Symposium

Process evaluation of complex behaviour change interventions
MRC guidance for process evaluations of complex interventions

Dr Graham Moore, Research Fellow, DECIPHer
Process evaluation within the MRC complex interventions framework

- 2000 MRC framework almost exclusively emphasised outcomes (Campbell et al. 2000)
  - Effect sizes from RCTs can tell us that the intervention ‘worked’ (i.e. did more good than harm, in one specific time and place)
  - But what does this mean for policymakers who want to apply this evidence, or for development of future interventions?
Aims of process evaluation within 2008 MRC guidance (Craig et al. 2008)

‘Process evaluation nested within a trial can be used to assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in outcomes.’
Development of guidance

- MRC PHSRN workshop in 2010 discussed need for guidance

- Guideline development group formed, including 11 researchers, from MRC units / UKCRC CoEs
  - **Guidance development lead:** Graham Moore
  - **Chair:** Janis Baird
  - **Guidance development group members (alphabetically):** Suzanne Audrey, Mary Barker, Lyndal Bond, Chris Bonell, Wendy Hardeman, Laurence Moore, Alicia O'Cathain, Tannaze Tinati, Danny Wight
Development of guidance

- MRC PHSRN funding for cross-unit appointment
- Review of theoretical and substantive literature and thematic analysis of author case studies.
- Structure sent to stakeholder group for comment.
- Full guidance drafted and circulated.
- Conference workshops held throughout to obtain feedback on ideas (including UKSBM 2013, and BPS Seminar series)
- Final guidance sent to key health research funders for endorsement. Endorsed by:
  - MRC Population Health Science Group
  - MRC Methodology Research Panel
  - NIHR NETSCC
New MRC framework for process evaluation

Context
Contextual factors which affect (and may be affected by) implementation, intervention mechanisms and outcomes. Causal mechanisms present within the context which act to sustain the status quo, or potentiate effects.

Implementation
- How delivery is achieved (training, resources etc.)
- What is delivered
  - Fidelity
  - Dose
  - Adaptations
  - Reach

Mechanisms of impact
- Participant responses to and interactions with the intervention
- Mediators
- Unanticipated pathways and consequences

Outcomes

Description of intervention and its causal assumptions
A whistle-stop tour of some key recommendations: planning a PE

- The nature of relationships between evaluators and other intervention stakeholders
  - Close enough to observe the intervention, but distant enough to remain independent
- Assemble an appropriate research team
  - usually including expertise in quantitative and qualitative methods, and inter-disciplinary expertise
- Consider the degree of integration between process and outcomes evaluation teams
  - Lots of arguments for differing degrees of integration
A whistle-stop tour of some key recommendations: designing a PE

- Carefully clarify what the intervention is and underlying causal assumptions
- Process evaluation will never answer all the uncertainties a complex intervention poses
  - Identify key questions and answer them well rather than trying to do everything.
- Select appropriate quantitative and qualitative methods to address the key questions.
  - Are there similar process evaluations you can build on?
  - Can you collect data at multiple time-points to understand how the intervention and its context change over time?
  - Plan to integrate process and outcomes data from the outset
A case study. The National Exercise Referral Scheme in Wales

- GP referral to exercise professionals in local authority leisure centres
  - Effectiveness evaluated using a pragmatic RCT (Murphy et al. 2012)
- Process evaluation methods
  - Structured observation of one-to-one consultations (fidelity and dose)
  - Use of routine data to assess patterning in reach
  - Mediational analysis of quantitative process measures (e.g. autonomous motivation)
  - Qualitative interviews with patients, professionals, coordinators and health professionals
A case study. National Exercise Referral Scheme in Wales: some key findings

- Implementation checks showed some areas of weak fidelity
  - Some activities (e.g. motivational interviewing not delivered)
  - Others (goal setting, relapse prevention) inconsistently delivered
- Qualitative data indicated other mechanisms increased patient motivation (e.g. emergent social support networks)
- Trial showed significant increases in activity
  - Changes mediated by increased autonomous motivation.
- Hence, NERS ‘worked’. Without process data, would have
  - attributed effects to activities which weren’t even delivered, and
  - failed to identify key emerging mechanisms
Dissemination and training

  - Stand alone sections on PE theory, PE practice and detailed case studies

- **Summary paper (key practical recommendations):** revised and resubmitted. Decision awaited


- **Short training workshops** planned for delivery in Melbourne in May 2015, and as part of DECIPHer short course in June 2015

- Currently developing a 2-day training course linked to the guidance, to be piloted in Bristol in summer 2015.
Acknowledgments

- The work was funded by the MRC Population Health Science Research Network

- Acknowledgements to the numerous stakeholders who contributed to the guidance are listed in the full document.

