unsure/Don’t know</td>
<td>6 (2.3)</td>
</tr>
<tr>
<td>Comprehensive Intervention Fidelity Guide (Gearing et al 2011)</td>
<td>5 (1.9)</td>
</tr>
<tr>
<td>Other</td>
<td>15 (5.8)</td>
</tr>
<tr>
<td>Medical Research Council Guidance on Process Evaluation of Complex Interventions</td>
<td>3 (1.2)</td>
</tr>
<tr>
<td>TIDieR checklist</td>
<td>2 (0.8)</td>
</tr>
<tr>
<td>Developed specifically for study</td>
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</tr>
<tr>
<td>Multiple ‘ad hoc’ publications consulted</td>
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</tr>
<tr>
<td>RE-AIM framework</td>
<td>1 (0.4)</td>
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<tr>
<td>Framework/Taxonomy of Implementation</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Precede-Proceed</td>
<td>1 (0.4)</td>
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<tr>
<td>Conceptual Framework of Implementability</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Process Evaluation ‘How-to’ Guide</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>BCT Taxonomy v1</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Karas and Plankis 2016</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Durlak and DuPre 2008</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>SPIRIT Intervention Fidelity Assessment Tool</td>
<td>1 (0.4)</td>
</tr>
</tbody>
</table>
Conceptual Framework for Implementation Fidelity (CFIF) (Carroll et al 2007)
Modified CFIF (Hasson et al. 2010)
## Assessment of major fidelity components

<table>
<thead>
<tr>
<th>Intervention design</th>
<th>Intervention training</th>
<th>Monitoring intervention delivery</th>
<th>Monitoring intervention receipt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement</td>
<td>Measurement</td>
<td>Measurement</td>
<td>Measurement</td>
</tr>
<tr>
<td>1) Types of instruments</td>
<td>1) Types of instruments</td>
<td>1) Types of instruments</td>
<td>1) Types of instruments</td>
</tr>
<tr>
<td>A. Planned what instrument to use</td>
<td>A. Use pre- and post-test knowledge measures</td>
<td>A. Checklists</td>
<td>A. Checklists</td>
</tr>
<tr>
<td>2) Measurement raters</td>
<td>2) Measurement raters</td>
<td>A. Likert scales</td>
<td>B. Likert scales</td>
</tr>
<tr>
<td>A. Planned type(s) of evaluators</td>
<td>B. Frequency</td>
<td>C. Frequency</td>
<td>C. Frequency</td>
</tr>
<tr>
<td>3) Method of observation</td>
<td>D. Dose delivered</td>
<td>E. Use pre- and post-test</td>
<td>E. Use pre- and post-test knowledge measures</td>
</tr>
<tr>
<td>A. Selected method(s) of observation.</td>
<td>E. Case formulations</td>
<td>F. Specify measures</td>
<td>F. Specify measures</td>
</tr>
<tr>
<td>4) Psychometric properties</td>
<td>2) Measurement raters</td>
<td>I. Self-report on understanding</td>
<td>I. Self-report on understanding</td>
</tr>
<tr>
<td>A. Validity</td>
<td>A. Internal evaluators</td>
<td>II. Self-report on behaviors</td>
<td>II. Self-report on behaviors</td>
</tr>
<tr>
<td>B. Reliability</td>
<td>B. Study participant</td>
<td>III. Chart review on client behaviors</td>
<td>III. Chart review on client behaviors</td>
</tr>
<tr>
<td>C. Confirmed in previous literature or pilot study</td>
<td>III. Supervisors</td>
<td>IV. Client satisfaction measures</td>
<td>IV. Client satisfaction measures</td>
</tr>
<tr>
<td>5) Sampling for consistency</td>
<td>IV. Others</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A. Planned protocol for sampling</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6) Attendance for full training</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7) Understanding components of intervention measure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8) Skill acquisition measure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9) Belief in intervention effectiveness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10) Understanding components of intervention measure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11) Skill acquisition measure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12) Belief in intervention effectiveness</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Rate:** Present, Absent but should be present, and Not Applicable. If present, describe the strategy used for that component

