Symposium: The potential for using novel trial designs to evaluate complex behaviour change interventions

Discussant: Mary Barker
Contributors: Dorota Juszczyk, Suzanne McDonald, Leanne Morrison, Hazel Inskip, Mary Barker
A Systematic Review of N-of-1 Methods: Applications and Opportunities

Suzanne McDonald

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What does evidence tell us about individuals?

1. Complex interventions may be effective *on average*

2. Behaviours may change over time *on average*

But was the intervention effective for **ALL** participants?

But did this pattern apply to **ALL** individuals?
What are N-of-1 methods?

The repeated measurement of one individual (or individual unit) over time to reach conclusions about that individual.
Meet (some of) the n-of-1 family

Observational design

Outcome

Time

AB design

Outcome

Baseline (A)  Intervention (B)

Time

ABAB design

Outcome

Baseline (A)  Intervention (B)  Baseline (A)  Intervention (B)

Time

N-of-1 RCT

Alternating treatments design

Outcome

Condition A  Condition B  Condition C

Time

Outcome

Condition ?  Condition ?  Condition ?

Time
Developing and evaluating complex interventions: new guidance

Craig et al (2008)

CONSORT extension for reporting N-of-1 trials (CENT) 2015 Statement


The Single-Case Reporting Guideline In BEhavioural Interventions (SCRIBE) 2016 Statement

Tate et al (2016)

Using N-of-1 methods to study or change health-related behaviour and outcomes: A symposium summary

McDonald & Davidson (2015)

Personalizing behavioural medicine interventions through N-of-1 studies

Kronish et al (2016)
A Systematic Review of N-of-1 Methods in Health Behaviour Research

McDonald, Quinn, Vieira, O’Brien, White, Johnston & Sniehotta (under review)

Methods
Comprehensive search strategy (PROSPERO CRD42014007258) used to search electronic databases (PsycINFO, Embase, MEDLINE)

Inclusion criteria: Population: Any
Intervention: Behavioural interventions
Comparator: Participant is own control
Outcome(s): Any health-related behaviour
Study design: N-of-1 design
Applications of N-of-1 Methods

39 papers identified

**Populations:**
Patients with chronic conditions and healthy volunteers, aged 2-89 years

**Interventions:**
From individual intervention components to full intervention packages

**Outcomes:**
Treatment adherence, diet, sleep, physical activity, drugs/alcohol, smoking

**Study designs:**
Observational, AB, ABA, ABABA, alt. treatment, RCT, multiple baseline, changing criterion

McDonald et al., (under review)
Future Opportunities

1. **Advance knowledge about individual behaviour**
   - Understand temporal nature of behaviour (Johnston & Johnston, 2013)
   - Knowledge can lead to intervention tailoring (e.g. O’Brien et al., 2015)

2. **Test intervention components within individuals**
   - Identify individual response to interventions (e.g. Sniehotta et al. 2012)
   - Test individual BCTs, combinations, sequences and doses (McDonald et al. 2016)

3. **Combine with technology and novel intervention designs**
   - Ecological momentary assessment (Shiffman & Stone, 2008)
   - Just-in-time adaptive interventions (Riley et al., 2015)

McDonald, Araujo-Soares & Sniehotta (2016)
Acknowledgements

References

- Johnston & Johnston (2013). Useful theories should apply to individuals. *British journal of health psychology*, 18, 469
Symposium: The potential for using novel trial designs to evaluate complex behaviour change interventions

Discussant: Mary Barker
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Applying an N-of-1 approach to evaluate a digital weight management intervention

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1st December, UKSBM 2016, Cardiff
Background

• Digital programmes show promise as a cost-effective means of intervention
  – CHALLENGE: How can we encourage greater uptake and maintain engagement?

• Smartphones offer new opportunities for delivering behaviour change interventions
  – Ubiquitous, feature-rich, context-aware sensing capabilities
  – Stand-alone vs. hybrid interventions

• Few in depth examinations of how participants use and experience app-based intervention tools
Study Aims

1. Examine the impact of a supplemental Smartphone app for online weight management
   Q: Can it enhance engagement with personal weight management goals?