- **Full author group**: Graham Moore, Suzanne Audrey, Mary Barker, Lyndal Bond, Chris Bonell, Wendy Hardeman, Laurence Moore, Alicia O'Cathain, Tannaze Tinati, Danny Wight, Janis Baird
BPS funded research seminar series 2013-14:

Using process evaluation to understand and improve the psychological underpinnings of health-related behaviour change interventions (BCIs)

(with focus on weight loss, physical activity & diet interventions)

For further information, copies of presentations etc contact:

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Aims

• From BPS: “…tangible goals explicitly focused upon the extension & development of understanding psychological processes”

• Bring together a core group of psychologists involved in overlapping research synthesis, intervention development, process evaluation work

• Focus on understanding and enhancing psychological and related processes underpinning health-related behaviour change interventions, particularly for weight loss (i.e. diet & physical activity)

• Involve other behavioural scientists, methodological experts, public health researchers, clinicians etc in seminars at host institutions (Exeter, Norwich/Cambridge, Cardiff)

• Share knowledge, skills, experiences, ideas from recent and on-going research synthesis, quantitative & qualitative process evaluation work on behaviour change (esp. weight loss) interventions
1) Exeter 2/5/13 Lessons from evidence synthesis of BCIs
   • BCT taxonomies, meta-regression, non-traditional synthesis
   • Example reviews & associated methodological work in weight loss
   • Intro to MRC process evaluation (PE) guidance

2) Norwich 25/10/13 Methods & methodological issues in PE
   • Draft MRC process evaluation guidance
   • Measures, role of psychological & wider socio-environmental factors, mediation analysis, place of qualitative research
   • Example PEs alongside trials of weight loss, PA & diet interventions

3) Cardiff 9/6/14 State of the art in PE: intervention fidelity
   • Final MRC guidance (and what it says re: fidelity)
   • Example fidelity work alongside weight loss, PA & diet interventions
Achievements & outcomes

- Total of 75+ attendees across all seminars, representing 14 different institutions /affiliated centres
- Closer collaborations and capacity-building across core research teams
  - e.g. Research Fellow in Process Evaluation at UEMS
  - e.g. GW4 (Bath, Bristol, Cardiff, Exeter) Health-Related Behaviour Interventions (HeRBI) collaboration
- Establishment of a larger collaborative, multi-disciplinary network of people interested in process evaluation of BCIs?
- Input into draft MRC guidance and its dissemination
- Identification of some key approaches, issues, recommendations, and ideas for future research to address
Some key issues

• Links (& common mismatch) between BCI design & PE
• Linking planning and reporting/publishing of PE to outcome evaluation
• Selection, validity and reporting of process measures
• Importance of qualitative and related approaches in synthesis, development and evaluation of interventions
• Accounting for changing contexts, systems (e.g. NHS)
• All complex interventions essentially behavioural?
• Meaning and importance of intervention fidelity
• Similarities and differences in PEs alongside trials of weight loss, PA and dietary interventions
Symposium presentations

Weight loss maintenance in adults: the WILMA trial process evaluation
- Speaker: Sharon Simpson, MRC/CSO Social & Public Health Sciences Unit, University of Glasgow

A case study of the utility of including process evaluation in the evaluation of established health promotion practice
- Speaker: Fiona Gillison, Department for Health, Bath

Capturing fidelity and engagement within the process evaluation of the Healthy Lifestyles Programme (HeLP) Trial
- Speakers: Jenny Lloyd & Katrina Wyatt, University of Exeter Medical School
Including process evaluation in the evaluation of standard care

Fiona Gillison, Fay Beck, Martyn Standage
University of Bath
The Problem

- Project to evaluate and improve a local exercise referral service

- Service was reportedly ‘evidence based’ and was routinely monitored, but no protocol or information on what was routinely delivered
Method

- Recorded and observed of 22% of initial client consultations over one month (N=22)

- Content independently coded by two Health Psychologists (1 MSc, 1 PhD) according to:
  - Service protocol – to rate adherence, and consistency within/between advisors
  - CALO-RE taxonomy – to rate ‘active ingredients’ in terms of common BCTs (and match vs evidence)
  - BECCI checklist of counselling style – to rate how client centred consultations were
CALO-RE taxonomy – to rate ‘active ingredients’ in terms of common BCTs (and match vs evidence)