| Design | 1) Provided information about treatment dose in the intervention condition:  
|        |   - Length of contact (minutes)  
|        |   - Number of contacts  
|        |   - Duration of intervention  
|        |   - Content of treatment  
| 2) Provided information about treatment dose in the intervention condition:  
|        |   - Length of contact (minutes)  
|        |   - Number of contacts  
|        |   - Duration of intervention  
|        |   - Content of treatment  
| 3) Provided information about treatment dose in the intervention condition:  
|        |   - Length of contact (minutes)  
|        |   - Number of contacts  
|        |   - Duration of intervention  
|        |   - Content of treatment  
| 4) Provided information about treatment dose in the intervention condition:  
|        |   - Length of contact (minutes)  
|        |   - Number of contacts  
|        |   - Duration of intervention  
|        |   - Content of treatment  
| 5) Provided information about treatment dose in the intervention condition:  
|        |   - Length of contact (minutes)  
|        |   - Number of contacts  
|        |   - Duration of intervention  
|        |   - Content of treatment  
| 6) Provided information about treatment dose in the intervention condition:  
|        |   - Length of contact (minutes)  
|        |   - Number of contacts  
|        |   - Duration of intervention  
|        |   - Content of treatment  
| 7) Provided information about treatment dose in the intervention condition:  
|        |   - Length of contact (minutes)  
|        |   - Number of contacts  
|        |   - Duration of intervention  
|        |   - Content of treatment  

| Training Providers | 7) If more than one intervention is described, all described equally well*  
| 1) Description of how providers will be trained (manual of training procedures)  
| 2) Standardization of provider training (especially if multiple waves of training are needed for multiple groups of providers)  
| 3) Assessment of provider skill acquisition  
| 4) Assessment and monitoring of provider skill maintenance over time  
| 5) Characteristics being sought in a treatment provider are articulated a priori. Characteristics that should be avoided in a treatment provider are articulated a priori*  
| 6) At the hiring stage, assessment of whether or not there is a good fit between the provider and the intervention (e.g., ensure that providers find the intervention acceptable, credible and potentially efficacious)*  
| 7) There is a training plan that takes into account trainees' different education and experience and learning styles*  

| Delivery of Treatment | 1) Method to ensure that the content of the intervention is delivered as specified  
| 2) Method to ensure that the dose of the intervention is delivered as specified  
| 3) Mechanism to assess if the provider actually adhered to the intervention plan or in the case of computer delivered interventions, method to assess participants’ contact with the information  
| 4) Assessment of nonspecific treatment effects  
| 5) Used treatment manual  
| 6) There is a plan for the assessment of whether or not the active intervention was changed  

Borrelli et al 2005, Borrelli et al 2011
Framework comparisons

- **Carroll et al 2007/Hasson et al 2010 (CFIF):**
  - Led by psychology researchers, no specific setting
  - Conceptual level

- **Gearing et al 2011 (CIFG):**
  - Community-based psychological, social, and behavioural intervention research
  - Less utilised
  - Structured, comprehensive

- **Bellg/Borrelli et al 2004/2005/2011 (NIHBCC):**
  - Health behaviour change interventions
  - Validity and reliability tested
  - Structured, comprehensive
Framework similarities

• Consider fidelity as broader than delivery
  – Fidelity to intervention design/theory
  – Importance of how providers are trained
  – Involvement of participants

• Strategies to enhance (i.e. improve), assess (monitor) and report fidelity
What do these fidelity strategies look like?
Systematic reviews of fidelity strategies

Methods used to address fidelity of receipt in health intervention research: a citation analysis and systematic review

Lorna Rixon\textsuperscript{1}, Justine Baron\textsuperscript{2}, Nadine McGale\textsuperscript{1}, Fabiana Lorencatto\textsuperscript{1}, Jill Francis\textsuperscript{1} and Ani
Assessing fidelity of delivery (Walton et al 2017)