2. Examine individuals’ experience of using a supplemental Smartphone app alongside an online weight management programme
   Q: When, why, and how is the app used?
Online programme to support users to adopt a sustainable and positive approach to weight management

- **POWeR Tracker**: Android smartphone application to accompany the online programme

  - Theory and evidence-based
    - Self-regulation tools (goal setting, planning, self-monitoring)
    - Social support and modeling through "POWeR stories"
    - Maintain awareness of personal POWeR goals
    - Monitor progress
Study design: Mixed-method case studies

- Each participant followed over **4 weeks** in a series of in-depth case studies (ABAB vs. BABA)

- Compare web-based POWeR **with and without** POWeR Tracker app

A: Week 1  B: Week 2  A: Week 3  B: Week 4
Measures

1. Daily self-report on goal perceptions
2. Weekly telephone interview
   - Goal self-efficacy
3. Web and app usage
   - Goal achievement

Q1. Can the app enhance engagement with personal weight management goals?
Q2. When, why, and how is the app / website used?

Completed via the POWeR Tracker app. Available from 5pm – 11am each day.
Participants \((N = 13)\)

- 18 – 52 years of age \((Mdn = 27\) years\)
- 7 female, 6 male
- BMI 23.69 – 38.51 \((Mdn = 26)\)
- Educated to degree level
- Android Smartphone owners
Impact of P0W3R Tracker app (n = 12)

- Access to the app significantly enhanced perceptions of eating goals

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<th>$\beta_1$</th>
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<th>P ($\beta_1$)</th>
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Impact of POWeR Tracker app \((n = 12)\)

- Significant **individual variation in magnitude of change** for:
  - goal awareness (eating and physical activity goals)
  - achievement (eating goals)

<table>
<thead>
<tr>
<th>Participant</th>
<th>Goal awareness (eating)</th>
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<th>Goal awareness (physical activity)</th>
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<td>(\beta_{1i})</td>
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<td>P13b</td>
<td>6.70</td>
<td>-0.32</td>
<td>6.57</td>
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Engagement with POWeR

- Individual variation in usage of POWeR Tracker
  - Duration and tool use
  - Positive correlation between duration of app use and awareness of eating goals ($r = .620, p = .03$)
  - No correlation between use of specific app-tools (e.g. tracking) and goal engagement ($r = .39 - .53, p = .08 - .21$)
Engagement with POWeR

• Stronger effects on goal engagement for participants who valued using both the app and the website

“OK um if we were comparing the website and the app...I spend a lot of time across the two ... Anything like recording the foods, the diaries and the activity food, I prefer doing that on my computer and I’ve got time to do it. The app is useful, the most useful to look up the lists of food and stuff like that.”

“So...apps are just a lot more instant ... You can work it around yourself instead of having to physically go to a computer to do it. So...yeah I think using an app, I prefer to use an app than going, logging into the website, personally..”
Engagement with POWeR

• Role of notifications?

“but I think the thing that partly reminding me to go to the app is the reminders so ‘cause sometimes you hear your phone sound like and reminding you of something sounds like you got the message, like you got the message so you tend to look at your phone so maybe if the app can remind me to look at my phone then I think it would be a bit better”

– Participants for whom access to the app had a stronger effect on goal engagement appeared more likely to request notifications

– But, no sig correlation between number of notifications received and effect of app access on goal engagement \( (r = -.07 - .17, p = .60 - .82) \)
Engagement with POWeR

- Strong influence of **daily routine and lifestyle** on POWeR Tracker use

- **Example:** strongest effect of app access for:
  - Term time
  - Fresher's week
  - Start of lectures
  - Summer vacation
  - Getting up early, sleeping late
  - Living in student accommodation
  - Limited Internet access
  - Control over meal choices
Summary

• Value of **mixed methods, n-of-1** approach
  – Individual variation in tool preference and patterns of use could be mapped to effect of app access on goal engagement
  – Individual preferences are not necessarily what leads to better health-related outcomes

• Offering a supplemental app alongside an online intervention **encouraged greater goal awareness**
  – Particularly for those who perceived value in accessing BOTH the app and website
  – Perceived the app to be relevant for addressing current needs
Acknowledgements

• Collaborators: Charlie Hargood, Sharon Lin, Derek Johnston, Marie Johnston, Susan Michie, Paul Little, Peter Smith, Mark Weal, Lucy Yardley

• Our participants

• Funders: EPSRC, UBhave: “Ubiquitous and social computing for positive behaviour change”
Thank you for your attention
Symposium: The potential for using novel trial designs to evaluate complex behaviour change interventions

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Complex outcome measures – identifying novel approaches

UKSBM symposium: The potential for using novel trial designs to evaluate complex behaviour change interventions

December 1st 2016

Hazel Inskip and Mary Barker
MRC Lifecourse Epidemiology Unit and NIHR Southampton Biomedical Research Centre, University of Southampton and University Hospital Southampton NHS Foundation Trust
The challenge

Many interventions target one behaviour and have a clear outcome
e.g. smoking cessation
weight loss

Often community-based interventions aim for behaviour change across multiple domains

e.g. Family Nurse Partnership
Health Trainers
The challenge

Complex interventions targeting behaviour change may have different outcomes for each participant.