<table>
<thead>
<tr>
<th>Technique</th>
<th>Supporting evidence*</th>
<th>% frequency in P2H consultations</th>
<th>% of P2H advisors demonstrating technique</th>
<th>Within-advisor variation</th>
<th>Between-advisor variation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide information on where and when to perform the behaviour</td>
<td>no significant effect</td>
<td>86%, N = 19</td>
<td>100% N=6</td>
<td>0.55</td>
<td>0.27</td>
</tr>
<tr>
<td>Goal setting (outcome)</td>
<td>Olander***</td>
<td>82%, N = 18</td>
<td>100% N = 6</td>
<td>0.78</td>
<td>0.28</td>
</tr>
<tr>
<td>Provide information on the consequences of the behaviour to the individual</td>
<td>Olander***</td>
<td>55%, N = 12</td>
<td>100% N = 6</td>
<td>1.82</td>
<td>0.24</td>
</tr>
<tr>
<td>Goal setting (behaviour)</td>
<td>Olander***</td>
<td>45%, N =10</td>
<td>83% N = 5</td>
<td>2.25</td>
<td>0.44</td>
</tr>
<tr>
<td>Action planning</td>
<td>no significant effect</td>
<td>45%, N = 10</td>
<td>83% N = 5</td>
<td>2.25</td>
<td>0.44</td>
</tr>
<tr>
<td>Plan social support/social change</td>
<td>Olander***</td>
<td>36%, N = 8</td>
<td>67% N = 4</td>
<td>1.27</td>
<td>0.53</td>
</tr>
<tr>
<td>Time management</td>
<td>no significant effect</td>
<td>27%, N = 8</td>
<td>83% N = 5</td>
<td>2.25</td>
<td>0.11</td>
</tr>
<tr>
<td>Prompt generalisation of target behaviour</td>
<td>Negative effect:</td>
<td>23%, N = 5</td>
<td>50% N = 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barrier identification/problem solving</td>
<td>Olander***</td>
<td>18%, N = 4</td>
<td>50% N = 3</td>
<td>0.50</td>
<td>0.56</td>
</tr>
</tbody>
</table>
Adherence to protocol

- Median adherence to the protocol was 64% (36-75%)
Behaviour Change Techniques:

- The most consistently delivered behaviour change techniques (observed in 100% advisors) were not the most evidence-based:
  - providing information about where and when to perform the behaviour (86% of sessions)
  - Setting outcome goals (82%)
  - Providing information on the consequences of behaviour to the individual (55%)

- Occurrence of our ‘top 4’ BCTs:
  - Self-monitoring (18%, 33% of advisors)
  - Barrier identification/problem solving (18%, 50% of advisors)
  - Planning social support (36%, 67% of advisors)
  - Goal setting [behaviour] (45%, 83% of advisors)
• Only 3 advisors delivered their sessions in a client-centred format (score >2) at all - and these didn’t do it all the time…
• Overall, greater within, than between variation across all checklists...

Variation not all due to ability, but advisors conscious or non-conscious responses to clients
• Lower adherence (and much less client-centred) with more challenging clients (i.e., less motivated or less well educated)
Then what?

Worked with the council to deliver training:

- Provided feedback

- Presented a rationale for focusing on specific strategies – talking in terms of ‘active ingredients’ and recent advances in the science of behaviour change

- Provided information instruction on four behaviour change techniques we felt were missing – what they are, why important, how they work in practice
Adherence to the protocol, and variability between sessions did not change……
Thank you for listening

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Weight Loss Maintenance in Adults: the WILMA trial

Sharon A Simpson
University of Glasgow
Dr Rachel McNamara
Chris Shaw
Mark Kelson
Elizabeth Randell
Aude Espinasse
Yvonne Moriarty
David Cohen
Fasih Alam,
Kerry Hood
David Gillespie,
Donna Duncan
Katy Tapper
Andy Hill
Julia Townson
Eleri Owen-Jones
Lauren Copeland
Simon Williams
Rhys Thomas
Background

- Few RCTs specifically exploring weight loss maintenance (WLM)

- Studies of WLM
  - have had limited effectiveness with weight regain common
  - approx 1/3 of weight lost during intervention regained in next year
  - WLM interventions associated with smaller weight gains compared to no contact
  - small differences between intervention & control

- Reviews have identified issues important for maintenance including:
  - physical activity; low calorie/low fat diet; self monitoring; tailoring; internal motivation and self efficacy.
  - These are central to the intervention being evaluated in this trial.
Design

Design:
- 3 arm individually randomised feasibility trial (intensive/less intensive/control)

Outcomes:
- Primary outcome = feasibility/acceptability and BMI at one year
- Number of secondary outcomes

Population:
- 170 obese adults aged 18-70 (current or previous BMI 30+) who have lost at least 5% body weight (independently verified) from exercise referral schemes, slimming clubs, GP surgeries and advertising.

Follow-up:
- 6 months during the intervention, end of intervention (1yr post-randomisation)
Intervention

Intensive or less intensive groups will receive a 12 month individually tailored intervention based on 2 key elements: Motivational Interviewing and self monitoring

Intensive Intervention Group:
- 6 one-to-one MI sessions
- 9 telephone MI sessions

Less Intensive Intervention Group:
- 2 one-to-one MI sessions
- 2 telephone MI sessions

Control:
- Leaflet advising on healthy eating & exercise for weight maintenance
Process Evaluation

- We developed a theoretical framework and logic model to explain how the intervention might work and are measuring mediators of intervention effects.
- Also used this to identify what aspects we were measuring and how.
- Comprehensive process evaluation model was developed looking at eight key elements: context, reach, fidelity, exposure, recruitment, retention, contamination and theory testing.
**Intervention components**