<table>
<thead>
<tr>
<th>Type of measures used</th>
<th>Observational measures ($n = 17; 38.6%$):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Video ($n = 2; 4.55%$)$^{27,51}$</td>
</tr>
<tr>
<td></td>
<td>Audio ($n = 13; 29.5%$)$^{7,19,21,22,38,40,45,48,55,57,58,63,64}$</td>
</tr>
<tr>
<td></td>
<td>Non-specific ($n = 2; 4.55%$)$^{1,34}$</td>
</tr>
<tr>
<td>Self-report measures ($n = 15; 34%$):</td>
<td>Provider (hand) ($n = 7; 15.9%$)$^{6,10,14,16,41,42,59}$</td>
</tr>
<tr>
<td></td>
<td>Provider (computer) ($n = 3; 6.8%$)$^{24,23,36}$</td>
</tr>
<tr>
<td></td>
<td>Participant (hand) ($n = 2; 4.6%$)$^{28,11}$</td>
</tr>
<tr>
<td></td>
<td>Participant (computer) ($n = 1; 2.3%$)$^{49}$</td>
</tr>
<tr>
<td></td>
<td>Non-specific (computer) ($n = 2; 4.6%$)$^{52,66}$</td>
</tr>
<tr>
<td>Multiple measures ($n = 11; 25%$):</td>
<td>Provider and participant self-report ($n = 4; 9%$)$^{2,30,35,50}$</td>
</tr>
<tr>
<td></td>
<td>Audio and provider self-report ($n = 3; 6.8%$)$^{20,26,39}$</td>
</tr>
<tr>
<td></td>
<td>Video + provider self-report ($n = 1; 2.3%$)$^{5}$</td>
</tr>
<tr>
<td></td>
<td>Observation and exercise log (participant) ($n = 1; 2.3%$)$^{31}$</td>
</tr>
<tr>
<td></td>
<td>Direct observation and rating ($n = 1; 2.3%$)$^{29}$</td>
</tr>
<tr>
<td></td>
<td>Participant self-report and patient files ($n = 1; 2.3%$)$^{60}$</td>
</tr>
<tr>
<td>Other measures ($n = 1; 2.3%$):</td>
<td>Quantitative rated interviews with providers ($n = 1; 2.3%$)$^{33}$</td>
</tr>
</tbody>
</table>
Survey findings – assessment strategies identified

<table>
<thead>
<tr>
<th>FIDELITY STRATEGIES</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider self-report record</td>
<td>115 (63.5)</td>
</tr>
<tr>
<td>Direct observation</td>
<td>106 (58.6)</td>
</tr>
<tr>
<td>Participant interview</td>
<td>106 (58.6)</td>
</tr>
<tr>
<td>Provider interview</td>
<td>81 (44.8)</td>
</tr>
<tr>
<td>Participant self-report record</td>
<td>73 (40.3)</td>
</tr>
<tr>
<td>Audio recording</td>
<td>67 (37)</td>
</tr>
<tr>
<td>Participant follow up visits</td>
<td>57 (31.5)</td>
</tr>
<tr>
<td>Exit questionnaires</td>
<td>56 (30.9)</td>
</tr>
<tr>
<td>Video recording</td>
<td>27 (14.9)</td>
</tr>
<tr>
<td>None</td>
<td>1 (0.6)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FIDELITY STRATEGIES</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other</td>
<td>8 (4.4)</td>
</tr>
<tr>
<td>Simulated patients</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Audit or chart review</td>
<td>2 (1.1)</td>
</tr>
<tr>
<td>Web analytics (digital interventions)</td>
<td>3 (1.7)</td>
</tr>
<tr>
<td>Blood tests</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Use of validated fidelity measures</td>
<td>1 (0.6)</td>
</tr>
</tbody>
</table>
Survey findings – enhancement strategies identified

<table>
<thead>
<tr>
<th>FIDELITY STRATEGIES</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training manual</td>
<td>148 (81.3)</td>
</tr>
<tr>
<td>Reminder checklists</td>
<td>137 (75.3)</td>
</tr>
<tr>
<td>Treatment manual/scripted curriculum/standard operating procedures</td>
<td>118 (64.8)</td>
</tr>
<tr>
<td>Protocol review group</td>
<td>84 (46.2)</td>
</tr>
<tr>
<td>None</td>
<td>4 (2.2)</td>
</tr>
<tr>
<td>Other</td>
<td>7 (3.8)</td>
</tr>
<tr>
<td>Ongoing support/supervision for providers</td>
<td>2 (1.1)</td>
</tr>
<tr>
<td>Observation/audit of providers delivering intervention</td>
<td>3 (1.6)</td>
</tr>
<tr>
<td>Colour coding materials for providers</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>Interim analysis</td>
<td>1 (0.5)</td>
</tr>
</tbody>
</table>
Quality of fidelity assessment strategies