Participants often set their own goals and individuals will target different behaviours.

One outcome doesn’t fit all.

Can we combine outcomes?
Composite outcomes

- Used quite widely in cancer trials and follow-up studies
- Multiple endpoints and the outcome is the first to occur, so endpoint-free survival is the focus
- e.g. time to recurrence
time to death
time to reduced quality of life
time to biochemical markers reaching a defined point etc.

Inappropriate in behaviour change as behaviours fluctuate and timing varies and each outcome is not necessarily possible for each participant
Motivation

- LifeLab Plus. An intervention to improve health behaviours in teenagers through an education programme during which the students make pledges and these are reinforced through teacher support and game technology.
LifeLab pledges

- Pledges vary from improving diet and physical activity to getting more sleep
- What is the primary outcome for this trial?
- Two primary outcomes: diet and physical activity
- But what about those pledging to improve other behaviours?
- Challenging to prove effect of the intervention if only a proportion of the participants ever focus on the primary outcome
Goal setting and pledges

- **S** Specific
- **M** Measurable
- **A** Achievable
- **R** Realistic
- **T** Timed
- **E** Evaluated
- **R** Reviewed
### Examples

<table>
<thead>
<tr>
<th>Specific</th>
<th>Measurable</th>
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<tbody>
<tr>
<td>Increase fruit and vegetable consumption</td>
<td>Portions per week</td>
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<tr>
<td>Decrease crisps and confectionery consumption</td>
<td>Portions per week</td>
</tr>
<tr>
<td>Improve dietary quality</td>
<td>Dietary quality score</td>
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<tr>
<td>Increase walking</td>
<td>Steps per day</td>
</tr>
<tr>
<td>Swim at least twice a week</td>
<td>Times per month</td>
</tr>
<tr>
<td>Reduce cigarette consumption</td>
<td>Cigarettes per day</td>
</tr>
<tr>
<td>Reduce alcohol consumption</td>
<td>Units per week</td>
</tr>
<tr>
<td>Increased sleep</td>
<td>Minutes per night</td>
</tr>
</tbody>
</table>
Primary outcome

So what is the primary outcome for such trials?

Focusing on diet, physical activity, smoking or alcohol means that the outcome is irrelevant for some participants.

Students who do not improve their diets (and never intended to) put a drag on the overall diet outcome, making the identification of effects even harder than ever.

Can we derive goal/pledge-based outcomes?
Continuous or binary?

- Binary outcome is relatively simple – did the participant achieve the goal or not?
- But power is low and studies require large numbers
- There is no nuancing of the outcome for those who almost achieve the goal or exceed it greatly

- Continuous outcomes need standardising
- Normally distributed variables can be standardised
- Non-Normally distributed can often be mapped onto a Normal distribution using percentiles or Fisher-Yates transformation
Challenges

- Is combining outcomes valid?
- Is 1SD change in diet quality equivalent to 1SD change in walking or cigarette consumption?
- Do we expect the same amount of change for each outcome?
- What about those who pledge to improve more than one behaviour?
- What is a realistic effect size for a trial?
- How do we interpret an SD change in the overall outcome?
- How do we present the results to researchers and general audiences?
- Are there alternative approaches to consider?
Acknowledgments

Many colleagues at the MRC Lifecourse Epidemiology Unit, LifeLab and the University of Southampton for discussions about this issue, including:

Janis Baird
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Taylor Rose
Sofia Strömmer
Sarah Crozier
Holly Syddall
Paul Little

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The potential for using novel trial designs to evaluate complex behaviour change interventions

Mary Barker, Suzanne McDonald, Leanne Morrison, Philip Pallmann, Hazel Inskip

UKSBM, December 1st 2016
Novel Trial Designs - why do we need them?
Issues for discussion

- N-of-1 – how do we turn what we learn from these into interventions that show benefit across individuals?
- How can we use SMART and adaptive designs in evaluation of complex behavioural interventions?
- Combined outcome measures – is this possible and what would the data mean?
- And many more …