**Inputs**
- MI (engage, guide, evoke, plan)
- Self-monitoring
- Social support

**Behaviours/outputs**
- Increased skills/knowledge
- Increased intrinsic motivation+
- Increased problem solving
- Goal setting & development of Implementation Intentions/action planning
- Increased self-monitoring
- Increased behavioural self-regulation (e.g. monitor progress against goals)
- Increased self-efficacy
- Establish/boost social support

**Outcomes**
- Increased physical activity/less time in sedentary behaviour
- Healthy diet (Low fat/low sugar/high fibre diet; increased fruit & vegetable consumption; regular breakfast/meals)
- Habit formation/automaticity

**WEIGHT MAINTENANCE (& weight loss)**

- * MI style/techniques
- + Theorised mediators
<table>
<thead>
<tr>
<th>Process evaluation component</th>
<th>Sources of information</th>
</tr>
</thead>
</table>
| **Context**                 | MI practitioner and Group Facilitator (GF) demographics  
Where MI was delivered  
Contextual issues explored in the focus groups and participant interviews |
| **Reach**                   | Attendance at the intervention sessions  
Demographics of participants compared to those not recruited  
Participant interviews |
| **Fidelity**                | Motivational Integrity Treatment Inventory (MITI) assessment of recorded consultations at baseline  
MITI assessment of randomly selected recorded consultations  
Delivery of other intervention elements (post-session Case Report Forms (CRFs))  
Focus groups |
| **Exposure**                | Attendance at intervention sessions  
MIP post session CRFs  
Audio recorded consultations  
Data from WILMA online  
Focus groups and interviews |
| **Recruitment**             | Demographics of sample compared to those approached but not recruited  
Interviews and focus groups |
| **Retention**               | Drop out by trial arm  
Demographics of those dropping out compared with those remaining  
Focus groups |
| **Contamination**           | Participants asked if they shared study information  
Participants asked about other services they utilised |
| **Theory testing**          | Mediation analyses using questionnaire data  
Participant interviews and Session CRFs |
Theory testing....
Mediation Analyses

- Hypothesised mediators assessed using questionnaires and tested via mediation analyses were:
  - self-monitoring;
  - intrinsic motivation;
  - self-efficacy;
  - habits;
  - social support.

- We also considered goal setting, problem solving and planning to be important and explored these and the above in the qualitative work.
Mediation Analyses

- The results did not show any impact of the intervention on the mediators tested.
- Of the twenty comparisons made, two provided a positive value for the percentage of the total effect that was via the mediator and one was zero.
- However, interpretation of the mediation analyses is limited by,
  - the small sample size,
  - the absence of a statistically significant effect of the intervention on the primary outcome
  - the absence of any statistically significant between group differences in the analyses of mediators.
- Five of the ten mediators had a statistically significant association with BMI in the expected direction.
## Mediation analyses

<table>
<thead>
<tr>
<th>Mediator*</th>
<th>Coefficient**</th>
<th>Lower 95% CI</th>
<th>Upper 95% CI</th>
<th>p-value</th>
<th>Brief interpretation (as mediator increases...)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight Efficacy Lifestyle Questionnaire (WELS)</td>
<td>-0.03</td>
<td>-0.05</td>
<td>-0.02</td>
<td>&lt;0.001</td>
<td>BMI decreases</td>
</tr>
<tr>
<td>Exercise Self-Efficacy Scale (ESES)</td>
<td>-0.28</td>
<td>-0.51</td>
<td>-0.05</td>
<td>0.015</td>
<td>BMI decreases</td>
</tr>
<tr>
<td>Social Support and Exercise Survey (SSEX) – support domain</td>
<td>-0.26</td>
<td>-0.48</td>
<td>-0.04</td>
<td>0.022</td>
<td>BMI decreases</td>
</tr>
<tr>
<td>Self-reported habit index (diet) at 12 months</td>
<td>-0.49</td>
<td>-0.85</td>
<td>-0.13</td>
<td>0.007</td>
<td>BMI decreases</td>
</tr>
<tr>
<td>Self-reported habit index (exercise) at 12 months</td>
<td>-0.36</td>
<td>-0.61</td>
<td>-0.12</td>
<td>0.004</td>
<td>BMI decreases</td>
</tr>
</tbody>
</table>

**Table 21: Relationship between mediators and BMI**

*Mediator collected at six month time point unless specified otherwise.

**This is the effect per unit increase in mediator on post-intervention BMI, adjusted for baseline BMI, trial arm and variables balanced on at randomisation.
Insights from qualitative work…

- In the qualitative work there was discussion about ongoing motivation, self efficacy, social support, habits and self monitoring.

- ‘Ongoing motivation’ was seen as crucial for weight loss maintenance. This was facilitated by support from four sources: professionals, peers and family and friends.

- Positive reinforcement given by peers/family/professionals and also acquired through a sense of achievement. Continuing success was crucial in maintaining motivation. Weight maintenance did not elicit the same levels of positive reinforcement which made maintenance difficult.

