Automated assessment of key behavioural outcomes in intervention studies: what are the prospects?

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Declaration of interests

• I undertake research and consultancy for companies that develop and manufacture smoking cessation medications
• I am a trustee of QUIT
• I am co-director of the NHS Centre for Smoking Cessation and Training
• I collaborate with companies that develop behaviour change applications
Aim

• To consider the opportunities and challenges for automated data capture for key behavioural outcomes using digital applications
Behavioural outcomes

• Behaviours that one seeks to alter through an intervention
• Examples
  – Smoking cessation
  – Reduction in alcohol consumption
  – Increase in physical activity
The opportunity

• Measuring behavioural outcomes is typically expensive and time consuming
• This can be done using digital interventions by:
  – Sensors (e.g. accelerometers)
  – Self-report (e.g. smoking status)
• This permits data collection at minimal or low cost from large numbers of users
The challenges

- Two main challenges
  - Missing data because of loss to follow up or non-engagement
  - Validity of data
- Critical issues for outcome measures
Missing data

- Where data are missing this typically leads existing data to produce biased estimates
- With automated data collection the problem is particularly acute because so much data tends to be missing
- Presents difficulties in deciding how to handle the missing data
Validity

- Self-report measures are potentially subject to reporting bias
  - Incorrectly claiming abstinence from smoking
  - Underestimating alcohol consumption
  - Underestimating food intake
Example

- SF28 (SmokeFree 28)
  - Application to aid cessation for at least 28 days
- Smokers set a target quit date and when they open the app they record whether they have smoked since the last time they opened it
- Smokers typically disengage from smoking cessation interventions if they go back to smoking
- Can we use self reported abstinence from the app to assess outcome?
Outcome measure

- Abstinent
  - Opened the app at least 28 days after the target quit
  - On every occasion that the app was opened up to this point, reported abstinence (up to 2 slips allowed)

- Smoking
  - Opened the app and reported smoking (3 or more slips)
  - Did not open the app at least 28 days after the target quit date

Missing = smoking assumption
Criteria for validity of outcome measure

• Plausible results
  – E.g. Is the percentage of participants who are abstinent within the range that would be expected?

• Construct validity
  – Do variables that are known to correlate with the outcome actually correlate with it when measured in this way?
## Overall success rate

<table>
<thead>
<tr>
<th>Percentage</th>
<th>95% confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of users who set a quit date, logged in on or after the quit date and recorded at least 28 days’ abstinence with no more than 2 lapses</td>
<td>18.9</td>
</tr>
</tbody>
</table>

Plausible
## Predictors of recorded 28-day abstinence

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Odds ratio</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age category</td>
<td>1.66 (1.30-2.13)</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td>Non manual occupational group</td>
<td>1.45 (1.08-1.95)</td>
<td>P=0.013</td>
</tr>
<tr>
<td>Cigarette consumption category</td>
<td>1.16 (0.95-1.43)</td>
<td>P=0.152</td>
</tr>
<tr>
<td>Intended use of stop-smoking medicine</td>
<td>1.56 (1.16-2.12)</td>
<td>P=0.003</td>
</tr>
</tbody>
</table>

Acceptable construct validity
The future

• Further challenges
  – What about studies comparing interventions that may have differing levels of engagement?
  – How to increase confidence in validity of self-report?

• Possible solutions
  – Use a ‘minimally demanding - maximally engaging’ (MDME) application to gather key outcome data independent of the intervention being assessed
  – Use sensors to validate self-report
How’s It Going? (HIG)

• User sets frequency of engagement (up to once per month) and
• Simple one or two press response
• Opportunity to change status
• Immediate feedback
• Can be used to randomise to interventions
• Undergoing initial user testing
• Can add biomarker data
Key points

• Automated data gathering from digital behaviour change interventions could in some cases be sufficiently robust to use for key outcome measures
• Need to address issues of bias arising from missing data and reliance in some cases on self-report
• Can assess outcome measures in terms of plausibility and construct validity
• The future may lie in MDME tracker apps running in parallel and no- or low cost sensors