- Psychometric qualities - reliability and validity
- Implementation qualities – acceptability, practicality and cost

- Rixon et al 2016 - assessment of receipt
  - 90.0% = subjective assessments of receipt only
  - 26.0% reported on the reliability or validity
- Walton et al – assessment of delivery
  - 84.1% reported either reliability or validity
  - 27.3% reported implementation quality
Fidelity and adaptation

- Fidelity **versus** adaptation/flexibility?
  - Form or function?
  - Theory or content?
  - Adherence or competence?

Hawe 2015; Toomey and Hardeman 2017

that standardization should be conducted in a different way (67). They suggest that the form that the components take may vary across sites, but the function that they perform in the local context is always the same. Standardizing by function, rather than by form, requires investigators to consider the role that a component plays in the overall change process (67). Standardizing by function is the chief means by which a complex intervention is allowed to adapt to local context without sacrificing fidelity. Fidelity resides in the theory of the change process, rather than in any particular technology, component, or delivery channel per se. Thus, the role and meaning behind a particular component, rather than its face value, are what matter. Local-level adaptation is important for maximizing effects and encouraging ongoing sustainability (15, 107, 108). Byng and
Reporting of intervention fidelity

- Reporting of use of strategies to enhance or assess fidelity
- Reporting results of fidelity assessment
- Limitation of all reviews: have empirical data to support this

Conceptualisation and nomenclature. However, it must also be acknowledged that conduct and reporting are two distinct concepts (Leeden et al., 2014), and while the fidelity of the included studies may not necessarily be poor, its reporting clearly is. Although key reporting guidelines exist for the reporting and publication of clinical trials as the CONSORT (Schulz et al., 2010) and TREND (Des Jarlais et al., 2004) statements, only the latter refers briefly to fidelity but does not give specific guidance as to how it should be reported within trials. Some of the aspects of the CONSORT and TREND checklists overlap with components on the NIH guidelines checklist (e.g. content and dosage of intervention), but there are a number of elements that they do not address, such as the use of treatment manuals and details of provider training. This overlap is illustrated by the fact that only three studies explicitly reported addressing fidelity (Hughes et al., 2004, 2006; Johnson et al., 2007; Coleman et al., 2012), yet all included studies addressed some aspect of fidelity, more than likely as coincidental standard trial reporting required by the CONSORT and TREND guidelines. As yet,
Figure 2: Frequency of use of assessment strategies, enhancement strategies and reporting

- **Never**: 1.7% (n=3), 9.4% (n=17)
- **Rarely**: 21.5% (n=39), 19.3% (n=35)
- **Sometimes**: 32.6% (n=59), 29.8% (n=54)
- **Frequently**: 35.4% (n=63), 34.8% (n=55)
- **Always**: 13.8% (n=25), 5.5% (n=10)

- Use of assessment strategies
- Use of enhancement strategies
- Reporting use of strategies
Activity 2
Activity 2 feedback

- What are the difficulties?
  - Overlap between enhance and assess? Receipt and enactment?
  - Practicalities - what to do if resources limited?
    - Key uncertainties?
    - Sampling based on sites etc?
    - Theoretical fidelity v content?
- What else might you want to include?
  - Existing fidelity measures (e.g. Motivational Interviewing)
  - Influences of context on intervention fidelity?
  - Mechanisms of action?
- How and what will you report?
### Training of Providers

| Description of how providers will be trained (manual of training procedures) | Yes | A standardized training manual detailing content, structure, timing, and setting will be used by the research team to deliver the training.
Scripted role plays will be used.
Predeveloped written case studies will be used.
The development of training of providers enhancement strategies will be detailed fully elsewhere. |
| --- | --- | --- |

| Standardization of provider training (especially if multiple waves of training are needed for multiple groups of providers) | Yes | A standardized training manual detailing content, structure, timing, and setting will be used by the research team to deliver the training for each training wave.
For each wave, providers from all sites will attend the same training.
Scripted role plays will be used.
Predeveloped written case studies will be used. |
| --- | --- | --- |

| The content, structure, timing, setting, and number and characteristics of trainers will be recorded on a post-training record form, which will be completed by the research team trainers subsequent to the training. The development of training of providers assessment strategies will be detailed fully elsewhere. Audio recordings of role plays used during the training will be conducted. |
| --- | --- | --- |