- A sense of control was also perceived as reinforcing and empowering with loss of control sometimes resulting in bingeing. In a maintenance situation self-monitoring provided a sense of control.

- Participants felt that it was important for changes in lifestyle to become routine and habitual in order to be maintained.

- So overall some support for our theorised mediators.
Fidelity......
Training of Intervention Staff

- Training consisted of a 2 day face-to-face workshop covering 3 key issues:
  - elements related to MI including challenges delivering it by telephone, in 2 sessions etc;
  - the weight loss maintenance elements including self monitoring, information on diet and physical activity.;
  - specific issues related to working with this client group eg challenges of WLM.

- In the workshops we utilised didactic methods, interactive small group discussions and practice with a simulated patient.

- To try to enhance intervention fidelity we provided practitioners with a handbook containing information covered during the training as well as further information on the topics.

- We also produced one page summaries of key information for use within or outwith the sessions.
Ongoing support related to fidelity

- We assessed competence in MI before practitioners saw any participants using the MITI.

- We planned four workshops for practitioners with specific WILMA related topics as a refresher and an opportunity to share challenges.

- We planned four ‘peer group support sessions’, where small groups of MIPs met up to listen to an audio recording and share their experiences.

- We also intended to provide feedback on four recorded sessions to prevent ‘drift’ in intervention delivery.
Measuring fidelity

We measured intervention fidelity in a number of ways.

- We assessed audio recordings of consultations using the Motivational Interviewing Treatment Integrity Scale (MITI).

- We asked MIPs to complete a Case Report Form (CRF) for each session and these were analysed to assess whether the five key WILMA ‘hot’ topics (diet, physical activity, self-monitoring, goal setting and planning) were covered.

- We conducted MI practitioner focus groups where we explored whether they felt that they had delivered the MI with fidelity, whether they covered the “hot topics” and whether they delivered anything differently or in addition to the guidance in the manual.
The MITI assessment

- MIPs were asked to record all sessions where participants consented.

- The face-to-face MI recordings were then assessed for fidelity to MI using the MITI which measures both global rating and behaviour counts.

- Four recordings each were randomly selected, a stratified sample included sessions delivered in both intervention arms of the trial and across all MIPs.

- For each of the 12 MIPs, four raters independently rated one individual consultation each for that practitioner.

- One MIP had no recordings and two others had only one or two recordings respectively, so it was not possible to randomly select recordings so these 3 were coded using MITI.
<table>
<thead>
<tr>
<th>MIP</th>
<th>Number of face-to-face recordings</th>
<th>Total number of face-to-face sessions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>33</td>
</tr>
<tr>
<td>2</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>11</td>
<td>12</td>
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<td>5</td>
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<tr>
<td>6</td>
<td>8</td>
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<tr>
<td>7</td>
<td>0</td>
<td>79</td>
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<td>8</td>
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<td>23</td>
<td>30</td>
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<tr>
<td>15</td>
<td>5</td>
<td>17</td>
</tr>
</tbody>
</table>
Agreement between raters

- Guidance indicates that agreement of 0.21 to 0.40 constitutes fair agreement
- Behaviour counts indicate high reliability overall with less reliability for MI-adherent and complex reflection ratings

<table>
<thead>
<tr>
<th>Global rating</th>
<th>Kappa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evocation</td>
<td>0.359</td>
</tr>
<tr>
<td>Empathy</td>
<td>0.267</td>
</tr>
<tr>
<td>Direction</td>
<td>0.232</td>
</tr>
<tr>
<td>Collaboration</td>
<td>0.315</td>
</tr>
<tr>
<td>Autonomy/Support</td>
<td>0.192</td>
</tr>
<tr>
<td>Overall</td>
<td><strong>0.282</strong></td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Behaviour count</th>
<th>ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple Reflection</td>
<td>0.507</td>
</tr>
<tr>
<td>Open Question</td>
<td>0.827</td>
</tr>
<tr>
<td>MI Non-adherent</td>
<td>0.760</td>
</tr>
<tr>
<td>MI adherent</td>
<td>0.218</td>
</tr>
<tr>
<td>Giving Information</td>
<td>0.468</td>
</tr>
<tr>
<td>Complex Reflection</td>
<td>0.191</td>
</tr>
<tr>
<td>Closed Question</td>
<td>0.668</td>
</tr>
<tr>
<td>Overall</td>
<td><strong>0.798</strong></td>
</tr>
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</table>
Rating of sessions

- The results indicate that overall no MIPs failed to reach ‘proficiency’ on any measure.
- All MIPs reached the cut-off for ‘competent’ on the 5 globals and percent complex reflections.
Session CRFs

- The MIPs asked rated the extent to which they discussed the different topics in each counselling session using a ten point Likert scale.

- Overall 391 session CRFs were completed (face to face).

