Exploring Implementation Fidelity within Complex Behaviour Change Interventions

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Current role

- HRB ICE postdoctoral fellow
- http://www.nuigalway.ie/hbcrg/
Overview

- Background - What is fidelity? Why does it matter?
- Current knowledge - What do we know?
- Current gaps - What do we not know? Why?
- How can this be addressed?
Background...
Implementation fidelity

- Implementation fidelity (IF) - ‘extent to which intervention is implemented as intended by developers’

- ‘Methodological strategies to monitor (assess) and enhance reliability and validity of behavioural interventions’

Carroll et al 2007, Bellg et al 2004
Implementation fidelity

- Implementation fidelity.... OR
- Treatment fidelity, treatment integrity, intervention fidelity, 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 do we know?

- Increasing area of interest
- Good theoretical papers and frameworks
  - Theoretical papers e.g. MRC Guidance for Process Evaluations of Complex Interventions (Moore et al 2015)
- Fidelity is complex - important to address systematically, comprehensively
National Institutes of Health Behaviour Change Consortium (NIHBCC) Fidelity Framework

- Study Design
- Provider Training
- Treatment Delivery (TD)
- Treatment Receipt (TR)
- Treatment Enactment (TE)

<table>
<thead>
<tr>
<th>Design</th>
<th>Provided information about treatment dose in the intervention condition:</th>
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<tbody>
<tr>
<td></td>
<td>Length of contact (minutes)</td>
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<tr>
<td></td>
<td>Number of contact sessions</td>
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<tr>
<td></td>
<td>Content of treatment</td>
</tr>
<tr>
<td></td>
<td>Duration of contact</td>
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<table>
<thead>
<tr>
<th>Training Providers</th>
<th>7) If more than one intervention is described, all described equally well*</th>
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<tbody>
<tr>
<td></td>
<td>1) Description of how providers will be trained (manual of training procedures)</td>
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<tr>
<td></td>
<td>2) Standardization of provider training (especially if multiple waves of training are needed for multiple groups of providers)</td>
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<tr>
<td></td>
<td>3) Assessment of provider skill acquisition</td>
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<tr>
<td></td>
<td>4) Assessment and monitoring of provider skill maintenance over time</td>
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<tr>
<td></td>
<td>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*</td>
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<td></td>
<td>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)*</td>
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<td></td>
<td>7) There is a training plan that takes into account trainees’ different education and experience and learning styles*</td>
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<table>
<thead>
<tr>
<th>Delivery of Treatment</th>
<th>1) Method to ensure that the content of the intervention is delivered as specified</th>
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<tbody>
<tr>
<td></td>
<td>2) Method to ensure that the dose of the intervention is delivered as specified</td>
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<td></td>
<td>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</td>
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<td></td>
<td>4) Assessment of nonspecific treatment effects</td>
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<td></td>
<td>5) Used treatment manual</td>
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<tr>
<td></td>
<td>6) Training plan for the assessment of whether or not the active ingredient was administered</td>
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Borrelli et al 2005, Borrelli et al 2011
Training

Delivery

Receipt

Design

Enactment

Assess

Report

FIDELITY

Enhance
Treatment Delivery:

- **Enhancement:**
  - Intervention manuals...
- **Assessment:**
  - Direct observations
  - Self-report
  - Audio-recordings

Treatment Receipt/Enactment:

- **Enhancement:**
  - Handbooks, booklets, pedometers...
- **Assessment:**
  - Diaries?
  - Interviews?
What are the gaps?

Countless reviews - IF still poorly addressed

- Moncher and Prinz, 1991,
- Dane and Schneider, 1998,
- Parham et al., 2007,
- Naleppa and Cagle, 2010,
- McArthur et al., 2012,
- Schinckus et al., 2014,
- Garbacz et al 2014,
- Prowse and Nagel, 2015,
- Toomey et al 2015....
What are the gaps?

- Use of existing knowledge - frameworks not used, not used fully (Mars et al 2013, Dyas et al 2014, French et al 2015)
- Few examples in an Irish context (Spillane et al 2007)
- Few examples in physiotherapy settings (Huijg et al 2015)
- Treatment receipt and enactment still not focused on (Prowse and Nagel 2015)
  - 42% studies emphasised TR/TE, 74% emphasised TD
Barriers to fidelity (researchers and practitioners) - time constraints, limited IF resources, lack of guidance/knowledge (Perepletchikova et al 2009, Huijg et al 2015)

Few pragmatic guidance and methodology papers (Perepletchikova et al 2009, O’Donnell 2008)

Lack of focus on feasibility of IF assessment methods

Argument that benefits of fidelity assessment outweighs time and cost (Mars et al 2013) - is this realistic?
PhD research

- **Context** - SOLAS feasibility randomised controlled trial (RCT)
  - Complex behaviour change intervention to promote self-management
  - Chronic low back pain and/or osteoarthritis
  - Irish primary care physiotherapy setting
  - 6 weekly sessions
  - Group-based education and exercise

Hurley et al 2016a, 2016b
## SOLAS intervention

<table>
<thead>
<tr>
<th>Session number</th>
<th>Self-management behaviour/skills targeted</th>
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<tbody>
<tr>
<td>1</td>
<td>Physical activity, goal-setting</td>
</tr>
<tr>
<td>2</td>
<td>Pacing, physical activity, goal-setting</td>
</tr>
<tr>
<td>3</td>
<td>Balanced weight, physical activity, goal-setting</td>
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<tr>
<td>4</td>
<td>Pain relief (e.g. medication use), physical activity, goal-setting</td>
</tr>
<tr>
<td>5</td>
<td>Managing mood/stress (relaxation), physical activity, goal-setting</td>
</tr>
<tr>
<td>6</td>
<td>Long-term management, physical activity, goal-setting</td>
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Hurley et al 2016a, 2016b
Research aims