### Design

A 2-phase mixed-methods design was used.
A multidimensional intervention for audit and feedback to reduce unnecessary blood transfusions: study protocol

Fabiana Lorencatto, Natalie J. Huxley, Robert Cicero, Liz Glidewell, Sharon R. Smith, Susan Michie, Jill J. Francis

STUDY PROTOCOL

Table 1 BCC fidelity dimensions (Bellg et al. [11]) and their application in the AFFINITIE trial

<table>
<thead>
<tr>
<th>Fidelity dimensions</th>
<th>Application intervention 1 (enhanced content — feedback reports)</th>
<th>Application intervention 2 (enhanced follow-on support — web-based toolkit + telephone support)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>• Intervention content and delivery parameters described in separate intervention development papers for each intervention.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Description of intervention content in terms of component behaviour change techniques (BCTs) using established BCT taxonomy.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Treatment differentiation: comparison of BCTs between both interventions and between each intervention and corresponding control standard practice comparator. BCTs will be compared in terms of frequency, mode of delivery, behavioural specificity and enactment instruction. BCTs that are identified at least once in either intervention and/or comparator will be classified as either fully convergent (present in similar frequency/mode of delivery/behavioural specificity/enactment instruction in both intervention/comparator), partially convergent (present in both, but at different frequencies/modes of delivery/behavioural specificity/enactment instruction) or unique (present in only intervention or comparator). The percentage of BCTs in each category will be assessed, with a higher proportion of fully/partially convergent BCTs indicating lower treatment differentiation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Hospitals in the intervention and control trial arms for intervention 1 will both receive at least one feedback report and feedback PowerPoint presentations as per standard practice.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• However, dose may differ in terms of the number of feedback reports received per condition, as the enhanced feedback report condition includes multiple feedback reports following a graded entry approach (i.e. level 1 — key findings level 3 — detailed supplementary findings report).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The enhancement guidance manual will be used to produce a report template containing the proposed enhancements, which will be populated with hospital specific data for each hospital. Using a template will help ensure the format and content of reports is consistent across hospital specific reports.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• N/A; All hospitals randomised to the enhanced condition for intervention 2 will receive the toolkit and initial telephone support at equivalent doses. However, hospitals in the control condition for intervention 2 will not receive an equivalent dose of intervention 2 as the comparator is a standard practice/no intervention condition.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The same web-based toolkit will be delivered to all intervention 2 hospitals. Dose is standard within condition.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• All hospitals will receive one initial facilitator-initiated telephone support call.</td>
<td></td>
</tr>
</tbody>
</table>

Method to ensure dose is equivalent between conditions.

NUI Galway
OÉ Gaillimh
Final fidelity thoughts...

- Use a framework/existing tools
- Think about fidelity as more than delivery
- Clarify how you are defining/conceptualising it
- Consider both enhancement and assessment strategies
- Assessment strategies - comprehensiveness v feasibility
  - How much/how many to assess? Purposive sampling?
  - Consider psychometric (reliability, validity) and implementation (feasibility) properties of assessment measures
  - Existing measures?
  - Mixed methods
  - Objective and subjective
- Reporting and further action
3. Application to own context
Conclusions
Key references and recommended reading


Key references and recommended reading


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Twitter: @MollyByrneIre @hbcr @oonaghmeade @ElaineToomey1
Website: http://www.nuigalway.ie/hbcrg/
32nd Annual Conference of the European Health Psychology Society

Health Psychology Across the Lifespan: Uniting Research, Practice and Policy

Galway, Ireland | 21 - 25 August 2018

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