- For all topics over all sessions, the median rating was six or above which indicates that coverage of each topic was somewhere between ‘talked a little about’ and ‘talked in detail about’.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Median rating</th>
<th>Interquartile range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal setting</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Planning</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Self-monitoring</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Physical activity</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Diet</td>
<td>8</td>
<td>3</td>
</tr>
</tbody>
</table>
Focus group data

One issue MIPs struggled with was to deliver according to the timelines.

**MIP3:** I didn’t stay on time track as closely as I should have… and then I remember I used to get these emails back to say (…) ‘you’ve kind of missed your deadline’. I got a fright because I didn’t actually realise there were deadlines, but of course there were and they described them in the handbook.

Another issue was that often what the patient wanted to discuss or needed help with made it difficult to get the focus on weight related issues.

**MIP5:** I had somebody who was slipping into a clinical eating disorder, having lost weight and were getting very distressed by significant body image and body checking behaviours and was wanting me to help them with them.

Also for some clients an hour was too long.

**MIP5:** I really didn’t maintain was the time scale I had some clients where I just couldn’t you know actually for us to sit there for an hour would have been a form of torture (laughter) so it wasn’t, you know he wasn’t chatty he didn’t want to talk about the emotional content so you know it was quite often you know half an hour max.
Focus group data

MIPs said the ‘hot topics’ occurred naturally throughout their sessions and were at the heart of supporting participant’s weight management goals.

**MIP3:** *I covered them but not… I didn’t sort of consciously work with them. I didn’t sort of, you know, take them out and say ‘right, today we’re going to talk about such and such.’...em but we certainly did dip into that because those are things that you know just came up quite naturally in the conversation.*

A few MIPs said they were unsure whether they delivered pure MI and said they tended to use MI as part of their overall delivery method.

**MIP6:** *I never do pure MI, so this is very different for me because I’m, I’m a CBT therapist so I use MI as part of my whole intervention. So yeah, very different to do a whole 50 minutes of MI. I’m not convinced still that I did. (laughs)*
Focus group data

Some MIPs reflected that knowing the sessions would be MITI’d affected the way that they practiced.

**MIP1**: *I say that because when I was there with the client I mean I’m there with a client as I say and then using the tools that I use regularly, umm, so other than checking myself, I was very aware when I did the MITI assessment, I was almost had a tick list well I need to get scaling in, right there I can get scaling in, do you know what, I was also not listening to the client in the MITI assessment, I was making sure that I did these things and then when I’m working with the clients and I’m making sure I’m listening to the clients*
Conclusions/Challenges

- Overall the intervention appears to have been delivered with reasonable fidelity.

- We only managed to record 47% of sessions overall and for some MIPs very few or none. Issues related to MIPs and patients not liking being recorded, forgetting, technical issues.

- Those where we didn’t have a large proportion of sessions may mean that they have been specially selected = bias

- There were a number of issues with using the MITI for fidelity including problems with ‘a gold standard’, training, drift, cost etc.

- Completion of CRF quite good but not objective – we could compare these to the recordings for those we have.

- Issue with ‘over-manualising’ MI – Project Match etc
Conclusions/Challenges

- Main challenge is deciding what the key active elements of the intervention are and ensuring those are delivered whilst still allowing a degree of flexibility in delivery.

- Other key challenge is finding valid and reliable ways of measuring intervention fidelity.

- We need to know what is actually being assessed in the trial – so we need to know what is being delivered. However, balancing the resources needed to assess fidelity adequately with other requirements of the trial is challenging.
<table>
<thead>
<tr>
<th>Mediator*</th>
<th>Trial arm (compared to control)</th>
<th>Total effect</th>
<th>Direct effect (not via mediator)</th>
<th>Indirect effect (total - direct)</th>
<th>Percentage of total effect through mediator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight Efficacy Lifestyle</td>
<td>Intensive</td>
<td>-0.96</td>
<td>-0.87</td>
<td>-0.09</td>
<td>9.38</td>
</tr>
<tr>
<td></td>
<td>Less intensive</td>
<td>-0.21</td>
<td>-0.25</td>
<td>0.04</td>
<td>-19.05</td>
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<tr>
<td>Questionnaire (WELS)</td>
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<tr>
<td>Self-reported habit index (diet) at 12 months</td>
<td>Intensive</td>
<td>-0.96</td>
<td>-0.92</td>
<td>-0.04</td>
<td>4.17</td>
</tr>
<tr>
<td></td>
<td>Less intensive</td>
<td>-0.21</td>
<td>-0.42</td>
<td>0.21</td>
<td>-100.00</td>
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</tbody>
</table>
Capturing Fidelity and Engagement within the process evaluation of the The Healthy Lifestyles Programme Trial (HeLP)