Aim:
To explore implementation fidelity of complex behaviour change interventions

Research questions:
1. How has IF been previously addressed in complex interventions in this context?
2. How can IF be best addressed within a complex intervention in this context?
Research overview

Study 1:
Rapid review of the IF and effectiveness of group-based PT interventions to promote self-management

Study 2:
Development of an IF protocol within a complex intervention to promote self-management

Study 3:
Applying the IF protocol: Assessment of Treatment Delivery

Study 4:
Applying the IF protocol: Assessment of Treatment Receipt/Enactment

Research Question 1:

Research Question 2:

SOLAS pilot study

SOLAS feasibility RCT
Development of a Feasible Implementation Fidelity Protocol Within a Complex Physical Therapy–Self Management Intervention

Open Access

BMJ Open

Sexual counselling for patients with cardiovascular disease: protocol for a pilot study of the CHARMS sexual counselling intervention

Patrick J Murphy, Jenny Mc Sharry, Dympna Casey, Sally Doherty, Paddy Gillespie, Tiny Jaarsma, Andrew W Murphy, John Newell, Martin O'Donnell, Elaine E Steinke, Elaine Toomey, Molly Byrne
How can IF be assessed feasibly and comprehensively in complex interventions?

1. Mixed methods approach extremely valuable for assessing fidelity
   - Studies 2,3,4 – integrating qualitative and quantitative
Study 3: Assessing treatment delivery

- **Aims:** Establish IF of delivery and influencing factors
- **Methods:**
  - Quantitative - direct observations, self-report, audio-recordings
  - Qualitative - interviews with physiotherapists
  - Integration using triangulation
Study 3: Assessing treatment delivery

IF findings:
- Convergence
  - SOLAS delivered with high fidelity
    - DO 82.7% SR 92.7% AO 81.7%
    - Some variation between Physiotherapists

Factors influencing IF:
- Convergence
  - Physiotherapist factors - knowledge and experience
- Qualitative
  - Participant factors – individual needs
  - Programme factors - resources
Mixed methods approach extremely valuable for assessing fidelity

- Understanding ‘what’ and ‘why’ of IF
- Strengthen and increase certainty
- Provide information on feasibility of quantitative measures
- Can be feasible as part of routine trial development/feasibility
How can IF be assessed feasibly and comprehensively in complex interventions?

1. Mixed methods approach extremely valuable for assessing fidelity

2. Combination of multiple quantitative assessment methods - spectrum
   - Studies 2, 3 - use of DO, SR and AO
   - Study 4 (tentative findings) - use of attendance rates, outcome measures
Combination of multiple quantitative assessment methods - spectrum

Influencing variables
e.g. total number of sessions, availability of IF resources
How can IF be assessed feasibly and comprehensively in complex interventions?

1. Mixed methods approach extremely valuable for assessing fidelity
2. Combination of multiple quantitative assessment methods - spectrum
3. Knowledge of factors influencing fidelity - help understand and address adaptations
   ▶ Studies 2,3,4 - knowledge, resources, individual needs
Knowledge of factors influencing fidelity - help understand and address adaptations

- Factors influencing fidelity - how and why adaptations have occurred
- Adaptation v fidelity debate

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<thead>
<tr>
<th>Exercise</th>
<th>Participants given a chance/encouraged to contribute to discussion</th>
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<tbody>
<tr>
<td>Room set up for exercise (equipment, sheets)</td>
<td>□ □ □ □</td>
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<tr>
<td>Protocol exercises demonstrated</td>
<td>□ □ □ □</td>
</tr>
<tr>
<td>Attention drawn to Exercise Programme Diary within intervention folder, encouraged use</td>
<td>□ □ □ □</td>
</tr>
<tr>
<td>Rationale for exercises provided</td>
<td>□ □ □ □</td>
</tr>
<tr>
<td>Participants given a chance to attempt and practice protocol exercises</td>
<td>□ □ □ □</td>
</tr>
<tr>
<td><strong>Individual feedback provided</strong></td>
<td>□ □ □ □</td>
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- Planned adaptations - flexibility within fidelity...
- Unforeseen modifications - assessment important!
Key recommendations...

- Use existing frameworks and knowledge
  - NIHBCC useful for addressing IF - potential for refinement
- Enhance, assess and report fidelity each stage assumption is made
  - Overlap between these and between domains
- Assessing IF in complex interventions
  - Mixed methods approach
  - Spectrum of IF assessment - multiple quantitative methods
  - Understanding factors influence IF across multiple domains - address adaptations
Future research - suggestions??

- Associations between fidelity and effectiveness
- Weighting of fidelity components/NIHBCC components
- Reporting criteria for fidelity
References/resources

Understanding fidelity (theoretical):

- http://www.bmj.com/content/350/bmj.h1258 (Moore et al 2015)

Reviews of fidelity:


Practical/methodology examples:

- http://ptjournal.apta.org/content/early/2016/03/02/ptj.20150446 (Toomey et al 2016)

Minimising research waste:

- http://www.thelancet.com/series/research