Dr Jenny Lloyd & Dr Katrina Wyatt

J.J. Lloyd@exeter.ac.uk
K.M.Wyatt@exeter.ac.uk
The HeLP Programme

*HeLP is conceptualised as a complex intervention within a dynamic system*

- Seeks to create enabling environments within schools and families
- Key to this are building relationships and engaging schools, children and their families
- Deliverers are as much a part of the intervention as the components within each phase
- Crucial that the deliverers had the necessary skills and competencies to ensure quality delivery
Principles underpinning PE

• Need to understand how the intervention has been conceptualised in order to guide essential data collection – avoids an unwieldy PE

• Internal learning – how HeLP is working

• External learning – how best to assess delivery characteristics and engagement
  – Use this information to inform future behaviour change interventions
<table>
<thead>
<tr>
<th>Research Question</th>
<th>Process Evaluation Dimension (HeLP terminology)</th>
<th>Process Evaluation Dimension (other terminology)</th>
<th>Data Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do the children receive all of the HeLP components in the correct order?</td>
<td><strong>Delivery - Fidelity to form</strong></td>
<td>Fidelity 1</td>
<td>Observation checklists</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dose delivered 1</td>
<td></td>
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<td></td>
<td></td>
<td>Adherence 2</td>
<td></td>
</tr>
<tr>
<td>Is the programme delivered in the spirit of HeLP?</td>
<td><strong>Delivery - Fidelity to function</strong></td>
<td>Quality of delivery 2</td>
<td>Observation checklists</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Field notes</td>
</tr>
<tr>
<td>How much of HeLP are children and families receiving?</td>
<td>Uptake</td>
<td>Dose received 1</td>
<td>Child and/or family registers for each component</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reach 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Exposure 2</td>
<td></td>
</tr>
<tr>
<td>How are schools, children and families responding to HeLP?</td>
<td><strong>Reach (engagement) Experience</strong></td>
<td>Participant responsiveness 2</td>
<td>Observations</td>
</tr>
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<td></td>
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<td>Field notes</td>
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<td>Attendance registers</td>
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<td>Parental signature</td>
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<td>Parent questionnaire</td>
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<td>Qualitative evaluation</td>
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<td>(interviews and focus groups with teachers, children and parents)</td>
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<td>Are there contextual and environmental factors which have the potential to influ</td>
<td><strong>Context</strong></td>
<td>Context 1</td>
<td>Observations</td>
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<tr>
<td>ence delivery, reach and experience?</td>
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<td></td>
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<td>Research team reflection</td>
</tr>
</tbody>
</table>

1 Based on process evaluation components outlined by Baronowski and Stables (2000) and Linnan and Steckler (2002)

2 Based on implementation fidelity components outlined by Dane and Schneider (1998)
Assessing fidelity to ‘form’

Were the components of HeLP delivered according to the manual and in the correct order?

• Four phases with multiple components, each phase builds on the previous one to further support and enable behaviour change

• Each component has been manualised to describe the activity, however the how and the when are adaptive to local context

• Checklists for content for each component in each phase are completed by HeLP Coordinators/Trial Manager

• Presented as percentage of components delivered in the right order and complete form per Year 5 class
Assessing fidelity to ‘function’

Have the components of HeLP been delivered in the ‘spirit’ of HeLP?

- Are components delivered with enthusiasm, an open body language, in a friendly manner and were deliverers responsive to child/school needs?

- ‘Qualities’ of delivery and responsiveness of children, teachers and parents assessed

- A rating of between 1-10 for how component is delivered (for specific components) in each phase (PI/TM/HC)
  - Interrater reliability assessed

- An average score for a school of 8 plus will be considered as having been delivered in the ‘spirit’ of HeLP.
<table>
<thead>
<tr>
<th>Intervention Phase</th>
<th>Component</th>
<th>Delivered by</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase 1</strong></td>
<td></td>
<td></td>
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<tr>
<td>Creating a Supportive Context</td>
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<td>HeLP Coordinator</td>
</tr>
<tr>
<td></td>
<td>Newsletter articles</td>
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</tr>
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<tr>
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<tr>
<td><strong>Phase 2</strong></td>
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<tr>
<td>Healthy Lifestyles Week</td>
<td>PSHE lessons (morning)</td>
<td>Class teacher</td>
</tr>
<tr>
<td></td>
<td>Drama workshops (afternoon)</td>
<td>Drama group</td>
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<tr>
<td><strong>Phase 3</strong></td>
<td></td>
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</tr>
<tr>
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<td>1-1 goal setting interview</td>
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Assessing Engagement

**School**

Head teacher/year 5 teacher(s)/support staff - given an engagement score, based on observation over the intervention period (score 0-3). Total score out of 9 (0-3=less engaged; 4-9=engaged)

**Child**

For each child engagement is determined from the 1:1 goal setting process in Year 5 (score 0-3) (≤1 less engaged; >1 engaged)

**Parent**

Attendance at one or more HeLP components and input on goal setting sheet (score 0-2) (0=not engaged, ≥1=engaged)
Conclusion

- HeLP utilises a relational approach to changing behaviour
- Process evaluation has been developed to capture the nature and qualities of the relationships
- It will help us to capture and understand the nature and levels of engagement which are sufficient to change behaviours
- It will allow us to characterise the necessary qualities for intervention delivery
- It will *not* attempt to isolate active ingredients of HeLP
- We are conducting the process evaluation in a way which we hope will strengthen and build relationships for future studies/possible roll out
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</table>
Definitive Trial Process Evaluation

Context
School deprivation, size of school/class, school ethos, school healthy lifestyle initiatives, school policies

Logic Model/theory of change
Health Promoting Schools (HPS) Framework
Social Cognitive Theory
- Information, Motivation and Behavioural Skills (IMB) Model
- Health Action Process Approach (HAPA)

Delivery mechanisms
Building trusting and supportive relationships
Recruitment and training (actors and HCs), manuals, SOPs, resources, communication structures (HC-teachers, HC–actors, actors-actors)

Delivery
Fidelity (content and spirit of delivery)
Uptake (HeLP components received by each child/family)

Adaptations (adaptations to HeLP components have been made to better fit context of school, but fidelity to function has been maintained)

Mechanisms of impact
- Engagement (schools, children, families)
- Knowledge and skills, self-efficacy, intentions, peer norms, peer and family approval, attitudes
- Empowerment
- Ownership
- Identification
- Enjoyment

Outcomes
Short term
Children
Talking to parents, self-reflection, self-monitoring, trying new foods, resisting temptation, cooking, shopping, adapting goals.
Parents
Buying healthy snacks and making them available, reinforcing rules and promoting HeLP messages.

Medium term
- Physical Activity
- Sedentary Behaviours
- Healthier Diet

Long term
- ↓BMI sds
- ↓BF sds
- ↓WC sds
Hypothesised role of engagement in affecting weight status

Child Engagement
Engaged/less engaged

Parent Engagement
Engaged/less engaged

School Engagement
Engaged/less engaged

Diet and PA behaviours

18 month BMI SDS

24 month BMI SDS
<table>
<thead>
<tr>
<th>Intervention Phase</th>
<th>Function</th>
<th>Behaviour Change Technique</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase 1</strong></td>
<td>Relationship building&lt;br&gt;Raise awareness /increase knowledge&lt;br&gt;Promote positive attitude and norms&lt;br&gt; Increase self-efficacy for behaviour change</td>
<td>Provide info and create social norms&lt;br&gt;Exchange information&lt;br&gt;Communicate messages implying positive evaluations and norms&lt;br&gt;Role modelling and skill building</td>
</tr>
<tr>
<td>Creating a Supportive Context</td>
<td></td>
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<tr>
<td><strong>Phase 2</strong></td>
<td>Strengthen relationships&lt;br&gt;Increase knowledge /self awareness&lt;br&gt;Increase self-efficacy&lt;br&gt;Develop communication and problem solving skills&lt;br&gt; Increase social support</td>
<td>Exchange info&lt;br&gt;Decision balance&lt;br&gt;Problem solving tasks&lt;br&gt;Modelling/demonstrating behaviour&lt;br&gt;Providing role models&lt;br&gt;Communication skills training</td>
</tr>
<tr>
<td>Healthy Lifestyles Week</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Phase 3</strong></td>
<td>Increase awareness of own behaviour&lt;br&gt;Increase self-efficacy for change&lt;br&gt;Develop planning skills&lt;br&gt; Increase parental support</td>
<td>Self monitoring&lt;br&gt;Identification and resolution of barriers&lt;br&gt;Provide models of others setting goals&lt;br&gt;Prompt intention and specific goal formation&lt;br&gt;Behavioural contract</td>
</tr>
<tr>
<td>Personal Goal Setting (with parental support)</td>
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</tr>
<tr>
<td><strong>Phase 4</strong></td>
<td>Increase self awareness&lt;br&gt;Prioritise healthy goals&lt;br&gt;Consolidate social support&lt;br&gt;Develop monitoring and coping skills&lt;br&gt; Increase parental support</td>
<td>Prompt self monitoring&lt;br&gt;Prompt intention formation&lt;br&gt;Provide social approval&lt;br&gt;Prompt practice&lt;br&gt;Prompt review of goals&lt;br&gt;Prompt barrier identification/coping plans</td>
</tr>
<tr>
<td>Reinforcement Activities</td>
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</table>
Discussion points

• How does the nature of the intervention effect how we define fidelity, or understand intervention mechanisms?
  – Many PH interventions (e.g. WILMA/NERS) involve one-to-one delivery and target intrapersonal changes
  – But others (e.g. HeLP) involve changing the functioning of systems such as schools to align them with health

• How does the context of the process evaluation affect the questions posed?
  – Feasibility trial stage (Wilma/HELP)
  – Effectiveness evaluation (NERS)
  – Routine practice

• What complementary roles can quantitative and qualitative methods play in answering key process questions?

• What future areas of PE methods development should we focus on (and funding sources)?